

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Mirikizumab (Omvo®)

Lilly Deutschland GmbH

Modul 4 A

Erwachsene Patienten mit mittelschwerem bis schwerem aktiven Morbus Crohn, die auf eine konventionelle Therapie oder eine Biologika-Behandlung unzureichend angesprochen haben, nicht mehr darauf ansprechen oder eine Unverträglichkeit zeigen

Anhang 4-G

Stand: 10.03.2025

Inhaltsverzeichnis

	Seite
Anhang 4-G Ergänzende Unterlagen.....	3
Anhang 4-G.1 Untersuchungszeitpunkte in der RCT VIVID-1.....	4
Anhang 4-G.2 Informationen zu erlaubten und nicht erlaubten Vor- und Begleittherapien in RCT VIVID-1	6
Anhang 4-G.3 Teilpopulation A.....	9
Anhang 4-G.3.1 Charakterisierung der Studienpopulation in RCT VIVID-1 in Teilpopulation A	9
Anhang 4-G.3.2 Begleitmedikation in RCT VIVID-1 in Teilpopulation A.....	13
Anhang 4-G.3.3 Behandlungsdauer in RCT VIVID-1 in Teilpopulation A.....	55
Anhang 4-G.3.4 Patientenberichtete Endpunkte in RCT VIVID-1 in Teilpopulation A	57
Anhang 4-G.3.4.1 Anzahl der imputierten Werte je Endpunkt in RCT VIVID-1 in Teilpopulation A.....	57
Anhang 4-G.3.4.2 Rücklaufquoten der patientenberichteten Endpunkte in RCT VIVID-1 in Teilpopulation A	61
Anhang 4-G.3.4.2.1 Klinische Remission.....	61
Anhang 4-G.3.4.2.2 Symptomatik.....	64
Anhang 4-G.3.4.2.3 Gesundheitszustand	76
Anhang 4-G.3.4.2.4 Gesundheitsbezogene Lebensqualität.....	85
Anhang 4-G.3.4.3 Ergebnisse für die Veränderung der kontinuierlichen Endpunkte bis Woche 52 in RCT VIVID-1 in Teilpopulation A	90
Anhang 4-G.3.4.3.1 Klinische Remission.....	90
Anhang 4-G.3.4.3.2 Symptomatik.....	94
Anhang 4-G.3.4.3.3 Gesundheitszustand	110
Anhang 4-G.3.4.3.4 Gesundheitsbezogene Lebensqualität.....	124
Anhang 4-G.3.4.4 Verlaufsbeobachtungen der kontinuierlichen Endpunkte in RCT VIVID-1 in Teilpopulation A	134
Anhang 4-G.3.4.4.1 Klinische Remission.....	134
Anhang 4-G.3.4.4.2 Symptomatik.....	136
Anhang 4-G.3.4.4.3 Gesundheitszustand	144
Anhang 4-G.3.4.4.4 Gesundheitsbezogene Lebensqualität.....	151
Anhang 4-G.3.5 Unerwünschte Ereignisse (UE) nach SOC/PT in RCT VIVID-1 in Teilpopulation A	154
Anhang 4-G.3.6 Ergebnisse der Subgruppenanalysen mit nicht statistisch signifikantem Interaktionsterm in der Gesamtpopulation in RCT VIVID-1 in Teilpopulation A	160
Anhang 4-G.3.6.1 Morbidität.....	160
Anhang 4-G.3.6.1.1 Klinische Remission.....	160
Anhang 4-G.3.6.1.2 Symptomatik.....	172
Anhang 4-G.3.6.1.3 Gesundheitszustand	251
Anhang 4-G.3.6.2 Gesundheitsbezogene Lebensqualität.....	284
Anhang 4-G.3.6.3 Sicherheit	318
Anhang 4-G.3.6.3.1 Unerwünschte Ereignisse (UE) Gesamtraten	318

Anhang 4-G.3.6.3.2	Unerwünschte Ereignisse von speziellem Interesse (UESI)....	353
Anhang 4-G.3.6.3.3	Unerwünschte Ereignisse (UE) nach SOC/PT	409
Anhang 4-G.4	Teilpopulation B.....	427
Anhang 4-G.4.1	Charakterisierung der Studienpopulation in RCT VIVID-1 in Teilpopulation B.....	427
Anhang 4-G.4.2	Begleitmedikation in RCT VIVID-1 in Teilpopulation B	432
Anhang 4-G.4.3	Behandlungsdauer in RCT VIVID-1 in Teilpopulation B.....	488
Anhang 4-G.4.4	Patientenberichtete Endpunkte in RCT VIVID-1 in Teilpopulation B.....	490
Anhang 4-G.4.4.1	Anzahl der imputierten Werte je Endpunkt in RCT VIVID- 1 in Teilpopulation B.....	490
Anhang 4-G.4.4.2	Rücklaufquoten der patientenberichteten Endpunkte in RCT VIVID-1 in Teilpopulation B.....	494
Anhang 4-G.4.4.2.1	Klinische Remission.....	494
Anhang 4-G.4.4.2.2	Symptomatik.....	497
Anhang 4-G.4.4.2.3	Gesundheitszustand	509
Anhang 4-G.4.4.2.4	Gesundheitsbezogene Lebensqualität.....	518
Anhang 4-G.4.4.3	Ergebnisse für die Veränderung der kontinuierlichen Endpunkte bis Woche 52 in RCT VIVID-1 in Teilpopulation B	523
Anhang 4-G.4.4.3.1	Klinische Remission.....	523
Anhang 4-G.4.4.3.2	Symptomatik.....	527
Anhang 4-G.4.4.3.3	Gesundheitszustand	543
Anhang 4-G.4.4.3.4	Gesundheitsbezogene Lebensqualität.....	557
Anhang 4-G.4.4.4	Verlaufsbeobachtungen der kontinuierlichen Endpunkte in RCT VIVID-1 in Teilpopulation B.....	567
Anhang 4-G.4.4.4.1	Klinische Remission.....	567
Anhang 4-G.4.4.4.2	Symptomatik.....	569
Anhang 4-G.4.4.4.3	Gesundheitszustand	577
Anhang 4-G.4.4.4.4	Gesundheitsbezogene Lebensqualität.....	584
Anhang 4-G.4.5	Unerwünschte Ereignisse nach SOC/PT in RCT VIVID-1 in Teilpopulation B.....	587
Anhang 4-G.4.6	Ergebnisse der Subgruppenanalysen mit nicht statistisch signifikantem Interaktionsterm in der Gesamtpopulation in RCT VIVID-1 in Teilpopulation B.....	592
Anhang 4-G.4.6.1	Morbidität.....	592
Anhang 4-G.4.6.1.1	Klinische Remission.....	592
Anhang 4-G.4.6.1.2	Symptomatik.....	603
Anhang 4-G.4.6.1.3	Gesundheitszustand	677
Anhang 4-G.4.6.2	Gesundheitsbezogene Lebensqualität.....	712
Anhang 4-G.4.6.3	Sicherheit	744
Anhang 4-G.4.6.3.1	Unerwünschte Ereignisse (UE) Gesamtraten	744
Anhang 4-G.4.6.3.2	Unerwünschte Ereignisse von speziellem Interesse (UESI)....	778
Anhang 4-G.4.6.3.3	Unerwünschte Ereignisse (UE) nach SOC/PT	845

Anhang 4-G Ergänzende Unterlagen

In den statistischen Outputs ist der Datenschnitt auf den 23. August 2023 datiert. Dieses Datum entspricht der letzten Patientenvisite. Das Datum des vorliegenden Datenschnitts ist der 4. Oktober 2023.

Anhang 4-G.1 Untersuchungszeitpunkte in der RCT VIVID-1

Übersicht der Untersuchungszeitpunkte der patientenrelevanten Endpunkte in RCT VIVID-1

	Screening	Induktionstherapie (Periode 1)						Erhaltungstherapie (Periode 2)												UA/SV ^d	Follow-up nach Behandlungsende (Periode 3)	
Visite Nr.	V1	V2	V3 ^a	V4	V5 ^a	V6	V7	V8	V9	V10	V11	V12	V13	V14	V15	V16	V17	ETV ^b	V997 ^c		V801	V802
Woche bezogen auf den Behandlungsbeginn	-5	0	2	4	6	8	12	16	20	24	28	32	36	40	44	48	52	n.a.	n.a.		LV/ETV + 4	LV/ETV +12/16
Tage bezogen auf den Behandlungsbeginn Zeitfenster	≤35 bis V2	1	15 ± 3	29 ± 3	43 ± 3	57 ± 3	85 ± 6	113 ± 7	141 ± 7	169 ± 7	197 ± 7	225 ± 7	253 ± 7	281 ± 7	309 ± 7	337 ± 7	365 ± 7	n.a.	n.a.		± 10	± 10
Körperliche Untersuchungen																						
Körperliche Untersuchung ^e	X	X		X		X	X	X	X	X	X	X	X	X	X	X	X	X	Opt		X	X
EIM		X		X		X	X	X	X	X	X	X	X	X	X	X	X	X	Opt		X	X
Fisteln		X		X		X	X	X	X	X	X	X	X	X	X	X	X	X	Opt		X	X
Fragebögen																						
CDAI-SF, CDAI-AP und CDAI-GWB	^f																					
IBDQ ^g		X					X										X	X				
SF-36 ^g		X					X										X	X				
EQ-5D-5L ^g		X					X										X	X				
WPAI-CD ^g		X					X										X	X				
PGIC ^g				X		X	X										X	X				
PGRS	^f																					
FACIT-Fatigue ^g		X					X										X	X				
QIDS-SR16 ^g	X	X					X			X			X				X	X	Opt	Opt		
Urgency NRS	^f																					
Unerwünschte Ereignisse																						
Unerwünschte Ereignisse	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X

CD: Crohn's disease (Morbus Crohn); CDAI: Crohn's Disease Activity Index; CRF: Case Report Form (Prüfbogen); AP: Abdominal pain (abdominelle Schmerzen); EIM: Extraintestinale Manifestation; EQ-5D-5L: European Quality of Life 5–Dimension 5 Level; ETV: Early termination visit (Visite bei vorzeitigem Abbruch), FACIT-Fatigue Functional Assessment of Chronic Illness Therapy-Fatigue; IBDQ: Inflammatory Bowel Disease Questionnaire, LV = Letzte Visite; n.a. = Nicht anwendbar; NRS: Numeric Rating Scale (numerische Bewertungsskala); Opt: Optional; PGIC: Patient Global Impression of Change; PGRS: Patient Global Rating of Severity; QIDS-SR16: Quick Inventory of Depressive Symptomatology-Self Report (16 items); SF: Stuhlfrequenz; SF-36: Medical Outcomes Study 36-Item Short Form Health Survey; UA/SV: Unscheduled Assessments during a Scheduled Visit (nicht geplante Untersuchungen während einer geplanten Visite); V997 = Nicht geplante Visite; V = Visite; GWB: General Well-being (Allgemeinbefinden); WPAI-CD = Work Productivity and Activity Impairment Questionnaire Crohn's Disease.

Alle Screening-/Baseline-Aktivitäten sollten vor der Verabreichung der Studienmedikation abgeschlossen sein, sofern nicht anders angegeben.

a: Telefonische Visite.

b: Visiten bei vorzeitigem Abbruch (ETV) konnten zu jedem Zeitpunkt stattfinden, ungeachtet der regulär geplanten Visiten. Lag die letzte Endoskopie bereits mindestens 16 Wochen zurück, sollte erneut eine Endoskopie durchgeführt werden. Während der Periode 1 und dem Follow-up nach der Behandlung war keine ETV-Endoskopie vorgesehen.

c: Die nicht geplante Visite V997 konnte im Ermessen des Prüfarztes zwischen den protokollgemäß geplanten Visiten stattfinden. Bei allen nicht geplanten Visiten mussten die Begleitmedikationen und unerwünschte Ereignisse dokumentiert werden. Andere Untersuchungen und Bewertungen waren hingegen optional (oben gekennzeichnet als Opt), mussten aber gemäß der Studienanforderungen dokumentiert werden (CRF, Laboruntersuchungen und/oder Quelldokumente).

d: Während einer protokollgemäß geplanten Visite konnte der Prüfarzt nach eigenem Ermessen weitere, nicht geplante Untersuchungen vornehmen, die der protokollgemäß geplanten Visite zugeordnet wurden. Diese nicht geplanten Untersuchungen (oben gekennzeichnet als Opt) mussten gemäß der Studienanforderungen dokumentiert werden (CRF, Laboruntersuchungen und/oder Quelldokumente).

e: Beim Screening wurden die Patienten vollständig körperlich untersucht (ausgenommen Becken-, Rektal- und Brustuntersuchung), einschließlich der peripheren Lymphknoten. Nach dem Screening wurden die Patienten symptomorientiert und Augen, Herz, Lunge, Abdomen sowie die Haut visuell untersucht.

f: Den Patienten wurde während des Screenings ein elektronisches Patiententagebuch ausgehändigt. Die Patienten bewerteten den Endpunkt täglich mittels des elektronischen Patiententagebuchs.

g: Die Patienten bewerteten den Endpunkt zu den angegebenen Visiten mittels Tablet.

Anhang 4-G.2 Informationen zu erlaubten und nicht erlaubten Vor- und Begleittherapien in RCT VIVID-1

Erlaubte Begleitmedikationen in RCT VIVID-1

Erlaubte Begleittherapie	Anwendungsregeln	
	Stabile Dosis vor der Eingangsendoskopie (bzw. Baseline)	Während der Studie
Orale 5-ASA (z.B. Mesalamin, Balsalazid oder Olsalazin)	2 Wochen	Unverändert in der verschriebenen Dosierung, es sei denn, die Behandlung musste aufgrund von Toxizität abgebrochen werden.
Immunmodulatoren (z.B. AZA, 6-Mercaptopurin oder Methotrexat)	8 Wochen	
Orale Kortikosteroide (Prednison ≤ 30 mg/Tag oder Äquivalent oder Budesonid 9 mg/Tag)	2 Wochen	Unverändert bis zur Woche 12 Nach Woche 12 Ausschleichen nach einem festgelegten Schema (Kortikosteroid-Taper)
Antibiotika speziell zur Behandlung des MC (z.B. Rifaximin und Ciprofloxacin)	4 Wochen (vor Baseline)	Unverändert in der verschriebenen Dosierung
Antidiarrhoika (z.B. Loperamid oder Diphenoxylat mit Atropin)	Antidiarrhoika sollten während der Studie möglichst in unveränderter Dosierung beibehalten werden.	
Aspirin in niedriger Dosierung (75-162,2 mg)	Eine tägliche kardiovaskuläre Prophylaxe war erlaubt.	
Nicht-Lebendimpfstoffe (Tot- oder inaktivierter Impfstoff, Untereinheit oder RNA-basiert)	Nichtlebend-Impfstoffe waren während der Studie erlaubt, in Kombination mit Mirikizumab ist deren Wirksamkeit jedoch nicht bekannt.	
5-ASA: 5-Aminosalicylsäure; AZA: Azathioprin; MC: Morbus Crohn; mg: Milligramm		

Nicht erlaubte Vor- und Begleitmedikationen in RCT VIVID-1

Nicht erlaubte Vor- und Begleittherapien	Anwendungsregeln	
	Absetzen vor der Eingangsendoskopie (Baseline)	Während der Studie inklusive Ausnahmeregeln
• Anti-Integrin-Antikörper: Natalizumab • B- und T-Zell-depletierende Therapien (z.B. Rituximab, Alemtuzumab oder Visilizumab)	12 Monate 12 Monate (vor Baseline)	Nicht erlaubt Nicht erlaubt ^a
• TNF-α-Antagonisten (z.B. Infliximab, Adalimumab oder pegyliertes Certolizumab) • Andere Integrin-Inhibitoren wie Vedolizumab • Immunmodulatoren, einschließlich orales und i.v. Cyclosporin, Tacrolimus, Mycophenolatmofetil, Thalidomid oder JAK-Inhibitoren	4 Wochen	Nicht erlaubt
• Rektales 5-ASA (Klistiere und Zäpfchen) • Rektale Kortikosteroide (Klistiere und Zäpfchen)	2 Wochen	Nicht erlaubt
Kortikosteroide i.v.	2 Wochen	Nicht erlaubt, ausgenommen als Prämedikation für eine Infusion oder zur kurzfristigen Behandlung akuter Ereignisse, die nicht mit dem MC zusammenhängen (z. B. allergische Reaktionen) ^b
Systemische Kortikosteroide für andere Indikationen als MC (oral oder parenteral)	-	Woche 0-12: Keine Einleitung oder Dosisanpassung; Woche 12-52: Vorübergehender Einsatz oder Dosiserhöhung (d.h. für < 4 Wochen) erlaubt, aus Gründen, die nicht im Zusammenhang mit einem Verlust des Ansprechens auf die Behandlung des MC stehen: z. B. Stressdosen von Kortikosteroiden vor Operationen, bei Asthma oder allergischen Reaktionen; Kortikosteroide zur lokalen Anwendung erlaubt (z. B. inhalativ, intranasal, intraartikulär oder topisch); Systemische Kortikosteroide bei Nebennierenrindeninsuffizienz erlaubt.
• Anti-IL-23p19-Antikörper (z.B. Risankizumab, Brazikumab, Guselkumab oder Tildrakizumab für	Nicht zutreffend	Keine Vorbehandlung und nicht erlaubt

Nicht erlaubte Vor- und Begleittherapien	Anwendungsregeln	
	Absetzen vor der Eingangsendsoskopie (Baseline)	Während der Studie inklusive Ausnahmeregeln
jegliche Indikation, einschließlich als Prüfpräparat • Anti-IL 12/23p40-Antikörper (z.B. Ustekinumab)	16 Wochen ^c	Nicht erlaubt
• Prüfpräparat biologischen Ursprungs • Prüfpräparat nicht biologischen Ursprungs	8 Wochen oder 5 Halbwertszeiten 4 Wochen oder 5 Halbwertszeiten	Nicht erlaubt
Interferon	8 Wochen	Nicht erlaubt
Leukozytenaphere (z.B. Adacolumn)	3 Wochen	Nicht erlaubt
Impfung gegen Bacillus Calmette-Guérin Abgeschwächter Lebendimpfstoff	12 Monate (vor Baseline) 3 Monate (vor Baseline)	Nicht erlaubt bis 12 Monate nach Behandlungsende Nicht erlaubt bis 3 Monate nach Behandlungsende
Medizinisches und nicht medizinisches Marihuana (einschließlich Cannabidiol-Öl)	Vor dem Screening	Nicht erlaubt ^d
5-ASA: 5-Aminosalicylsäure; i.v.: intravenös; IL: Interleukin; MC: Morbus Crohn; s.c.: subkutan; TNF: Tumornekrosefaktor a: Lagen zum Zeitpunkt der Eingangsendsoskopie Hinweise auf eine weiterhin andauernde, gezielte Lymphozytendepletion vor, durften die Patienten nicht an der Studie teilnehmen. b: Kortikosteroide i.v. zur Behandlung von MC konnten zu einem Abbruch der Behandlung führen. c: Patienten, die einen Anti-IL12/23p40-Antikörper wie Ustekinumab mindestens 16 Wochen vor der Eingangsendsoskopie aus nicht medizinischen Gründen (z.B. Wechsel der Krankenkasse) abgesetzt hatten, konnten an der Studie teilnehmen. Zusätzlich durften diese Patienten nicht mehr als die i.v. Dosis zur Induktion und eine Dosis s.c. erhalten haben. Dieser Anteil war auf 10% der Studienpopulation beschränkt. d: Die Anwendung von Marihuana während der Studie konnte nach Rücksprache mit dem medizinischen Monitor zum Ausschluss des Patienten aus der Studie führen.		

Anhang 4-G.3 Teilpopulation A**Anhang 4-G.3.1 Charakterisierung der Studienpopulation in RCT VIVID-1 in
Teilpopulation A**

Demografische und Krankheitscharakteristika in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Merkmal	Mirikizumab (N=331)	Ustekinumab (N=164)
Demografie		
Alter (Jahre)		
MW (SD)	36,54 (13,20)	37,10 (12,93)
Alter, n (%)		
<65	322 (97,3)	160 (97,6)
≥65	9 (2,7)	4 (2,4)
Geschlecht, n (%)		
Männlich	178 (53,8)	83 (50,6)
Weiblich	153 (46,2)	81 (49,4)
Abstammung, n (%)		
Amerikanisch nativ oder Alaska nativ	2 (0,6)	2 (1,2)
Asiatisch	58 (17,5)	22 (13,4)
Schwarz oder Afroamerikanisch	1 (0,3)	2 (1,2)
Weiß/kaukasisch	268 (81,0)	137 (83,5)
Multiple	1 (0,3)	0
Region, n (%)		
Asien	58 (17,5)	23 (14,0)
Nordamerika	31 (9,4)	13 (7,9)
Zentral- oder Südamerika	11 (3,3)	7 (4,3)
Europa und restliche Welt	231 (69,8)	121 (73,8)
Gewicht (kg)		
MW (SD)	69,57 (18,82)	68,14 (18,24)
BMI (kg/m ²)		
MW (SD)	23,74 (5,80)	23,48 (5,78)
Krankheitsspezifische Charakterisierung		
Zeit seit Diagnose (Jahre)		
MW (SD)	6,07 (7,97)	5,18 (5,88)
Alter bei Diagnose		

Merkmal	Mirikizumab (N=331)	Ustekinumab (N=164)
MW (SD)	31,04 (12,09)	32,42 (12,72)
Disease location, n (%)		
Colonic	135 (40,8)	73 (44,5)
Ileal	41 (12,4)	24 (14,6)
Ileal-Colonic	155 (46,8)	65 (39,6)
History of surgical bowel resection, n (%)		
Ja	35 (10,6)	8 (4,9)
Nein	296 (89,4)	156 (95,1)
Number of surgical bowel resection, n (%)		
0	296 (89,4)	156 (95,1)
1	28 (8,5)	5 (3,0)
2	7 (2,1)	3 (1,8)
Baseline C-reactive Protein (CRP) (mg/L)		
MW (SD)	14,33 (22,79)	13,50 (21,47)
Baseline Fecal calprotectin (ug/g)		
MW (SD)	1.970,57 (3.326,98)	2.255,61 (4.399,46)
Baseline SES-CD total score		
MW (SD)	11,95 (6,49)	12,23 (6,49)
Baseline CDAI total score		
MW (SD)	314,82 (80,32)	313,37 (88,33)
Baseline abdominal pain		
MW (SD)	2,14 (0,59)	2,13 (0,58)
Baseline stool frequency		
MW (SD)	5,44 (2,49)	5,53 (2,53)
Baseline IBDQ total score		
MW (SD)	128,04 (33,16)	123,74 (35,18)
Baseline IBDQ bowel symptoms subscore		
MW (SD)	38,21 (9,74)	37,33 (10,36)
Baseline IBDQ systemic symptoms subscore		
MW (SD)	17,97 (5,75)	17,41 (5,88)
Baseline IBDQ emotional function subscore		
MW (SD)	50,91 (14,12)	49,30 (14,94)
Baseline IBDQ social function subscore		

Merkmal	Mirikizumab (N=331)	Ustekinumab (N=164)
MW (SD)	20,95 (7,04)	19,70 (7,72)
Baseline Urgency NRS		
MW (SD)	6,47 (2,10)	6,57 (2,03)
Baseline Fistulae, n (%)		
Ja	17 (5,1)	13 (7,9)
Nein	314 (94,9)	151 (92,1)
Baseline Facit-Fatigue		
MW (SD)	31,88 (11,28)	29,97 (12,07)
Baseline SF-36 MCS		
MW (SD)	43,38 (10,94)	42,26 (10,78)
Baseline SF-36 PCS		
MW (SD)	39,96 (7,26)	40,00 (8,02)
Baseline WPAI-CD score		
MW (SD)	53,95 (25,36)	53,93 (25,04)
Baseline QIDS-SR16 score		
MW (SD)	6,37 (4,51)	7,15 (4,83)
Baseline EQ-5D-5L index score		
MW (SD)	0,65 (0,22)	0,62 (0,23)
Baseline EQ-5D-5L VAS		
MW (SD)	54,30 (19,34)	53,54 (18,48)
Baseline DSI-CD total score		
MW (SD)	34,20 (10,90)	34,80 (11,42)
Baseline IBD-DI total score		
MW (SD)	38,89 (17,85)	43,40 (18,69)
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; DSI: Disease Severity Index; EQ-5D: Fragebogen der EuroQol-Gruppe zur Lebensqualität auf 5 Dimensionen; IBD-DI: Inflammatory Bowel Disease Questionnaire Disability Index; IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; kg: Kilogramm; MCS: Mental Health Component Summary Score; MW: Mittelwert; n: Anzahl der Patienten; N: Anzahl der Patienten in der Analyse; NRS: Numeric Rating Scale; PCS: Physical Health Component Summary Score; QIDS-SR16: Quick Inventory of Depressive Symptomatology - Self Report (16 items); RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SES: Simple Endoscopy Score; SF-36: 36-Item Short Form Health Survey; VAS: Visuelle Analogskala; WPAI: Work Productivity and Activity Impairment Questionnaire.		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_demo.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_demo_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba_23SEP2024 / 04:31

Abdominal Pain at Baseline in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Merkmal	Mirikizumab (N=331)	Ustekinumab (N=164)
Demografie		
Abdominal Pain at Baseline, n (%)		
<1	12 (3,6)	5 (3,0)
≥1 und <2	58 (17,5)	30 (18,3)
≥2 und <3	225 (68,0)	113 (68,9)
=3	35 (10,6)	16 (9,8)
Missing	1 (0,3)	0
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; n: Anzahl der Patienten; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie.		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_apcat_bl.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_apcat_bl_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba

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Anhang 4-G.3.2 Begleitmedikation in RCT VIVID-1 in Teilpopulation A

Begleitmedikation nach absteigender Häufigkeit in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
Patients with ≥ 1 concomitant medication	329 (99,4)	159 (97,0)
OSMOTICALLY ACTING LAXATIVES	233 (70,4)	111 (67,7)
MACROGOL 4000;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE	48 (14,5)	37 (22,6)
MAGNESIUM SULFATE;POTASSIUM SULFATE;SODIUM SULFATE	33 (10,0)	28 (17,1)
MACROGOL	33 (10,0)	14 (8,5)
ASCORBIC ACID;MACROGOL 3350;POTASSIUM;SODIUM CHLORIDE;SODIUM SULFATE	40 (12,1)	5 (3,0)
ASCORBIC ACID;MACROGOL 4000;POTASSIUM;SODIUM CHLORIDE;SODIUM SULFATE	27 (8,2)	12 (7,3)
CITRIC ACID;MACROGOL 4000;POTASSIUM;SIMETICONE;SODIUM CHLORIDE;SODIUM CITRATE;SODIUM SULFATE	17 (5,1)	3 (1,8)
ASCORBIC ACID;MACROGOL;POTASSIUM;SODIUM CHLORIDE;SODIUM SULFATE	17 (5,1)	2 (1,2)
MACROGOL 4000	14 (4,2)	5 (3,0)
MACROGOL 3350	9 (2,7)	5 (3,0)
MAGNESIUM SULFATE;POTASSIUM SULFATE;SIMETICONE;SODIUM SULFATE	7 (2,1)	3 (1,8)
MACROGOL 3350;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE	7 (2,1)	2 (1,2)
MANNITOL	6 (1,8)	1 (0,6)
MACROGOL;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE	4 (1,2)	2 (1,2)
MACROGOL 3350;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE	2 (0,6)	2 (1,2)
MACROGOL;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE	3 (0,9)	1 (0,6)
OSMOTICALLY ACTING LAXATIVES	4 (1,2)	0
LACTULOSE	2 (0,6)	1 (0,6)
MAGNESIUM CITRATE	3 (0,9)	0
MACROGOL;POTASSIUM;SODIUM BICARBONATE	1 (0,3)	1 (0,6)
MAGNESIUM SULFATE;POTASSIUM;SODIUM SULFATE	2 (0,6)	0

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
SODIUM PHOSPHATE	2 (0,6)	0
MACROGOL 3350;POTASSIUM;SODIUM CHLORIDE;SODIUM SULFATE	1 (0,3)	0
MAGNESIUM CARBONATE;MAGNESIUM OXIDE	1 (0,3)	0
MAGNESIUM HYDROXIDE	1 (0,3)	0
MAGNESIUM SULFATE	0	1 (0,6)
PHOSPHORIC ACID;SODIUM PHOSPHATE	1 (0,3)	0
POTASSIUM SULFATE	0	1 (0,6)
SODIUM SULFATE	0	1 (0,6)
AMINOSALICYLIC ACID AND SIMILAR AGENTS	202 (61,0)	104 (63,4)
MESALAZINE	197 (59,5)	100 (61,0)
SULFASALAZINE	5 (1,5)	4 (2,4)
BALSALAZIDE	1 (0,3)	0
OTHER GENERAL ANESTHETICS	166 (50,2)	84 (51,2)
PROPOFOL	164 (49,5)	83 (50,6)
ETOMIDATE	10 (3,0)	3 (1,8)
KETAMINE	10 (3,0)	2 (1,2)
NITROUS OXIDE;OXYGEN	3 (0,9)	1 (0,6)
BENZODIAZEPINE DERIVATIVES	112 (33,8)	61 (37,2)
MIDAZOLAM	106 (32,0)	57 (34,8)
LORAZEPAM	5 (1,5)	2 (1,2)
ALPRAZOLAM	3 (0,9)	0
ESTAZOLAM	2 (0,6)	0
BROMAZEPAM	0	1 (0,6)
CLONAZEPAM	0	1 (0,6)
DIAZEPAM	0	1 (0,6)
OTHER IMMUNOSUPPRESSANTS	98 (29,6)	53 (32,3)
AZATHIOPRINE	94 (28,4)	51 (31,1)
METHOTREXATE	4 (1,2)	2 (1,2)
OPIOID ANESTHETICS	89 (26,9)	50 (30,5)
FENTANYL	75 (22,7)	45 (27,4)
SUFENTANIL	13 (3,9)	5 (3,0)
REMIFENTANIL	4 (1,2)	1 (0,6)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
ALFENTANIL	2 (0,6)	0
GLUCOCORTICOIDS	84 (25,4)	43 (26,2)
PREDNISON	45 (13,6)	28 (17,1)
METHYLPREDNISOLONE	25 (7,6)	11 (6,7)
DEXAMETHASONE	6 (1,8)	4 (2,4)
HYDROCORTISONE	5 (1,5)	4 (2,4)
BUDESONIDE	5 (1,5)	1 (0,6)
DEFLAZACORT	2 (0,6)	1 (0,6)
CICLESONIDE	1 (0,3)	1 (0,6)
CORTISONE	2 (0,6)	0
BECLOMETASONE	0	1 (0,6)
FLUTICASONE	0	1 (0,6)
MOMETASONE	0	1 (0,6)
PREDNISOLONE	0	1 (0,6)
CONTACT LAXATIVES	74 (22,4)	41 (25,0)
CITRIC ACID;MAGNESIUM OXIDE;SODIUM PICOSULFATE	59 (17,8)	33 (20,1)
BISACODYL	13 (3,9)	3 (1,8)
SODIUM PICOSULFATE	5 (1,5)	1 (0,6)
SENNOSIDE A+B	1 (0,3)	4 (2,4)
BISACODYL;DOCUSATE	1 (0,3)	0
BISACODYL;MACROGOL	1 (0,3)	0
CITRIC ACID;MAGNESIUM CARBONATE;SODIUM PICOSULFATE	1 (0,3)	0
PROTON PUMP INHIBITORS	81 (24,5)	34 (20,7)
PANTOPRAZOLE	44 (13,3)	16 (9,8)
OMEPRazole	20 (6,0)	8 (4,9)
ESOMEPRazole	11 (3,3)	9 (5,5)
RABEPRazole	4 (1,2)	3 (1,8)
DEXLANSOPRAZOLE	4 (1,2)	0
LANSOPRAZOLE	1 (0,3)	0
ANILIDES	68 (20,5)	20 (12,2)
PARACETAMOL	61 (18,4)	15 (9,1)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	3 (0,9)	1 (0,6)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
ASCORBIC ACID;PARACETAMOL;PHENYLEPHRINE	2 (0,6)	1 (0,6)
ASCORBIC ACID;PARACETAMOL;PHENIRAMINE;PHENYLEPHRINE	0	2 (1,2)
CHLORPHENAMINE;PARACETAMOL	1 (0,3)	1 (0,6)
DEXTROMETHORPHAN;PARACETAMOL;PHENYLEPHRINE	2 (0,6)	0
PARACETAMOL;PHENIRAMINE;PHENYLEPHRINE	2 (0,6)	0
ACETANILIDE;ASCORBIC ACID;PHENIRAMINE;PHENYLEPHRINE	0	1 (0,6)
ASCORBIC ACID;CAFFEINE;PARACETAMOL;PHENYLEPHRINE;TERPIN	1 (0,3)	0
ASCORBIC ACID;PARACETAMOL;PHENIRAMINE	1 (0,3)	0
CAFFEINE;PARACETAMOL;PHENYLEPHRINE	1 (0,3)	0
DEXTROMETHORPHAN;DOXYLAMINE;PARACETAMOL	1 (0,3)	0
DEXTROMETHORPHAN;GUAIFENESIN;PARACETAMOL;PHENYL EPHRINE	1 (0,3)	0
IBUPROFEN;PARACETAMOL	0	1 (0,6)
NAPROXEN;PARACETAMOL	1 (0,3)	0
CORTICOSTEROIDS ACTING LOCALLY	54 (16,3)	29 (17,7)
BUDESONIDE	54 (16,3)	28 (17,1)
PREDNISOLONE	0	1 (0,6)
OTHER VIRAL VACCINES	53 (16,0)	18 (11,0)
COVID-19 VACCINE	53 (16,0)	18 (11,0)
OTHER VIRAL VACCINES	1 (0,3)	0
OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	35 (10,6)	17 (10,4)
SIMETICONE	21 (6,3)	6 (3,7)
DIMETICONE	4 (1,2)	3 (1,8)
BUTYRIC ACID	3 (0,9)	1 (0,6)
FENOVERINE	3 (0,9)	1 (0,6)
ALVERINE;SIMETICONE	0	3 (1,8)
PHLOROGLUCINOL	3 (0,9)	0
PINAVERIUM	1 (0,3)	1 (0,6)
ALVERINE	0	1 (0,6)
ATRACTYLODES MACROCEPHALA;GLYCYRRHIZA SPP.;LEVOGLUTAMIDE;PANAX GINSENG;PORIA COCOS	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	0	1 (0,6)
PHLOROGLUCINOL;TRIMETHYLPHLOROGLUCINOL	0	1 (0,6)
VITAMIN D AND ANALOGUES	31 (9,4)	16 (9,8)
COLECALCIFEROL	20 (6,0)	12 (7,3)
VITAMIN D NOS	11 (3,3)	3 (1,8)
CALCIFEDIOL	0	1 (0,6)
CALCITRIOL	1 (0,3)	0
BELLADONNA ALKALOIDS, SEMISYNTHETIC, QUATERNARY AMMONIUM COMPOUNDS	34 (10,3)	12 (7,3)
HYOSCINE	26 (7,9)	12 (7,3)
CIMETROPIUM	7 (2,1)	0
BUTYLSCOPOLAMINE	1 (0,3)	0
HOMATROPINE	1 (0,3)	0
PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS	32 (9,7)	13 (7,9)
DROSPIRENONE;ETHINYLESTRADIOL	14 (4,2)	5 (3,0)
ETHINYLESTRADIOL;GESTODENE	8 (2,4)	0
ETHINYLESTRADIOL;LEVONORGESTREL	2 (0,6)	4 (2,4)
DIENOGEST;ETHINYLESTRADIOL	4 (1,2)	0
DROSPIRENONE;ETHINYLESTRADIOL;LEVOMEFOLIC ACID	1 (0,3)	2 (1,2)
ETHINYLESTRADIOL;NORELGESTROMIN	2 (0,6)	0
ALGESTONE;ESTRADIOL	1 (0,3)	0
DROSPIRENONE;ESTETROL	0	1 (0,6)
ESTRADIOL;NORETHISTERONE	0	1 (0,6)
PROPIONIC ACID DERIVATIVES	33 (10,0)	12 (7,3)
IBUPROFEN	21 (6,3)	7 (4,3)
DEXKETOPROFEN	5 (1,5)	2 (1,2)
NAPROXEN	3 (0,9)	1 (0,6)
LOXOPROFEN	2 (0,6)	1 (0,6)
FLURBIPROFEN	1 (0,3)	0
KETOPROFEN	0	1 (0,6)
PELUBIPROFEN	1 (0,3)	0
ELECTROLYTE SOLUTIONS	25 (7,6)	18 (11,0)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
SODIUM CHLORIDE	19 (5,7)	10 (6,1)
POTASSIUM	4 (1,2)	2 (1,2)
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE;SODIUM CITRATE	2 (0,6)	3 (1,8)
CALCIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE	3 (0,9)	2 (1,2)
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE;SORBITOL	2 (0,6)	1 (0,6)
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM ACETATE;SODIUM CHLORIDE	1 (0,3)	0
MAGNESIUM SULFATE	1 (0,3)	0
POTASSIUM PHOSPHATE MONOBASIC	0	1 (0,6)
SODIUM BICARBONATE	0	1 (0,6)
FOLIC ACID AND DERIVATIVES	28 (8,5)	15 (9,1)
FOLIC ACID	28 (8,5)	14 (8,5)
DROSPIRENONE;ETHINYLESTRADIOL;LEVOMEFOLIC ACID	0	1 (0,6)
AMIDES	30 (9,1)	9 (5,5)
LIDOCAINE	28 (8,5)	8 (4,9)
BUPIVACAINE	1 (0,3)	0
LIDOCAINE;PHENYLEPHRINE	1 (0,3)	0
PRILOCAINE	1 (0,3)	0
TRIMECAINE	0	1 (0,6)
PYRAZOLONES	28 (8,5)	11 (6,7)
METAMIZOLE	28 (8,5)	11 (6,7)
ANTIDIARRHEAL MICROORGANISMS	26 (7,9)	11 (6,7)
SACCHAROMYCES BOULARDII	4 (1,2)	2 (1,2)
BACILLUS MESENTERICUS;CLOSTRIDIUM BUTYRICUM;ENTEROCOCCUS FAECALIS	3 (0,9)	2 (1,2)
LACTOBACILLUS NOS	4 (1,2)	0
ANTIDIARRHEAL MICROORGANISMS	2 (0,6)	1 (0,6)
BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM LACTIS;BUTYRIC ACID;INULIN	2 (0,6)	1 (0,6)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
BIFIDOBACTERIUM BREVE;BIFIDOBACTERIUM INFANTIS;BIFIDOBACTERIUM LONGUM;LACTIPLANTIBACILLUS PLANTARUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BULGARICUS;LACTOBACILLUS PARACASEI;	2 (0,6)	1 (0,6)
BIFIDOBACTERIUM LONGUM;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS	1 (0,3)	1 (0,6)
PROBIOTICS NOS	1 (0,3)	1 (0,6)
BACILLUS CLAUSII	1 (0,3)	0
BACILLUS SUBTILIS;ENTEROCOCCUS FAECALIS	1 (0,3)	0
BACTERIOPHAGES;BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM BREVE;BIFIDOBACTERIUM LONGUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS CASEI;LACTOBACILLUS RHAMNOSUS;STREPTOCOCCUS THERMOPHILUS	1 (0,3)	0
BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM BREVE;BIFIDOBACTERIUM LONGUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS PARACASEI;LACTOBACILLUS RHAMNOSUS;LACTOBACILLUS SALIVARIUS	1 (0,3)	0
BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM LACTIS;BIFIDOBACTERIUM LONGUM;CYNARA CARDUNCULUS;INULIN;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BULGARICUS;LACTOBACILLUS CASEI;RIBOFLAVIN;	1 (0,3)	0
BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM LONGUM;LACTOBACILLUS GASSERI	1 (0,3)	0
BIFIDOBACTERIUM BREVE;BIFIDOBACTERIUM LONGUM;FRUCTOOLIGOSACCHARIDES;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BULGARICUS;LACTOBACILLUS CASEI;LACTOBACILLUS RHAMNOSUS;STREPTOCOCCUS THERMOPHILUS	1 (0,3)	0
BIFIDOBACTERIUM BREVE;BIFIDOBACTERIUM LONGUM;LACTIPLANTIBACILLUS PLANTARUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS CASEI;LACTOBACILLUS HELVETICUS;LACTOBACILLUS RHAMNOSUS	1 (0,3)	0
BIFIDOBACTERIUM LACTIS;COLOSTRUM;LACTOBACILLUS ACIDOPHILUS	1 (0,3)	0
BIFIDOBACTERIUM LACTIS;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS PARACASEI;LACTOBACILLUS RHAMNOSUS	0	1 (0,6)
BIFIDOBACTERIUM LONGUM	0	1 (0,6)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
BIFIDOBACTERIUM NOS;LACTOBACILLUS NOS	0	1 (0,6)
LACTIPLANTIBACILLUS PLANTARUM	1 (0,3)	0
LACTOBACILLUS ACIDOPHILUS	1 (0,3)	0
LACTOBACILLUS HELVETICUS;LACTOBACILLUS RHAMNOSUS	1 (0,3)	0
BETA BLOCKING AGENTS, SELECTIVE	21 (6,3)	12 (7,3)
BISOPROLOL	9 (2,7)	4 (2,4)
METOPROLOL	6 (1,8)	6 (3,7)
NEBIVOLOL	4 (1,2)	2 (1,2)
ATENOLOL	2 (0,6)	0
FLUOROQUINOLONES	25 (7,6)	8 (4,9)
CIPROFLOXACIN	18 (5,4)	3 (1,8)
LEVOFLOXACIN	4 (1,2)	3 (1,8)
OFLOXACIN	4 (1,2)	0
NORFLOXACIN	1 (0,3)	2 (1,2)
LOMEFLOXACIN	1 (0,3)	0
PHENYLPIPERIDINE DERIVATIVES	24 (7,3)	9 (5,5)
PETHIDINE	17 (5,1)	6 (3,7)
FENTANYL	7 (2,1)	3 (1,8)
BELLADONNA ALKALOIDS, TERTIARY AMINES	12 (3,6)	17 (10,4)
ATROPINE	10 (3,0)	17 (10,4)
ANISODAMINE	1 (0,3)	0
HYOSCYAMINE	1 (0,3)	0
IRON BIVALENT, ORAL PREPARATIONS	22 (6,6)	7 (4,3)
IRON	16 (4,8)	3 (1,8)
ASCORBIC ACID;IRON	6 (1,8)	2 (1,2)
IRON POLYSACCHARIDE COMPLEX	0	2 (1,2)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	24 (7,3)	3 (1,8)
DESLORATADINE	5 (1,5)	1 (0,6)
BILASTINE	4 (1,2)	1 (0,6)
FEXOFENADINE	5 (1,5)	0
LORATADINE	4 (1,2)	1 (0,6)
EBASTINE	2 (0,6)	0

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
RUPATADINE	2 (0,6)	0
AZELASTINE	1 (0,3)	0
BEPOTASTINE	1 (0,3)	0
EPINASTINE	1 (0,3)	0
QUERCETIN	1 (0,3)	0
ACE INHIBITORS, PLAIN	18 (5,4)	7 (4,3)
RAMIPRIL	6 (1,8)	3 (1,8)
PERINDOPRIL	5 (1,5)	1 (0,6)
CAPTOPRIL	2 (0,6)	1 (0,6)
ENALAPRIL	1 (0,3)	2 (1,2)
LISINOPRIL	3 (0,9)	0
BENAZEPRIL	1 (0,3)	0
PAPAVERINE AND DERIVATIVES	18 (5,4)	7 (4,3)
DROTAVERINE	18 (5,4)	7 (4,3)
ANTIDOTES	18 (5,4)	6 (3,7)
FLUMAZENIL	16 (4,8)	6 (3,7)
NALOXONE	2 (0,6)	0
PENEHYCLIDINE	2 (0,6)	0
ANISODAMINE	1 (0,3)	0
IRON, PARENTERAL PREPARATIONS	16 (4,8)	8 (4,9)
IRON	16 (4,8)	8 (4,9)
PROPULSIVES	14 (4,2)	9 (5,5)
METOCLOPRAMIDE	11 (3,3)	6 (3,7)
DOMPERIDONE	1 (0,3)	2 (1,2)
ITOPRIDE	2 (0,6)	0
MOSAPRIDE	1 (0,3)	1 (0,6)
HMG COA REDUCTASE INHIBITORS	14 (4,2)	8 (4,9)
ATORVASTATIN	7 (2,1)	3 (1,8)
ROSUVASTATIN	4 (1,2)	5 (3,0)
SIMVASTATIN	1 (0,3)	1 (0,6)
LOVASTATIN	1 (0,3)	0
PRAVASTATIN	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	14 (4,2)	8 (4,9)
SODIUM CHLORIDE	3 (0,9)	3 (1,8)
CALCIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	3 (0,9)	1 (0,6)
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE;SODIUM CITRATE	2 (0,6)	1 (0,6)
ELECTROLYTES NOS	1 (0,3)	2 (1,2)
CALCIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE	1 (0,3)	1 (0,6)
GLUCONATE SODIUM;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE	2 (0,6)	0
CALCIUM CHLORIDE;GLUCOSE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	1 (0,3)	0
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	1 (0,3)	0
CALCIUM CHLORIDE;POTASSIUM;SODIUM LACTATE	0	1 (0,6)
CALCIUM GLUCONATE;GLUCOSE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM ACETATE;SODIUM CHLORIDE;SODIUM CITRATE	1 (0,3)	0
GLUCONATE SODIUM;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM ACETATE;SODIUM CHLORIDE	1 (0,3)	0
POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	1 (0,3)	0
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	1 (0,3)	0
IMIDAZOLE DERIVATIVES	12 (3,6)	8 (4,9)
METRONIDAZOLE	11 (3,3)	7 (4,3)
ORNIDAZOLE	1 (0,3)	1 (0,6)
OTHER OPIOIDS	16 (4,8)	4 (2,4)
TRAMADOL	10 (3,0)	3 (1,8)
DEZOCINE	4 (1,2)	1 (0,6)
NALOXONE;TILIDINE	1 (0,3)	0
TRIMEPERIDINE	1 (0,3)	0
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	13 (3,9)	7 (4,3)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	4 (1,2)	2 (1,2)
ACTAEA SPICATA;BRYONIA ALBA;COLCHICUM AUTUMNALE;FILIPENDULA ULMARIA;RUTA GRAVEOLENS	0	1 (0,6)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
ALOE VERA;BOSWELLIA SPP.;MATRICARIA CHAMOMILLA;MELISSA OFFICINALIS	0	1 (0,6)
ARTEMISIA ARGYI	1 (0,3)	0
BAICALIN;BUPLEURUM SPP.;COW BEZOAR	1 (0,3)	0
BIDENS BITERNATA;CAFFEINE;CHLORPHENAMINE;CHRYSANTHEMUM INDICUM;ILEX ASPRELLA;MELICOPE PTELEIFOLIA;MENTHA CANADENSIS;PARACETAMOL	1 (0,3)	0
BORNEOL;COW BEZOAR;MENTHA CANADENSIS;PANAX NOTOGINSENG;PEARL;SCUTELLARIA BAICALENSIS;SWINE BILE	1 (0,3)	0
CALCIUM SULFATE;DRYOPTERIS CRASSIRHIZOMA;EPHEDRA SPP.;FORSYTHIA SUSPENSIA;GLYCYRRHIZA SPP.;HOULTTUYNIA CORDATA;ISATIS TINCTORIA;LONICERA JAPONICA;MENTHOL;POGOSTEMON CABLIN;PRUNUS SPP.;RHEUM SPP.;	1 (0,3)	0
COPTIS CHINENSIS;FORSYTHIA SUSPENSIA;GLYCYRRHIZA URALENSIS;PAEONIA LACTIFLORA;PHELLODENDRON AMURENSE;SCUTELLARIA BAICALENSIS	1 (0,3)	0
CORYDALIS BUNGEANA;ISATIS TINCTORIA;SCUTELLARIA BAICALENSIS;TARAXACUM MONGOLICUM	0	1 (0,6)
ECHINACEA SPP.	1 (0,3)	0
GENTIANA SPP.	1 (0,3)	0
HERBAL EXTRACT NOS	0	1 (0,6)
LIGUSTICUM STRIATUM;PORIA COCOS;REYNOUTRIA MULTIFLORA	1 (0,3)	0
MONASCUS PURPUREUS	1 (0,3)	0
QUERCUS SPP.	1 (0,3)	0
SACCHAROMYCES CEREVISIAE	0	1 (0,6)
SILYBUM MARIANUM	1 (0,3)	0
IRON IN OTHER COMBINATIONS	12 (3,6)	7 (4,3)
ASCORBIC ACID;IRON	8 (2,4)	6 (3,7)
ASCORBIC ACID;FOLIC ACID;IRON;PYRIDOXINE;VITAMIN B12 NOS	1 (0,3)	1 (0,6)
ASCORBIC ACID;FOLIC ACID;IRON;PROTEASE NOS	1 (0,3)	0
CYANOCOBALAMIN;FOLIC ACID;IRON	1 (0,3)	0
HERBAL NOS;IRON;VITAMINS NOS	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
MACROLIDES	12 (3,6)	7 (4,3)
AZITHROMYCIN	8 (2,4)	7 (4,3)
CLARITHROMYCIN	2 (0,6)	0
ERYTHROMYCIN	1 (0,3)	0
ROXITHROMYCIN	1 (0,3)	0
PIPERAZINE DERIVATIVES	16 (4,8)	3 (1,8)
CETIRIZINE	13 (3,9)	2 (1,2)
HYDROXYZINE	2 (0,6)	0
LEVOCETIRIZINE	1 (0,3)	1 (0,6)
OXATOMIDE	1 (0,3)	0
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	11 (3,3)	8 (4,9)
VITAMIN B12 NOS	6 (1,8)	5 (3,0)
CYANOCOBALAMIN	4 (1,2)	3 (1,8)
COBAMAMIDE	1 (0,3)	0
MECOBALAMIN	1 (0,3)	0
MUCOLYTICS	14 (4,2)	4 (2,4)
AMBROXOL	5 (1,5)	0
ACETYLCYSTEINE	3 (0,9)	1 (0,6)
CARBOCISTEINE	2 (0,6)	1 (0,6)
ERDOSTEINE	2 (0,6)	1 (0,6)
BROMHEXINE	1 (0,3)	0
SODIUM CHLORIDE	1 (0,3)	0
STREPTODORNASE;STREPTOKINASE	0	1 (0,6)
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	12 (3,6)	6 (3,7)
PARACETAMOL;TRAMADOL	3 (0,9)	3 (1,8)
CODEINE;PARACETAMOL	4 (1,2)	0
CODEINE;PARACETAMOL;PSEUDOEPHEDRINE	2 (0,6)	0
HYDROCODONE;PARACETAMOL	1 (0,3)	1 (0,6)
CAFFEINE;CODEINE;PARACETAMOL	1 (0,3)	0
CAFFEINE;PAPAVER SOMNIFERUM;PARACETAMOL	0	1 (0,6)
DEXKETOPROFEN;TRAMADOL	1 (0,3)	0
IBUPROFEN;TRAMADOL	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
OXYCODONE;PARACETAMOL	0	1 (0,6)
SEROTONIN (5HT3) ANTAGONISTS	10 (3,0)	8 (4,9)
ONDANSETRON	8 (2,4)	7 (4,3)
GRANISETRON	2 (0,6)	0
RAMOSETRON	0	1 (0,6)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	11 (3,3)	5 (3,0)
DICLOFENAC	5 (1,5)	2 (1,2)
KETOROLAC	4 (1,2)	3 (1,8)
ACECLOFENAC	1 (0,3)	0
DICLOFENAC;LIDOCAINE	1 (0,3)	0
INDOMETACIN	1 (0,3)	0
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	10 (3,0)	6 (3,7)
CALCIUM CARBONATE;COLECALCIFEROL	5 (1,5)	3 (1,8)
CALCIUM;COLECALCIFEROL	3 (0,9)	1 (0,6)
BORON;CALCITRIOL;CALCIUM CARBONATE;DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID;FOLIC ACID;MECOBALAMIN	1 (0,3)	1 (0,6)
BORON;CALCIUM;CALCIUM CARBONATE;COLECALCIFEROL;COPPER;MAGNESIUM;MANGANESE;ZINC	1 (0,3)	0
CALCIUM;COLECALCIFEROL;MAGNESIUM;ZINC	0	1 (0,6)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	11 (3,3)	5 (3,0)
AMOXICILLIN;CLAVULANIC ACID	10 (3,0)	5 (3,0)
PIPERACILLIN;TAZOBACTAM	1 (0,3)	0
HEPARIN GROUP	11 (3,3)	5 (3,0)
ENOXAPARIN	6 (1,8)	3 (1,8)
NADROPARIN	4 (1,2)	1 (0,6)
BEMIPARIN	0	1 (0,6)
DALTEPARIN	1 (0,3)	0
SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP	9 (2,7)	7 (4,3)
MEBEVERINE	5 (1,5)	4 (2,4)
TRIMEBUTINE	3 (0,9)	3 (1,8)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
DICYCLOVERINE	1 (0,3)	0
ANTIPROPULSIVES	10 (3,0)	5 (3,0)
LOPERAMIDE	10 (3,0)	5 (3,0)
ASCORBIC ACID (VITAMIN C), PLAIN	10 (3,0)	5 (3,0)
ASCORBIC ACID	10 (3,0)	5 (3,0)
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	8 (2,4)	7 (4,3)
ACETYLSALICYLIC ACID	7 (2,1)	7 (4,3)
CLOPIDOGREL	0	2 (1,2)
ACETYLSALICYLIC ACID;MAGNESIUM HYDROXIDE	1 (0,3)	0
TICAGRELOR	0	1 (0,6)
THIRD-GENERATION CEPHALOSPORINS	10 (3,0)	5 (3,0)
CEFTRIAZONE	5 (1,5)	4 (2,4)
CEFIXIME	5 (1,5)	0
CEFOPERAZONE;SULBACTAM	0	1 (0,6)
CEFPODOXIME	0	1 (0,6)
CEFTAZIDIME	1 (0,3)	0
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN	11 (3,3)	3 (1,8)
LOSARTAN	3 (0,9)	2 (1,2)
TELMISARTAN	4 (1,2)	1 (0,6)
VALSARTAN	3 (0,9)	0
CANDESARTAN	1 (0,3)	0
POTASSIUM	9 (2,7)	5 (3,0)
POTASSIUM	9 (2,7)	2 (1,2)
MAGNESIUM;POTASSIUM ASPARTATE	0	2 (1,2)
POTASSIUM BICARBONATE;POTASSIUM CITRATE	0	1 (0,6)
SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	10 (3,0)	4 (2,4)
SALBUTAMOL	10 (3,0)	3 (1,8)
SALMETEROL	0	1 (0,6)
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	11 (3,3)	3 (1,8)
SERTRALINE	4 (1,2)	2 (1,2)
CITALOPRAM	4 (1,2)	0
ESCITALOPRAM	2 (0,6)	1 (0,6)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
FLUOXETINE	1 (0,3)	0
ANTIBIOTICS	9 (2,7)	4 (2,4)
RIFAXIMIN	5 (1,5)	3 (1,8)
RIFAMPICIN	2 (0,6)	0
BENZALKONIUM;BENZOCAINE;TYROTHRIN	0	1 (0,6)
FIDAXOMICIN	1 (0,3)	0
NIFURATEL;NYSTATIN	1 (0,3)	0
THYROID HORMONES	7 (2,1)	6 (3,7)
LEVOTHYROXINE	7 (2,1)	6 (3,7)
DIHYDROPYRIDINE DERIVATIVES	8 (2,4)	4 (2,4)
AMLODIPINE	7 (2,1)	3 (1,8)
NIFEDIPINE	2 (0,6)	0
LACIDIPINE	0	1 (0,6)
LERCANIDIPINE	0	1 (0,6)
INFLUENZA VACCINES	9 (2,7)	3 (1,8)
INFLUENZA VACCINE	9 (2,7)	3 (1,8)
IRON TRIVALENT, ORAL PREPARATIONS	8 (2,4)	4 (2,4)
IRON	8 (2,4)	4 (2,4)
MULTIVITAMINS, PLAIN	11 (3,3)	1 (0,6)
MULTIVITAMINS, PLAIN	9 (2,7)	1 (0,6)
VITAMINS NOS	2 (0,6)	0
OTHER ANTIDEPRESSANTS	6 (1,8)	6 (3,7)
TRAZODONE	3 (0,9)	2 (1,2)
MIRTAZAPINE	2 (0,6)	1 (0,6)
MIANSERIN	1 (0,3)	1 (0,6)
VENLAFAXINE	0	2 (1,2)
BUPROPION	0	1 (0,6)
DESVENLAFAXINE	1 (0,3)	0
DULOXETINE	0	1 (0,6)
VORTIOXETINE	1 (0,3)	0
SECOND-GENERATION CEPHALOSPORINS	8 (2,4)	4 (2,4)
CEFUROXIME	6 (1,8)	3 (1,8)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
CEFACLOR	1 (0,3)	0
CEFMINOX	1 (0,3)	0
CEFOTETAN	0	1 (0,6)
MAGNESIUM	9 (2,7)	2 (1,2)
MAGNESIUM	8 (2,4)	0
MAGNESIUM CARBONATE;MAGNESIUM OXIDE	0	2 (1,2)
MAGNESIUM OXIDE	1 (0,3)	0
OTHER ANALGESICS AND ANTIPYRETICS	6 (1,8)	5 (3,0)
NEFOPAM	3 (0,9)	1 (0,6)
GABAPENTIN	2 (0,6)	1 (0,6)
AMITRIPTYLINE	0	2 (1,2)
CARBAMAZEPINE	0	1 (0,6)
PREGABALIN	0	1 (0,6)
SANGUISORBA OFFICINALIS	1 (0,3)	0
SYMPATHOMIMETICS, PLAIN	7 (2,1)	4 (2,4)
OXYMETAZOLINE	3 (0,9)	3 (1,8)
XYLOMETAZOLINE	3 (0,9)	1 (0,6)
TRAMAZOLINE	1 (0,3)	0
ANESTHETICS FOR TOPICAL USE	7 (2,1)	3 (1,8)
LIDOCAINE	3 (0,9)	1 (0,6)
TETRACAINE	3 (0,9)	1 (0,6)
LIDOCAINE;PRILOCAINE	1 (0,3)	1 (0,6)
CALCIUM	6 (1,8)	4 (2,4)
CALCIUM	2 (0,6)	3 (1,8)
CALCIUM CARBONATE	4 (1,2)	1 (0,6)
CORTICOSTEROIDS, POTENT (GROUP III)	10 (3,0)	0
MOMETASONE	4 (1,2)	0
HALOMETASONE	2 (0,6)	0
METHYLPREDNISOLONE	2 (0,6)	0
BETAMETHASONE	1 (0,3)	0
FLUTICASONE	1 (0,3)	0
FAT/CARBOHYDRATES/PROTEINS/MINERALS/VITAMINS, COMBINATIONS	8 (2,4)	2 (1,2)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	4 (1,2)	0
CASEIN;FATS NOS;FIBRE, DIETARY;MALTODEXTRIN;MINERALS NOS;VITAMINS NOS	2 (0,6)	1 (0,6)
CASEIN;HERBAL OIL NOS;MALTODEXTRIN;MINERALS NOS;TRACE ELEMENTS NOS;VITAMINS NOS	1 (0,3)	1 (0,6)
ASCORBIC ACID;BIOTIN;CALCIUM;CARBOHYDRATES NOS;CHLORIDE;COLECALCIFEROL;COPPER;CYANOCOBALAMIN;FATS NOS;FOLIC ACID;IRON;MAGNESIUM;MANGANESE;NICOTINAMIDE;PANTOTHENIC ACID;PHOSPHORUS;POTASSIUM;	1 (0,3)	0
ASCORBIC ACID;BIOTIN;CALCIUM;CAROTENOIDS NOS;CHLORINE;CHOLINE;CHROMIUM;COPPER;FATS NOS;FLUORINE;FOLIC ACID;IODINE;IRON;MAGNESIUM;MALTODEXTRIN;MANGANESE;MOLYBDENUM;NICOTINIC ACID;PANTOTHENIC ACID;	1 (0,3)	0
CARBOHYDRATES NOS;CHOLINE;FATS NOS;FIBRE, DIETARY;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	1 (0,3)	0
CARBOHYDRATES NOS;CHOLINE;FATS NOS;LACTOSE;MEDIUM-CHAIN TRIGLYCERIDES;MINERALS NOS;PROTEINS NOS;TAURINE;VITAMINS NOS	1 (0,3)	0
FAT/CARBOHYDRATES/PROTEINS/MINERALS/VITAMINS, COMBINATIONS	1 (0,3)	0
HYDRAZIDES	5 (1,5)	5 (3,0)
ISONIAZID	4 (1,2)	5 (3,0)
FTIVAZIDE	1 (0,3)	0
MORPHINAN DERIVATIVES	4 (1,2)	6 (3,7)
NALBUPHINE	3 (0,9)	4 (2,4)
BUTORPHANOL	1 (0,3)	2 (1,2)
PENICILLINS WITH EXTENDED SPECTRUM	7 (2,1)	3 (1,8)
AMOXICILLIN	6 (1,8)	3 (1,8)
PIVMECILLINAM	1 (0,3)	0
COXIBS	5 (1,5)	4 (2,4)
ETORICOXIB	2 (0,6)	2 (1,2)
PARECOXIB	3 (0,9)	0
CELECOXIB	0	2 (1,2)
GENERAL NUTRIENTS	4 (1,2)	5 (3,0)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
NUTRIENTS NOS	3 (0,9)	3 (1,8)
GENERAL NUTRIENTS	1 (0,3)	2 (1,2)
H2-RECEPTOR ANTAGONISTS	7 (2,1)	2 (1,2)
FAMOTIDINE	6 (1,8)	1 (0,6)
LAFUTIDINE	0	1 (0,6)
NIZATIDINE	1 (0,3)	0
PURINE ANALOGUES	6 (1,8)	3 (1,8)
MERCAPTOPURINE	6 (1,8)	3 (1,8)
SOLUTIONS FOR PARENTERAL NUTRITION	6 (1,8)	3 (1,8)
GLUCOSE	5 (1,5)	2 (1,2)
ALANINE;ARGININE;ASPARTIC ACID;CALCIUM CHLORIDE;GLUCOSE;GLUTAMIC ACID;GLYCINE;GLYCINE MAX;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE;MAGNESIUM;M EDIUM-CHAIN TRIGLYCERIDES;METHIONINE;PHENYLALANINE;POTASSIUM;	0	1 (0,6)
ALANINE;ARGININE;CALCIUM CHLORIDE;FISH OIL;GLUCOSE;GLYCINE;GLYCINE MAX;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE;MAGNESIUM SULFATE;MEDIUM-CHAIN TRIGLYCERIDES;METHIONINE;OLEA EUROPAEA;PHENYLALANINE;	1 (0,3)	0
ACE INHIBITORS AND DIURETICS	4 (1,2)	4 (2,4)
INDAPAMIDE;PERINDOPRIL	3 (0,9)	3 (1,8)
FOSINOPRIL;HYDROCHLOROTHIAZIDE	1 (0,3)	0
HYDROCHLOROTHIAZIDE;LISINOPRIL	0	1 (0,6)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS	5 (1,5)	3 (1,8)
FLUTICASONE;VILANTEROL	2 (0,6)	2 (1,2)
BUDESONIDE;FORMOTEROL	2 (0,6)	1 (0,6)
BECLOMETASONE;FORMOTEROL	1 (0,3)	0
FLUTICASONE;SALMETEROL	1 (0,3)	0
CORTICOSTEROIDS	6 (1,8)	2 (1,2)
MOMETASONE	3 (0,9)	2 (1,2)
FLUTICASONE	2 (0,6)	0
AZELASTINE;FLUTICASONE	1 (0,3)	0
ENZYME PREPARATIONS	5 (1,5)	3 (1,8)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
PANCREATIN	3 (0,9)	2 (1,2)
LIPASE	1 (0,3)	0
PANCREATIN;SIMETICONE	1 (0,3)	0
TILACTASE	0	1 (0,6)
LINCOSAMIDES	5 (1,5)	3 (1,8)
CLINDAMYCIN	5 (1,5)	3 (1,8)
OTHER ANTIVIRALS	5 (1,5)	3 (1,8)
MOLNUPIRAVIR	2 (0,6)	1 (0,6)
DEHYDROANDROGRAPHOLIDE	1 (0,3)	0
ENISAMIUM IODIDE	1 (0,3)	0
FAVIPIRAVIR	0	1 (0,6)
IMIDAZOLYL ETHANAMIDE PENTANDIOIC ACID	0	1 (0,6)
UMIFENOVIR	1 (0,3)	0
SULFONAMIDES, PLAIN	4 (1,2)	4 (2,4)
FUROSEMIDE	4 (1,2)	3 (1,8)
BUMETANIDE	0	1 (0,6)
INDAPAMIDE	0	1 (0,6)
TORASEMIDE	0	1 (0,6)
ADRENERGIC AND DOPAMINERGIC AGENTS	3 (0,9)	4 (2,4)
EPHEDRINE	1 (0,3)	2 (1,2)
METARAMINOL	1 (0,3)	1 (0,6)
NOREPINEPHRINE	1 (0,3)	1 (0,6)
ALDOSTERONE ANTAGONISTS	4 (1,2)	3 (1,8)
SPIRONOLACTONE	4 (1,2)	3 (1,8)
BENZODIAZEPINE RELATED DRUGS	2 (0,6)	5 (3,0)
ZOLPIDEM	1 (0,3)	4 (2,4)
ESZOPICLONE	0	1 (0,6)
ZOPICLONE	1 (0,3)	0
BIGUANIDES	4 (1,2)	3 (1,8)
METFORMIN	4 (1,2)	2 (1,2)
ATOVAQUONE;PROGUANIL	0	1 (0,6)
FIBRATES	4 (1,2)	3 (1,8)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
FENOFIBRATE	3 (0,9)	3 (1,8)
BEZAFIBRATE	1 (0,3)	0
LOCAL ANESTHETICS	6 (1,8)	1 (0,6)
LIDOCAINE	4 (1,2)	0
PRAMOCAINE;ZINC	2 (0,6)	0
LIDOCAINE;TRIBENOSIDE	0	1 (0,6)
NATURAL OPIUM ALKALOIDS	3 (0,9)	4 (2,4)
MORPHINE	1 (0,3)	3 (1,8)
OXYCODONE	0	2 (1,2)
CODEINE	1 (0,3)	0
DIHYDROCODEINE	1 (0,3)	0
HYDROMORPHONE	0	1 (0,6)
NITROIMIDAZOLE DERIVATIVES	5 (1,5)	2 (1,2)
METRONIDAZOLE	4 (1,2)	2 (1,2)
TINIDAZOLE	1 (0,3)	0
OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STERIODS	5 (1,5)	2 (1,2)
SULFASALAZINE	4 (1,2)	2 (1,2)
NIMESULIDE	1 (0,3)	0
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	5 (1,5)	2 (1,2)
BISMUTH	1 (0,3)	2 (1,2)
REBAMIPIDE	3 (0,9)	0
SUCRALFATE	1 (0,3)	0
PERIPHERAL OPIOID RECEPTOR ANTAGONISTS	4 (1,2)	3 (1,8)
NALOXONE	4 (1,2)	3 (1,8)
PROGESTOGENS	7 (2,1)	0
MEDROXYPROGESTERONE	2 (0,6)	0
DESOGESTREL	1 (0,3)	0
DROSPIRENONE	1 (0,3)	0
ETONOGESTREL	1 (0,3)	0
LEVONORGESTREL	1 (0,3)	0
NORETHISTERONE	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
SUBSTITUTED ALKYLAMINES	1 (0,3)	6 (3,7)
PHENIRAMINE	1 (0,3)	3 (1,8)
CHLORPHENAMINE	0	3 (1,8)
SYMPATHOMIMETICS	6 (1,8)	1 (0,6)
PSEUDOEPHEDRINE	2 (0,6)	1 (0,6)
CHLORPHENAMINE;PSEUDOEPHEDRINE	1 (0,3)	0
IBUPROFEN;PSEUDOEPHEDRINE	1 (0,3)	0
PHENYLEPHRINE	1 (0,3)	0
PSEUDOEPHEDRINE;TRIPROLIDINE	1 (0,3)	0
ALPHA-ADRENORECEPTOR ANTAGONISTS	4 (1,2)	2 (1,2)
TAMSULOSIN	3 (0,9)	2 (1,2)
DOXAZOSIN	1 (0,3)	0
ANTIINFLAMMATORY PREPARATIONS, NON-STERIODS FOR TOPICAL USE	4 (1,2)	2 (1,2)
DICLOFENAC	2 (0,6)	1 (0,6)
KETOPROFEN	1 (0,3)	1 (0,6)
LOXOPROFEN	1 (0,3)	0
ENEMAS	5 (1,5)	1 (0,6)
BISACODYL	1 (0,3)	1 (0,6)
SODIUM PHOSPHATE	2 (0,6)	0
BENZOCAINE;DOCUSATE	1 (0,3)	0
GLYCEROL	1 (0,3)	0
FIRST-GENERATION CEPHALOSPORINS	5 (1,5)	1 (0,6)
CEFALEXIN	2 (0,6)	0
CEFAZOLIN	1 (0,3)	1 (0,6)
CEFADROXIL	1 (0,3)	0
CEFAZEDONE	1 (0,3)	0
CEFRADINE	1 (0,3)	0
IRON PREPARATIONS	5 (1,5)	1 (0,6)
IRON	5 (1,5)	1 (0,6)
OTHER ANXIOLYTICS	5 (1,5)	1 (0,6)
ESCITALOPRAM	3 (0,9)	1 (0,6)
PROPRANOLOL	2 (0,6)	0

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
PAROXETINE	1 (0,3)	0
TRIAZOLE DERIVATIVES	4 (1,2)	2 (1,2)
FLUCONAZOLE	3 (0,9)	2 (1,2)
ITRACONAZOLE	1 (0,3)	0
ANTISEPTICS	4 (1,2)	1 (0,6)
AMYLMETACRESOL;DICHLOROBENZYL ALCOHOL	2 (0,6)	0
CETYLPYRIDINIUM;LIDOCAINE;MENTHOL	0	1 (0,6)
DECAMETHOXINE	1 (0,3)	0
GUALENIC ACID	1 (0,3)	0
DIRECT FACTOR XA INHIBITORS	4 (1,2)	1 (0,6)
APIXABAN	2 (0,6)	1 (0,6)
RIVAROXABAN	3 (0,9)	0
IMIDAZOLE AND TRIAZOLE DERIVATIVES	4 (1,2)	1 (0,6)
CLOTRIMAZOLE	2 (0,6)	1 (0,6)
CLOBETASOL;KETOCONAZOLE	1 (0,3)	0
ECONAZOLE	1 (0,3)	0
MICONAZOLE	1 (0,3)	0
INTRAVAGINAL CONTRACEPTIVES	3 (0,9)	2 (1,2)
ETHINYLESTRADIOL;ETONOGESTREL	2 (0,6)	1 (0,6)
BENZALKONIUM	1 (0,3)	0
SPERMICIDES	0	1 (0,6)
OTHER ANTIBIOTICS FOR TOPICAL USE	5 (1,5)	0
FUSIDIC ACID	2 (0,6)	0
BACITRACIN;GRAMICIDIN;POLYMYXIN B	1 (0,3)	0
CHLORAMPHENICOL;METHYLURACIL	1 (0,3)	0
GENTAMICIN	1 (0,3)	0
OTHER BLOOD PRODUCTS	3 (0,9)	2 (1,2)
BLOOD, WHOLE	1 (0,3)	1 (0,6)
RED BLOOD CELLS	1 (0,3)	1 (0,6)
PLASMA	1 (0,3)	0
OTHER CENTRALLY ACTING AGENTS	3 (0,9)	2 (1,2)
CYCLOBENZAPRINE	1 (0,3)	1 (0,6)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
BACLOFEN	0	1 (0,6)
DIAZEPAM	1 (0,3)	0
EPERISONE	1 (0,3)	0
OTHER DRUGS FOR CONSTIPATION	2 (0,6)	3 (1,8)
OTHER DRUGS FOR CONSTIPATION	0	2 (1,2)
LINACLOTIDE	1 (0,3)	0
POTASSIUM;SODIUM BICARBONATE;SODIUM SULFATE	1 (0,3)	0
SAMBUCUS NIGRA	0	1 (0,6)
OTHER PLAIN VITAMIN PREPARATIONS	4 (1,2)	1 (0,6)
PYRIDOXINE	3 (0,9)	1 (0,6)
BIOTIN	1 (0,3)	0
VITAMIN E NOS	1 (0,3)	0
SALICYLIC ACID AND DERIVATIVES	3 (0,9)	2 (1,2)
ACETYLSALICYLIC ACID	2 (0,6)	2 (1,2)
SALICYLIC ACID	1 (0,3)	0
ALL OTHER THERAPEUTIC PRODUCTS	3 (0,9)	1 (0,6)
ALL OTHER THERAPEUTIC PRODUCTS	3 (0,9)	1 (0,6)
AMINO ACIDS	3 (0,9)	1 (0,6)
TRANEXAMIC ACID	1 (0,3)	1 (0,6)
ALANYL GLUTAMINE	1 (0,3)	0
ARGININE	1 (0,3)	0
BILE ACIDS AND DERIVATIVES	2 (0,6)	2 (1,2)
URSODEOXYCHOLIC ACID	2 (0,6)	2 (1,2)
BIOFLAVONOIDS	3 (0,9)	1 (0,6)
DIOSMIN;HESPERIDIN	3 (0,9)	1 (0,6)
BULK-FORMING LAXATIVES	3 (0,9)	1 (0,6)
PLANTAGO OVATA	3 (0,9)	1 (0,6)
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	3 (0,9)	1 (0,6)
INSULIN ASPART	2 (0,6)	1 (0,6)
INSULIN	1 (0,3)	0
INTRAUTERINE CONTRACEPTIVES	1 (0,3)	3 (1,8)
LEVONORGESTREL	1 (0,3)	2 (1,2)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
INTRAUTERINE CONTRACEPTIVE DEVICE	0	1 (0,6)
IRON IN COMBINATION WITH FOLIC ACID	3 (0,9)	1 (0,6)
FOLIC ACID;IRON	3 (0,9)	1 (0,6)
LIVER THERAPY	3 (0,9)	1 (0,6)
ARGININE GLUTAMATE	1 (0,3)	0
DL-METHIONINE;GLYCINE;GLYCYRRHIZIC ACID	1 (0,3)	0
POLYENE PHOSPHATIDYLCHOLINE	1 (0,3)	0
RIFAXIMIN	0	1 (0,6)
MUSCLE RELAXANTS	1 (0,3)	3 (1,8)
DILTIAZEM	1 (0,3)	3 (1,8)
NEURAMINIDASE INHIBITORS	3 (0,9)	1 (0,6)
OSELTAMIVIR	2 (0,6)	1 (0,6)
PERAMIVIR	1 (0,3)	0
NITROFURAN DERIVATIVES	3 (0,9)	1 (0,6)
FURAZIDIN	1 (0,3)	1 (0,6)
NITROFURAL	1 (0,3)	0
NITROFURANTOIN	1 (0,3)	0
OTHER AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE	2 (0,6)	2 (1,2)
OTHER AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE	1 (0,3)	1 (0,6)
ESCHERICHIA COLI;PHENOL	0	1 (0,6)
HYALURONIC ACID	1 (0,3)	0
STREPTODORNASE;STREPTOKINASE	1 (0,3)	0
OTHER ANTIALLERGICS	3 (0,9)	1 (0,6)
CROMOGLICIC ACID	3 (0,9)	0
OLOPATADINE	0	1 (0,6)
OTHER CARDIAC PREPARATIONS	3 (0,9)	1 (0,6)
ETHANOL	1 (0,3)	0
IVABRADINE	1 (0,3)	0
TRIMETAZIDINE	0	1 (0,6)
UBIDECARENONE	1 (0,3)	0
OTHER COUGH SUPPRESSANTS	3 (0,9)	1 (0,6)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
LEVODROPROPIZINE	3 (0,9)	0
BENZONATATE	0	1 (0,6)
OTHER DERMATOLOGICALS	4 (1,2)	0
BIOTIN;COLLAGEN	1 (0,3)	0
ESTRADIOL	1 (0,3)	0
FINASTERIDE	1 (0,3)	0
MINOXIDIL	1 (0,3)	0
OTHER DERMATOLOGICALS	1 (0,3)	0
OTHER HYPNOTICS AND SEDATIVES	1 (0,3)	3 (1,8)
DIPHENHYDRAMINE	0	2 (1,2)
HUMULUS LUPULUS;PASSIFLORA INCARNATA;VALERIANA OFFICINALIS	1 (0,3)	0
HYOSCINE	0	1 (0,6)
MELISSA OFFICINALIS;MENTHA X PIPERITA;VALERIANA OFFICINALIS	1 (0,3)	0
OTHER IMMUNOSTIMULANTS	4 (1,2)	0
LEUCOGEN	3 (0,9)	0
TRANSFER FACTOR	1 (0,3)	0
OTHER THROAT PREPARATIONS	4 (1,2)	0
CAMPHOR;CHLOROBUTANOL;EUCALYPTUS SPP.;MENTHOL	1 (0,3)	0
FLURBIPROFEN	1 (0,3)	0
IBUPROFEN	1 (0,3)	0
PROPOLIS	1 (0,3)	0
SYNTHETIC ANTICHOLINERGICS, QUATERNARY AMMONIUM COMPOUNDS	2 (0,6)	2 (1,2)
GLYCOPYRRONIUM	1 (0,3)	1 (0,6)
OTILONIUM	1 (0,3)	1 (0,6)
TETRACYCLINES	2 (0,6)	2 (1,2)
DOXYCYCLINE	2 (0,6)	2 (1,2)
THIAZIDES, PLAIN	4 (1,2)	0
HYDROCHLOROTHIAZIDE	4 (1,2)	0
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	4 (1,2)	0
CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	2 (0,6)	0

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
ARABINOGLACTAN;LACTOFERRIN	1 (0,3)	0
FIBRE, DIETARY	1 (0,3)	0
WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA	1 (0,3)	3 (1,8)
IOPROMIDE	1 (0,3)	1 (0,6)
IOHEXOL	0	1 (0,6)
IOMEPROL	0	1 (0,6)
IOPAMIDOL	0	1 (0,6)
ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS	2 (0,6)	1 (0,6)
FENOTEROL;IPRATROPIUM	1 (0,3)	1 (0,6)
OLODATEROL;TIOTROPIUM	1 (0,3)	0
AGENTS FOR DERMATITIS, EXCLUDING CORTICOSTEROIDS	3 (0,9)	0
TACROLIMUS	2 (0,6)	0
DL-METHIONINE;GLYCINE;GLYCYRRHIZIC ACID	1 (0,3)	0
AMINOALKYL ETHERS	3 (0,9)	0
DIPHENHYDRAMINE	2 (0,6)	0
CLEMASTINE	1 (0,3)	0
ANTICHOLINESTERASES	2 (0,6)	1 (0,6)
NEOSTIGMINE	1 (0,3)	1 (0,6)
DONEPEZIL	1 (0,3)	0
ANTIEMETICS AND ANTINAUSEANTS	1 (0,3)	2 (1,2)
METOCLOPRAMIDE	1 (0,3)	2 (1,2)
ANTIINFECTIVES FOR TREATMENT OF ACNE	3 (0,9)	0
BENZOYL PEROXIDE;CLINDAMYCIN	1 (0,3)	0
CLINDAMYCIN	1 (0,3)	0
LINCOMYCIN;PYRIDOXINE	1 (0,3)	0
BARBITURATES, PLAIN	0	3 (1,8)
THIOPENTAL	0	3 (1,8)
CARBAMIC ACID ESTERS	3 (0,9)	0
METHOCARBAMOL	2 (0,6)	0
METHOCARBAMOL;PARACETAMOL	1 (0,3)	0
CENTRALLY ACTING SYMPATHOMIMETICS	3 (0,9)	0

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
AMFETAMINE;DEXAMFETAMINE	2 (0,6)	0
METHYLPHENIDATE	1 (0,3)	0
CORTICOSTEROIDS, MODERATELY POTENT (GROUP II)	1 (0,3)	2 (1,2)
DESONIDE	1 (0,3)	0
HYDROCORTISONE	0	1 (0,6)
TRIAMCINOLONE	0	1 (0,6)
DIPHENYLMETHANE DERIVATIVES	2 (0,6)	1 (0,6)
HYDROXYZINE	2 (0,6)	1 (0,6)
HERBAL EXPECTORANTS AND EMOLLIENTS	0	3 (1,8)
EUCALYPTUS GLOBULUS	0	1 (0,6)
HEDERA HELIX	0	1 (0,6)
THYMUS VULGARIS	0	1 (0,6)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	2 (0,6)	1 (0,6)
INSULIN DEGLUDEC	1 (0,3)	1 (0,6)
INSULIN DETEMIR	1 (0,3)	0
LEUKOTRIENE RECEPTOR ANTAGONISTS	1 (0,3)	2 (1,2)
MONTELUKAST	1 (0,3)	1 (0,6)
DESLOTRADINE;MONTELUKAST	0	1 (0,6)
MELATONIN RECEPTOR AGONISTS	1 (0,3)	2 (1,2)
MELATONIN	1 (0,3)	2 (1,2)
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS	2 (0,6)	1 (0,6)
AMITRIPTYLINE	2 (0,6)	1 (0,6)
ORGANIC NITRATES	1 (0,3)	2 (1,2)
GLYCERYL TRINITRATE	1 (0,3)	2 (1,2)
ISOSORBIDE MONONITRATE	0	1 (0,6)
OTHER AMINOGLYCOSIDES	1 (0,3)	2 (1,2)
GENTAMICIN	0	2 (1,2)
ETIMICIN	1 (0,3)	0
OTHER ANTIBACTERIALS	1 (0,3)	2 (1,2)
FOSFOMYCIN	1 (0,3)	2 (1,2)
OTHER EMOLLIENTS AND PROTECTIVES	3 (0,9)	0

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
AQUAPHILUS DOLOMIAE;ELAEIS GUINEENSIS;GLYCEROL;OENOTHERA BIENNIS;PARAFFIN, LIQUID;TOCOPHEROL	1 (0,3)	0
DIMETICONE;PROPYLENE GLYCOL	1 (0,3)	0
OTHER EMOLLIENTS AND PROTECTIVES	1 (0,3)	0
OTHER NASAL PREPARATIONS	3 (0,9)	0
SODIUM CHLORIDE	2 (0,6)	0
SEA WATER	1 (0,3)	0
OTHER OPHTHALMOLOGICALS	2 (0,6)	1 (0,6)
CARBOMER	1 (0,3)	0
ECTOINE	1 (0,3)	0
HYALURONIC ACID;TREHALOSE	0	1 (0,6)
PREPARATIONS INHIBITING URIC ACID PRODUCTION	1 (0,3)	2 (1,2)
ALLOPURINOL	1 (0,3)	1 (0,6)
FEBUXOSTAT	0	1 (0,6)
PROTEASE INHIBITORS	3 (0,9)	0
NIRMATREL VIR;RITONAVIR	3 (0,9)	0
TONICS	2 (0,6)	1 (0,6)
CURCUMIN	0	1 (0,6)
DIETARY SUPPLEMENT	1 (0,3)	0
MAGNESIUM CITRATE;POTASSIUM	1 (0,3)	0
VITAMIN K	3 (0,9)	0
VITAMIN K NOS	2 (0,6)	0
PHYTOMENADIONE	1 (0,3)	0
ACE INHIBITORS AND CALCIUM CHANNEL BLOCKERS	2 (0,6)	0
AMLODIPINE;LISINOPRIL	2 (0,6)	0
ACE INHIBITORS, OTHER COMBINATIONS	1 (0,3)	1 (0,6)
AMLODIPINE;INDAPAMIDE;PERINDOPRIL	1 (0,3)	1 (0,6)
ALPHA AND BETA BLOCKING AGENTS	2 (0,6)	0
CARVEDILOL	2 (0,6)	0
AMINO ACIDS AND DERIVATIVES	1 (0,3)	1 (0,6)
ADEMETIONINE	1 (0,3)	1 (0,6)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), OTHER COMBINATIONS	2 (0,6)	0
AMLODIPINE;HYDROCHLOROTHIAZIDE;VALSARTAN	1 (0,3)	0
SACUBITRIL;VALSARTAN	1 (0,3)	0
BENZAMIDES	1 (0,3)	1 (0,6)
AMISULPRIDE	1 (0,3)	0
SULPIRIDE	0	1 (0,6)
BILE THERAPY	2 (0,6)	0
PINENE	1 (0,3)	0
TIMONACIC	1 (0,3)	0
BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS	0	2 (1,2)
ALBUMIN HUMAN	0	2 (1,2)
CARBAPENEMS	0	2 (1,2)
IMIPENEM	0	1 (0,6)
MEROPENEM	0	1 (0,6)
COLONY STIMULATING FACTORS	2 (0,6)	0
FILGRASTIM	1 (0,3)	0
GRANULOCYTE COLONY STIMULATING FACTOR	1 (0,3)	0
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM AND MAGNESIUM COMPOUNDS	2 (0,6)	0
ALUMINIUM;MAGNESIUM	1 (0,3)	0
CALCIUM CARBONATE;MAGNESIUM HYDROXIDE	1 (0,3)	0
COMBINATIONS OF ANTIBACTERIALS	1 (0,3)	1 (0,6)
CIPROFLOXACIN;ORNIDAZOLE	1 (0,3)	0
OFLOXACIN;ORNIDAZOLE	0	1 (0,6)
COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES	1 (0,3)	1 (0,6)
SULFAMETHOXAZOLE;TRIMETHOPRIM	1 (0,3)	1 (0,6)
CORTICOSTEROIDS, PLAIN	2 (0,6)	0
FLUOROMETHOLONE	1 (0,3)	0
LOTEPREDNOL	1 (0,3)	0
CORTICOSTEROIDS, POTENT, COMBINATIONS WITH ANTIBIOTICS	2 (0,6)	0
BETAMETHASONE;CLOTRIMAZOLE;GENTAMICIN	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
BETAMETHASONE;GENTAMICIN	1 (0,3)	0
CORTICOSTEROIDS, POTENT, OTHER COMBINATIONS	1 (0,3)	1 (0,6)
BETAMETHASONE;SALICYLIC ACID	0	1 (0,6)
BETAMETHASONE;UREA	1 (0,3)	0
CORTICOSTEROIDS, WEAK (GROUP I)	2 (0,6)	0
HYDROCORTISONE	2 (0,6)	0
CORTICOSTEROIDS, WEAK, OTHER COMBINATIONS	2 (0,6)	0
HYDROCORTISONE;LIDOCAINE	1 (0,3)	0
PREDNISOLONE;SALICYLIC ACID	1 (0,3)	0
COVID-19 VACCINES	2 (0,6)	0
COVID-19 VACCINE	2 (0,6)	0
DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES	1 (0,3)	1 (0,6)
CLOZAPINE	0	1 (0,6)
QUETIAPINE	1 (0,3)	0
DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS	1 (0,3)	1 (0,6)
ALOGLIPTIN	1 (0,3)	0
SITAGLIPTIN	0	1 (0,6)
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE	2 (0,6)	0
FESOTERODINE	1 (0,3)	0
SOLIFENACIN	1 (0,3)	0
EXPECTORANTS	2 (0,6)	0
GLYCYRRHIZIC ACID	1 (0,3)	0
GUAIFENESIN	1 (0,3)	0
HOMEOPATHIC PREPARATION	2 (0,6)	0
ACHILLEA MILLEFOLIUM;ACONITUM SPP.;ARNICA SPP.;ATROPA BELLA-DONNA;BELLIS PERENNIS;CALENDULA SPP.;ECHINACEA ANGUSTIFOLIA;ECHINACEA PURPUREA;HAMAMELIS SPP.;HYPERICUM SPP.;MATRICARIA CHAMOMILLA;	1 (0,3)	0
ACONITUM NAPELLUS;CINCHONA OFFICINALIS;MAGNESIUM PHOSPHATE;PSEUDOGNAPHALIUM OBTUSIFOLIUM;RHODODENDRON TOMENTOSUM;TOXICODENDRON PUBESCENS;VISCUM ALBUM	1 (0,3)	0
IMIDAZOLINE RECEPTOR AGONISTS	0	2 (1,2)
MOXONIDINE	0	1 (0,6)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
RILMENIDINE	0	1 (0,6)
INTERFERONS	2 (0,6)	0
INTERFERON ALFA-2B	2 (0,6)	0
INTERLEUKIN INHIBITORS	1 (0,3)	1 (0,6)
USTEKINUMAB	1 (0,3)	1 (0,6)
MULTIVITAMINS, OTHER COMBINATIONS	2 (0,6)	0
ASCORBIC ACID;BETACAROTENE;BIOTIN;BORON;CALCIUM;CHLORIDE;CH ROMIUM;COLECALCIFEROL;COPPER;CYANOCOBALAMIN;FOLI C ACID;IODINE;IRON;LYCOPENE;MAGNESIUM;MANGANESE;MOL YBDENUM;NICKEL;NICOTINAMIDE;	1 (0,3)	0
MULTIVITAMINS, OTHER COMBINATIONS	1 (0,3)	0
NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	2 (0,6)	0
ESTRADIOL	1 (0,3)	0
ETHINYLESTRADIOL	1 (0,3)	0
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	1 (0,3)	1 (0,6)
ACICLOVIR	1 (0,3)	1 (0,6)
OPIUM ALKALOIDS AND DERIVATIVES	2 (0,6)	0
CAFFEINE;CHLORPHENAMINE;DIHYDROCODEINE;METHYLEPH EDRINE	1 (0,3)	0
DIHYDROCODEINE	1 (0,3)	0
OPIUM DERIVATIVES AND EXPECTORANTS	2 (0,6)	0
CHLORPHENAMINE;DIHYDROCODEINE;GUAIFENESIN;METHYL EPHEDRINE	1 (0,3)	0
CODEINE;SULFOGAIACOL	1 (0,3)	0
OTHER ANTIEMETICS	1 (0,3)	1 (0,6)
DIMENHYDRINATE	1 (0,3)	1 (0,6)
OTHER ANTIEPILEPTICS	1 (0,3)	1 (0,6)
LEVETIRACETAM	1 (0,3)	1 (0,6)
OTHER ANTIFUNGALS FOR TOPICAL USE	2 (0,6)	0
CETYLPIRIDINIUM;UNDECYLENIC ACID	1 (0,3)	0
CICLOPIROX	1 (0,3)	0
OTHER ANTIMIGRAINE PREPARATIONS	2 (0,6)	0

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
CLONIDINE	1 (0,3)	0
TOPIRAMATE	1 (0,3)	0
OTHER ANTIPSYCHOTICS	2 (0,6)	0
ARIPIPRAZOLE	1 (0,3)	0
RISPERIDONE	1 (0,3)	0
OTHER ANTISEPTICS AND DISINFECTANTS	2 (0,6)	0
METHACRYLIC ACID	1 (0,3)	0
POTASSIUM PERMANGANATE	1 (0,3)	0
OTHER CARDIAC COMBINATION PRODUCTS	1 (0,3)	1 (0,6)
MAGNESIUM;POTASSIUM ASPARTATE	1 (0,3)	1 (0,6)
OTHER CHEMOTHERAPEUTICS	1 (0,3)	1 (0,6)
BENZOYL PEROXIDE	0	1 (0,6)
METRONIDAZOLE	1 (0,3)	0
OTHER COMBINATIONS OF NUTRIENTS	2 (0,6)	0
DOCOSAHEXAENOIC ACID	1 (0,3)	0
FISH OIL	1 (0,3)	0
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	2 (0,6)	0
HYALURONIC ACID	1 (0,3)	0
PERNA CANALICULUS EXTRACT	1 (0,3)	0
OTHER LIPID MODIFYING AGENTS	1 (0,3)	1 (0,6)
FISH OIL	1 (0,3)	0
OMEGA-3-ACID ETHYL ESTER	0	1 (0,6)
OTHER MINERAL PRODUCTS	2 (0,6)	0
MAGNESIUM;POTASSIUM ASPARTATE	2 (0,6)	0
OTHER NERVOUS SYSTEM DRUGS	1 (0,3)	1 (0,6)
GABAPENTIN	0	1 (0,6)
PROPRANOLOL	1 (0,3)	0
OTHER PSYCHOSTIMULANTS AND NOOTROPICS	1 (0,3)	1 (0,6)
PIRACETAM	1 (0,3)	0
VINPOCETINE	0	1 (0,6)
PHENYLALKYLAMINE DERIVATIVES	2 (0,6)	0
VERAPAMIL	2 (0,6)	0

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
PREGNADIEN DERIVATIVES	1 (0,3)	1 (0,6)
CHLORMADINONE	1 (0,3)	0
DIENOGEST	0	1 (0,6)
PYRETHRINES, INCL. SYNTHETIC COMPOUNDS	1 (0,3)	1 (0,6)
PERMETHRIN	1 (0,3)	1 (0,6)
RETINOIDS FOR TOPICAL USE IN ACNE	0	2 (1,2)
CLINDAMYCIN;TRETINOIN	0	1 (0,6)
ISOTRETINOIN	0	1 (0,6)
SELECTIVE SEROTONIN (5HT1) AGONISTS	2 (0,6)	0
ELETRIPTAN	1 (0,3)	0
SUMATRIPTAN	1 (0,3)	0
SELENIUM	1 (0,3)	1 (0,6)
SELENIUM	1 (0,3)	1 (0,6)
SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS	1 (0,3)	1 (0,6)
CANAGLIFLOZIN	0	1 (0,6)
DAPAGLIFLOZIN	1 (0,3)	0
SOFT PARAFFIN AND FAT PRODUCTS	1 (0,3)	1 (0,6)
BETACAROTENE;COLECALCIFEROL;ISOPROPYL MYRISTATE;PARAFFIN;TOCOPHEROL	0	1 (0,6)
EMULSIFYING WAX;PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	1 (0,3)	0
SOFTENERS, EMOLLIENTS	1 (0,3)	1 (0,6)
DOCUSATE	1 (0,3)	0
MAGNESIUM HYDROXIDE;PARAFFIN, LIQUID	0	1 (0,6)
MAGNESIUM HYDROXIDE;PARAFFIN, LIQUID;SODIUM PICOSULFATE	0	1 (0,6)
SULFONYLUREAS	2 (0,6)	0
GLIPIZIDE	2 (0,6)	0
SYNTHETIC ANTICHOLINERGIC AGENTS IN COMBINATION WITH ANALGESICS	2 (0,6)	0
FENPIVERINIUM;METAMIZOLE;PITOFENONE	2 (0,6)	0
SYNTHETIC ANTISPASMODICS, AMIDES WITH TERTIARY AMINES	2 (0,6)	0
TIROPRAMIDE	2 (0,6)	0
TETANUS VACCINES	1 (0,3)	1 (0,6)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
TETANUS VACCINE	1 (0,3)	1 (0,6)
THROAT PREPARATIONS	2 (0,6)	0
CHLOROBUTANOL;HEXETIDINE;SALICYLIC ACID	1 (0,3)	0
EUCALYPTUS GLOBULUS;GLYCEROL;MENTHA X PIPERITA;SULFANILAMIDE;SULFATHIAZOLE;THYMOL	1 (0,3)	0
TRIAZOLE AND TETRAZOLE DERIVATIVES	1 (0,3)	1 (0,6)
FLUCONAZOLE	1 (0,3)	1 (0,6)
TUMOR NECROSIS FACTOR ALPHA (TNF-) INHIBITORS	1 (0,3)	1 (0,6)
ADALIMUMAB	1 (0,3)	1 (0,6)
VITAMIN B-COMPLEX, PLAIN	2 (0,6)	0
VITAMIN B COMPLEX	2 (0,6)	0
VITAMIN B1, PLAIN	1 (0,3)	1 (0,6)
THIAMINE	0	1 (0,6)
VITAMIN B NOS	1 (0,3)	0
VITAMINS, OTHER COMBINATIONS	1 (0,3)	1 (0,6)
ALPHA-CAROTENE;ASCORBIC ACID;BETACAROTENE;BIOTIN;BORON;CALCIUM;CALCIUM CARBONATE;CHOLINE;CHROMIUM;CITROFLAVONOID;COCARB OXYLASE;COPPER;CRYPTOXANTHIN;ELEUTHEROCOCCUS SENTICOSUS;ERGOCALCIFEROL;	0	1 (0,6)
CALCIUM GLUCONATE;CYANOCOBALAMIN;ETHANOL;IRON;NICOTINAMI DE;PYRIDOXINE;RIBOFLAVIN;THIAMINE	1 (0,3)	0
MINERALS NOS;VITAMINS NOS	0	1 (0,6)
ZINC	1 (0,3)	1 (0,6)
ZINC	1 (0,3)	1 (0,6)
3-OXOANDROSTEN (4) DERIVATIVES	0	1 (0,6)
TESTOSTERONE	0	1 (0,6)
ADAMANTANE DERIVATIVES	0	1 (0,6)
AMANTADINE	0	1 (0,6)
ADRENERGICS IN COMBINATION WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS	0	1 (0,6)
FENOTEROL;IPRATROPIUM	0	1 (0,6)
ALUMINIUM COMPOUNDS	1 (0,3)	0
ALUMINIUM SILICATE	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
AMINO ACIDS/CARBOHYDRATES/MINERALS/VITAMINS, COMBINATIONS	0	1 (0,6)
AMINO ACIDS NOS;CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;VITAMINS NOS	0	1 (0,6)
ANALGESICS AND ANESTHETICS	1 (0,3)	0
SALICYLIC ACID	1 (0,3)	0
ANESTHETICS	1 (0,3)	0
ANESTHETICS	1 (0,3)	0
ANESTHETICS, LOCAL	1 (0,3)	0
ANESTHETICS, LOCAL	1 (0,3)	0
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND CALCIUM CHANNEL BLOCKERS	0	1 (0,6)
AMLODIPINE;VALSARTAN	0	1 (0,6)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS	1 (0,3)	0
CANDESARTAN;HYDROCHLOROTHIAZIDE	1 (0,3)	0
ANTACIDS WITH ANTIFLATULENTS	1 (0,3)	0
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE	1 (0,3)	0
ANTIANDROGENS AND ESTROGENS	1 (0,3)	0
CYPROTERONE;ETHINYLESTRADIOL	1 (0,3)	0
ANTIANDROGENS, PLAIN	1 (0,3)	0
CYPROTERONE	1 (0,3)	0
ANTIARRHYTHMICS, CLASS III	1 (0,3)	0
AMIODARONE	1 (0,3)	0
ANTICHOLINERGICS	0	1 (0,6)
GLYCOPYRRONIUM	0	1 (0,6)
ANTIHISTAMINES FOR TOPICAL USE	1 (0,3)	0
MEPYRAMINE	1 (0,3)	0
ANTIHYPERTENSIVES FOR PULMONARY ARTERIAL HYPERTENSION	1 (0,3)	0
MAGNESIUM SULFATE	1 (0,3)	0
ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT	1 (0,3)	0
LYSOZYME;PYRIDOXINE	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
ANTIINFLAMMATORY AGENTS, NON-STEROIDS	1 (0,3)	0
PRANOPROFEN	1 (0,3)	0
ANTISEPTICS AND DISINFECTANTS	0	1 (0,6)
ALKONIUM;TRIMECAINE	0	1 (0,6)
ANTIVERTIGO PREPARATIONS	0	1 (0,6)
BETAHISTINE	0	1 (0,6)
ANTIVIRALS	0	1 (0,6)
ACICLOVIR	0	1 (0,6)
ANTIVIRALS FOR TREATMENT OF HCV INFECTIONS	1 (0,3)	0
RIBAVIRIN	1 (0,3)	0
AZASPIRODECANEDIONE DERIVATIVES	1 (0,3)	0
BUSPIRONE	1 (0,3)	0
BENZOTHIAZEPINE DERIVATIVES	1 (0,3)	0
DILTIAZEM	1 (0,3)	0
BETA BLOCKING AGENTS, NON-SELECTIVE	1 (0,3)	0
SOTALOL	1 (0,3)	0
BETA-LACTAMASE INHIBITORS	0	1 (0,6)
CLAVULANIC ACID	0	1 (0,6)
BETA-LACTAMASE RESISTANT PENICILLINS	1 (0,3)	0
FLUCLOXACILLIN	1 (0,3)	0
BILE ACID SEQUESTRANTS	1 (0,3)	0
COLESTYRAMINE	1 (0,3)	0
BILE AND LIVER THERAPY	1 (0,3)	0
BICYCLOL	1 (0,3)	0
BISPHOSPHONATES	1 (0,3)	0
ALENDRONIC ACID	1 (0,3)	0
CALCIUM COMPOUNDS	1 (0,3)	0
CALCIUM CARBONATE	1 (0,3)	0
CHARCOAL PREPARATIONS	1 (0,3)	0
CHARCOAL, ACTIVATED	1 (0,3)	0
COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS	0	1 (0,6)
EMPAGLIFLOZIN;LINAGLIPTIN	0	1 (0,6)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
COMBINATIONS OF VARIOUS LIPID MODIFYING AGENTS	0	1 (0,6)
FENOFIBRATE;SIMVASTATIN	0	1 (0,6)
CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION	1 (0,3)	0
DEXAMETHASONE;TOBRAMYCIN	1 (0,3)	0
CORTICOSTEROIDS, VERY POTENT (GROUP IV)	1 (0,3)	0
CLOBETASOL	1 (0,3)	0
DIRECT THROMBIN INHIBITORS	0	1 (0,6)
DABIGATRAN	0	1 (0,6)
DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	0	1 (0,6)
MONTMORILLONITE	0	1 (0,6)
ENCEPHALITIS VACCINES	0	1 (0,6)
TICK-BORNE ENCEPHALITIS VACCINE	0	1 (0,6)
ENZYMES	1 (0,3)	0
HYALURONIDASE	1 (0,3)	0
ETHERS, CHEMICALLY CLOSE TO ANTIHISTAMINES	1 (0,3)	0
ORPHENADRINE	1 (0,3)	0
FOLIC ACID ANALOGUES	1 (0,3)	0
METHOTREXATE	1 (0,3)	0
FOURTH-GENERATION CEPHALOSPORINS	1 (0,3)	0
CEFEPIME	1 (0,3)	0
GLYCOPEPTIDE ANTIBACTERIALS	1 (0,3)	0
VANCOMYCIN	1 (0,3)	0
HEPATITIS VACCINES	1 (0,3)	0
HEPATITIS A VACCINE	1 (0,3)	0
HEPATITIS B VACCINE	1 (0,3)	0
HERBAL ANTIHEMORRHOIDS FOR TOPICAL USE	1 (0,3)	0
AMBER (FOSSILIZED TREE RESIN);BORIC ACID;BORNEOL;CALAMINE;COW BEZOAR;MUSK;PEARL	1 (0,3)	0
HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES	1 (0,3)	0
ASCORBIC ACID;ROSA CANINA	1 (0,3)	0
HERBAL ANTISPASMODIC AGENTS, OTHER	1 (0,3)	0
CORYDALIS YANHUSUO;IPOMOEIA NIL	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
HERBAL ANTIVIRALS FOR SYSTEMIC USE	0	1 (0,6)
CALCIUM SULFATE;DRYOPTERIS CRASSIRHIZOMA;EPHEDRA SPP.;FORSYTHIA SUSPENSIA;GLYCYRRHIZA SPP.;HOULTTUYNIA CORDATA;ISATIS TINCTORIA;LONICERA JAPONICA;MENTHOL;POGOSTEMON CABLIN;PRUNUS SPP.;RHEUM SPP.;	0	1 (0,6)
HERBAL DIAPHORETICS AND OTHER HERBAL COUGH AND COLD REMEDIES	0	1 (0,6)
PELARGONIUM SPP.	0	1 (0,6)
HERBAL DIGESTIVES, OTHER	0	1 (0,6)
ZINGIBER OFFICINALE	0	1 (0,6)
HERBAL IMMUNOMODULATORS	1 (0,3)	0
ANGELICA SINENSIS;ASINI CORII COLLA;ASTRAGALUS MONGHOLICUS;EPIMEDIUM BREVICORNU;LESPEDeza BUERGERI;SOPHORA FLAVESCENS;ZIZIPHUS JUJUBA	1 (0,3)	0
HERBAL THROAT PREPARATIONS (TONSILLITIS)	1 (0,3)	0
GARDENIA JASMINOIDES;ISATIS TINCTORIA;PHELLODENDRON CHINENSE;SCAPHIUM AFFINE;SCUTELLARIA BAICALENSIS	1 (0,3)	0
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE-ACTING	0	1 (0,6)
INSULIN HUMAN	0	1 (0,6)
IODINE PRODUCTS	0	1 (0,6)
POVIDONE-IODINE	0	1 (0,6)
LOCAL HEMOSTATICS	0	1 (0,6)
THROMBIN	0	1 (0,6)
MAGNESIUM COMPOUNDS	1 (0,3)	0
MAGNESIUM HYDROXIDE	1 (0,3)	0
MULTIVITAMINS WITH MINERALS	1 (0,3)	0
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM CARBONATE;CHROMIUM;COLECALCIFEROL;CUPRIC OXIDE;CYANOCOBALAMIN;DL-ALPHA TOCOPHEROL;FOLIC ACID;IRON;MAGNESIUM OXIDE;MANGANESE;NICOTINAMIDE;PANTOTHENIC ACID;	1 (0,3)	0
Not coded	1 (0,3)	0
Not coded [CMTRT=SYSTEMIC NON-TOPICAL CORTICOSTEROIDS]	1 (0,3)	0
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	0	1 (0,6)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
ESCHERICHIA COLI	0	1 (0,6)
OTHER ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE	0	1 (0,6)
CYPROTERONE;ETHINYLESTRADIOL	0	1 (0,6)
OTHER ANTIINFECTIVES AND ANTISEPTICS	0	1 (0,6)
LACTOBACILLUS NOS	0	1 (0,6)
OTHER ANTIPRURITICS	1 (0,3)	0
CALAMINE;GLYCEROL;ZINC	1 (0,3)	0
OTHER ANTIPSORIATICS FOR TOPICAL USE	1 (0,3)	0
BETAMETHASONE;CALCIPOTRIOL	1 (0,3)	0
OTHER CAPILLARY STABILIZING AGENTS	0	1 (0,6)
ESGIN	0	1 (0,6)
OTHER CICATRIZANTS	1 (0,3)	0
METHYLURACIL	1 (0,3)	0
OTHER COLD PREPARATIONS	0	1 (0,6)
CHLORPHENAMINE;PARACETAMOL;PHENYLEPHRINE;THIAMIN E	0	1 (0,6)
OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION	1 (0,3)	0
DENOSUMAB	1 (0,3)	0
OTHER DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	1 (0,3)	0
OTHER DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	1 (0,3)	0
OTHER GYNECOLOGICALS	0	1 (0,6)
OTHER GYNECOLOGICALS	0	1 (0,6)
OTHER INTESTINAL ADSORBENTS	0	1 (0,6)
DIOSMECTITE	0	1 (0,6)
OTHER IRRIGATING SOLUTIONS	0	1 (0,6)
MANNITOL	0	1 (0,6)
OTHER LOCAL ANESTHETICS	1 (0,3)	0
DYCLONINE	1 (0,3)	0
OTHER NUTRIENTS	1 (0,3)	0
LEVOGLUTAMIDE;NUTRIENTS NOS	1 (0,3)	0
OTHER QUATERNARY AMMONIUM COMPOUNDS	0	1 (0,6)
ROCURONIUM	0	1 (0,6)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
OTHER SYSTEMIC HEMOSTATICS	1 (0,3)	0
HAEMOCOAGULASE	1 (0,3)	0
OTHER THERAPEUTIC PRODUCTS	0	1 (0,6)
ACONITUM NAPELLUS;AEGLE MARMELOS;AMOMUM SPP.;AQUILEGIA VULGARIS;CALCIUM SULFATE;CALENDULA OFFICINALIS;CAMPHOR;CETRARIA ISLANDICA;DOLOMIAEA COSTUS;ELETTARIA CARDAMOMUM;GLYCYRRHIZA GLABRA;	0	1 (0,6)
OXAZOL, THIAZINE, AND TRIAZINE DERIVATIVES	1 (0,3)	0
CHLORZOXAZONE;PARACETAMOL	1 (0,3)	0
OXICAMS	0	1 (0,6)
MELOXICAM	0	1 (0,6)
PARAMAGNETIC CONTRAST MEDIA	1 (0,3)	0
GADOTERIC ACID	1 (0,3)	0
PERTUSSIS VACCINES	1 (0,3)	0
DIPHThERIA VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE	1 (0,3)	0
PHENOL AND DERIVATIVES	1 (0,3)	0
POLICRESULEN	1 (0,3)	0
PNEUMOCOCCAL VACCINES	1 (0,3)	0
PNEUMOCOCCAL VACCINE	1 (0,3)	0
PREGNEN (4) DERIVATIVES	1 (0,3)	0
PROGESTERONE	1 (0,3)	0
PROGESTOGENS AND ESTROGENS, SEQUENTIAL PREPARATIONS	0	1 (0,6)
DIENOGEST;ESTRADIOL	0	1 (0,6)
PROSTAGLANDIN ANALOGUES	1 (0,3)	0
LATANOPROST	1 (0,3)	0
PROTEIN SUPPLEMENTS	0	1 (0,6)
CARBOHYDRATES NOS;LIPIDS NOS;MINERALS NOS;PROTEINS NOS	0	1 (0,6)
RABIES VACCINES	0	1 (0,6)
RABIES VACCINE	0	1 (0,6)
RETINOIDS FOR TREATMENT OF ACNE	1 (0,3)	0
ISOTRETINOIN	1 (0,3)	0
SALT SOLUTIONS	0	1 (0,6)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
SODIUM CHLORIDE	0	1 (0,6)
SILICONE PRODUCTS	1 (0,3)	0
DIMETICONE	1 (0,3)	0
SOLUTIONS PRODUCING OSMOTIC DIURESIS	1 (0,3)	0
MANNITOL	1 (0,3)	0
SUBSTITUTED ETHYLENE DIAMINES	1 (0,3)	0
CHLOROPYRAMINE	1 (0,3)	0
SYMPATHOMIMETICS IN GLAUCOMA THERAPY	1 (0,3)	0
BRIMONIDINE	1 (0,3)	0
TYPHOID VACCINES	0	1 (0,6)
TYPHOID VACCINE	0	1 (0,6)
URINARY CONCREMENT SOLVENTS	1 (0,3)	0
ALLIUM CEPA;BETULA SPP.;CITRUS SPP.;ELYMUS REPENS;EQUISETUM SPP.;LEVISTICUM SPP.;MENTHA X PIPERITA;PETROSELINUM CRISPUM;PINUS SYLVESTRIS;POLYGONUM AVICULARE;SALVIA SPP.;SOLIDAGO SPP.;	1 (0,3)	0
VITAMIN A, PLAIN	1 (0,3)	0
RETINOL	1 (0,3)	0
VITAMIN B-COMPLEX, OTHER COMBINATIONS	1 (0,3)	0
VITAMIN B-COMPLEX, OTHER COMBINATIONS	1 (0,3)	0
VITAMIN B1 IN COMBINATION WITH VITAMIN B6 AND/OR VITAMIN B12	0	1 (0,6)
CYANOCOBALAMIN;PYRIDOXINE;THIAMINE	0	1 (0,6)
VITAMINS	1 (0,3)	0
ASCORBIC ACID;BIOTIN;COCARBOXYLASE;COLECALCIFEROL;DEXPANTH ENOL;DL-ALPHA TOCOPHEROL;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE;RETINOL;RIBOFLAVIN;VITA MIN B12 NOS	1 (0,3)	0
VITAMINS WITH MINERALS	1 (0,3)	0
IRON;VITAMINS NOS	1 (0,3)	0
WATERSOLUBLE, NEPHROTROPIC, HIGH OSMOLAR X-RAY CONTRAST MEDIA	0	1 (0,6)
AMIDOTRIZOIC ACID	0	1 (0,6)
XANTHINES	0	1 (0,6)

Medication Class Preferred Term	Mirikizumab (N=331) n (%)	Ustekinumab (N=164) n (%)
THEOPHYLLINE	0	1 (0,6)
XANTHINES AND ADRENERGICS	0	1 (0,6)
AMINOPHYLLINE;CHLORPHENAMINE;METHOXYPHENAMINE;N OSCAPINE	0	1 (0,6)
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; n: Anzahl der Patienten; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; TNF: Tumor Necrosis Factor.		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_conmed.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_conmed_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/adcm

/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba

23SEP2024 / 04:34

Anhang 4-G.3.3 Behandlungsdauer in RCT VIVID-1 in Teilpopulation A

Behandlungsdauer (Wochen) in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Merkmal	Mirikizumab (N=331)	Ustekinumab (N=164)
Weeks of exposure, n (%)		
> 0 week	331 (100,0)	164 (100,0)
≥ 4 weeks	331 (100,0)	163 (99,4)
≥ 8 weeks	325 (98,2)	161 (98,2)
≥ 12 weeks	319 (96,4)	158 (96,3)
≥ 16 weeks	314 (94,9)	156 (95,1)
≥ 24 weeks	309 (93,4)	155 (94,5)
≥ 32 weeks	302 (91,2)	153 (93,3)
≥ 40 weeks	297 (89,7)	150 (91,5)
≥ 48 weeks	288 (87,0)	148 (90,2)
Weeks of exposure, n (%)		
> 0 to < 4 weeks	0	1 (0,6)
≥ 4 to < 8 weeks	6 (1,8)	2 (1,2)
≥ 8 to < 12 weeks	6 (1,8)	3 (1,8)
≥ 12 to < 16 weeks	5 (1,5)	2 (1,2)
≥ 16 to < 24 weeks	5 (1,5)	1 (0,6)
≥ 24 to < 32 weeks	7 (2,1)	2 (1,2)
≥ 32 to < 40 weeks	5 (1,5)	3 (1,8)
≥ 40 to < 48 weeks	9 (2,7)	2 (1,2)
≥ 48 weeks	288 (87,0)	148 (90,2)
Patient weeks of exposure		
Number of patients	331	164
Mean weeks of exposure	49,38	50,01
SD	11,184	10,544
Minimum	4,4	2,1
Q1	52,00	52,00
Median	52,57	52,57
Q3	53,29	53,29
Maximum	66,4	59,4
Total patient-years ^a	313,27	157,19

Merkmal	Mirikizumab (N=331)	Ustekinumab (N=164)
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; n: Anzahl der Patienten; N: Anzahl der Patienten in der Analyse; Q1 (Q3): Quartil 1 (3); RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung. Behandlungsdauer ist berechnet als (Datum der letzten Visite der Behandlungsperiode - Datum der ersten Dosis + 1 Tag). a: Berechnet als (Summe der Behandlungsdauern über alle Patienten der jeweiligen Behandlungsgruppe / 365.25).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_exp.sas

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23SEP2024 / 04:33

Anhang 4-G.3.4 Patientenberichtete Endpunkte in RCT VIVID-1 in Teilpopulation A

Anhang 4-G.3.4.1 Anzahl der imputierten Werte je Endpunkt in RCT VIVID-1 in Teilpopulation A

Overview of imputed values by endpoint in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpoint (at week 52)	Mirikizumab n/N (%)	Ustekinumab n/N (%)
Reduction in Urgency NRS Score by at least 3 points		
NRI due to missing values	4/331 (1,2)	6/164 (3,7)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	49/331 (14,8)	26/164 (15,9)
Increase in FACIT-Fatigue Score by at least 8 points		
NRI due to missing values	8/331 (2,4)	2/164 (1,2)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	53/331 (16,0)	22/164 (13,4)
Increase in FACIT-Fatigue Score by at least 9 points		
NRI due to missing values	8/331 (2,4)	2/164 (1,2)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	53/331 (16,0)	22/164 (13,4)
Resolution of extra-intestinal manifestations^a		
NRI due to missing values	0	0
NRI due to discontinuation of study medication	11/72 (15,3)	5/40 (12,5)
Total imputed values	11/72 (15,3)	5/40 (12,5)
Reduction in Abdominal pain by at least 0.45 points		
NRI due to missing values	4/331 (1,2)	6/164 (3,7)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	49/331 (14,8)	26/164 (15,9)
Reduction in Stool Frequency by at least 15 percent-points		
NRI due to missing values	4/331 (1,2)	6/164 (3,7)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	49/331 (14,8)	26/164 (15,9)
Closure of draining cutaneous fistulae^b		
NRI due to missing values	1/17 (5,9)	1/13 (7,7)
NRI due to discontinuation of study medication	2/17 (11,8)	0

Endpoint (at week 52)	Mirikizumab n/N (%)	Ustekinumab n/N (%)
Total imputed values	3/17 (17,6)	1/13 (7,7)
Reduction in QIDS-SR16 Total Score by at least 4.05 points		
NRI due to missing values	6/331 (1,8)	1/164 (0,6)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	51/331 (15,4)	21/164 (12,8)
Increase in EQ-5D VAS Score by at least 15 points		
NRI due to missing values	8/331 (2,4)	2/164 (1,2)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	53/331 (16,0)	22/164 (13,4)
Reduction in percentage of impairment in activities by at least 15 percent-points^c		
NRI due to missing values	3/202 (1,5)	1/91 (1,1)
NRI due to discontinuation of study medication	25/202 (12,4)	10/91 (11,0)
Total imputed values	28/202 (13,9)	11/91 (12,1)
Reduction in PGRS score by at least 1 point		
NRI due to missing values	4/331 (1,2)	6/164 (3,7)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	49/331 (14,8)	26/164 (15,9)
Reaching a value of 1 or 2 or 3 of PGIC Score		
NRI due to missing values	7/331 (2,1)	3/164 (1,8)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	52/331 (15,7)	23/164 (14,0)
Increase in SF-36 PCS Score by at least 9.4 points		
NRI due to missing values	8/331 (2,4)	2/164 (1,2)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	53/331 (16,0)	22/164 (13,4)
Increase in SF-36 MCS Score by at least 9.6 points		
NRI due to missing values	8/331 (2,4)	2/164 (1,2)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	53/331 (16,0)	22/164 (13,4)
Increase in IBDQ Total Score by at least 28.8 points		
NRI due to missing values	8/331 (2,4)	2/164 (1,2)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	53/331 (16,0)	22/164 (13,4)

Endpoint (at week 52)	Mirikizumab n/N (%)	Ustekinumab n/N (%)
Increase in IBDQ Bowel Symptoms by at least 9 points		
NRI due to missing values	8/331 (2,4)	2/164 (1,2)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	53/331 (16,0)	22/164 (13,4)
Increase in IBDQ Systemic Symptoms by at least 4.5 points		
NRI due to missing values	8/331 (2,4)	2/164 (1,2)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	53/331 (16,0)	22/164 (13,4)
Increase in IBDQ Emotional Function by at least 10.8 points		
NRI due to missing values	8/331 (2,4)	2/164 (1,2)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	53/331 (16,0)	22/164 (13,4)
Increase in IBDQ Social Function by at least 4.5 points		
NRI due to missing values	8/331 (2,4)	2/164 (1,2)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	53/331 (16,0)	22/164 (13,4)
Reduction in General well being score by at least 0.6 points		
NRI due to missing values	4/331 (1,2)	6/164 (3,7)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	49/331 (14,8)	26/164 (15,9)
Clinical remission by PRO, defined as SF$\leq$3 and AP$\leq$1		
NRI due to missing values	4/331 (1,2)	6/164 (3,7)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	49/331 (14,8)	26/164 (15,9)
Clinical Remission by PRO (AP=0)		
NRI due to missing values	4/331 (1,2)	6/164 (3,7)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	49/331 (14,8)	26/164 (15,9)
Corticosteroid-free from week 40 to week 52 and achieving clinical remission by PRO at week 52		
NRI due to missing values	5/331 (1,5)	7/164 (4,3)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	50/331 (15,1)	27/164 (16,5)
Urgency NRS Score $\leq$ 2		

Endpoint (at week 52)	Mirikizumab n/N (%)	Ustekinumab n/N (%)
NRI due to missing values	4/331 (1,2)	6/164 (3,7)
NRI due to discontinuation of study medication	45/331 (13,6)	20/164 (12,2)
Total imputed values	49/331 (14,8)	26/164 (15,9)

Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; EIMs: Extra-Intestinal Manifestations; EQ-5D: Fragebogen der EuroQol-Gruppe zur Lebensqualität auf 5 Dimensionen; FACIT: Functional Assessment of Chronic Illness Therapy-Fatigue; GWB: General Well Being; IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; MCS: Mental Health Component Summary Score; n: Anzahl der Patienten; N: Anzahl der Patienten in der Analyse; NRI: Nonresponder Imputation; NRS: Numeric Rating Scale; PCS: Physical Health Component Summary Score; PGIC: Patient Global Impression of Change; PGRS: Patient Global Rating of Severity; PRO: Patient Reported Outcome, defined as 2 of the patient-reported items of the CDAI (SF and AP); QIDS-SR16: Quick Inventory of Depressive Symptomatology - Self Report (16 items); RCT: randomisierte, kontrollierte Studie; SF-36: 36-Item Short Form Health Survey; SF: Stool Frequency; VAS: Visuelle Analogskala.

a: Calculated for participants with EIMs at baseline.

b: Calculated for participants with draining cutaneous fistulae at baseline.

c: Calculated for participants with baseline employment status of Yes.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_observed.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_observed_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adresp_gba, adsl_gba

/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/adds

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Anhang 4-G.3.4.2 Rücklaufquoten der patientenberichteten Endpunkte in RCT VIVID-1 in Teilpopulation A

Anhang 4-G.3.4.2.1 Klinische Remission

Angaben zur Vollständigkeit der Daten für PRO (AP+SF) zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
PRO (AP+SF)		
Baseline		
N-obs (%2)	330 (99,7)	164 (100,0)
N-miss (%2)	1 (0,3)	0 (0,0)
Woche 2		
N-visit	331 (100,0)	164 (100,0)
N-obs (%1) (%2)	328 (99,1) (99,1)	161 (98,2) (98,2)
N-miss (%1) (%2)	3 (0,9) (0,9)	3 (1,8) (1,8)
N-miss (%2)	0 (0,0)	0 (0,0)
Woche 4		
N-visit	331 (100,0)	163 (99,4)
N-obs (%1) (%2)	325 (98,2) (98,2)	159 (97,5) (97,0)
N-miss (%1) (%2)	6 (1,8) (1,8)	4 (2,5) (2,4)
N-miss (%2)	0 (0,0)	1 (0,6)
Woche 6		
N-visit	326 (98,5)	158 (96,3)
N-obs (%1) (%2)	320 (98,2) (96,7)	157 (99,4) (95,7)
N-miss (%1) (%2)	6 (1,8) (1,8)	1 (0,6) (0,6)
N-miss (%2)	5 (1,5)	6 (3,7)
Woche 8		
N-visit	322 (97,3)	158 (96,3)
N-obs (%1) (%2)	317 (98,4) (95,8)	156 (98,7) (95,1)
N-miss (%1) (%2)	5 (1,6) (1,5)	2 (1,3) (1,2)
N-miss (%2)	9 (2,7)	6 (3,7)
Woche 12		
N-visit	319 (96,4)	157 (95,7)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
N-obs (%1) (%2)	316 (99,1) (95,5)	157 (100,0) (95,7)
N-miss (%1) (%2)	3 (0,9) (0,9)	0 (0,0) (0,0)
N-miss (%2)	12 (3,6)	7 (4,3)
Woche 16		
N-visit	314 (94,9)	156 (95,1)
N-obs (%1) (%2)	311 (99,0) (94,0)	152 (97,4) (92,7)
N-miss (%1) (%2)	3 (1,0) (0,9)	4 (2,6) (2,4)
N-miss (%2)	17 (5,1)	8 (4,9)
Woche 20		
N-visit	311 (94,0)	156 (95,1)
N-obs (%1) (%2)	307 (98,7) (92,7)	156 (100,0) (95,1)
N-miss (%1) (%2)	4 (1,3) (1,2)	0 (0,0) (0,0)
N-miss (%2)	20 (6,0)	8 (4,9)
Woche 24		
N-visit	309 (93,4)	155 (94,5)
N-obs (%1) (%2)	304 (98,4) (91,8)	151 (97,4) (92,1)
N-miss (%1) (%2)	5 (1,6) (1,5)	4 (2,6) (2,4)
N-miss (%2)	22 (6,6)	9 (5,5)
Woche 28		
N-visit	307 (92,7)	153 (93,3)
N-obs (%1) (%2)	302 (98,4) (91,2)	147 (96,1) (89,6)
N-miss (%1) (%2)	5 (1,6) (1,5)	6 (3,9) (3,7)
N-miss (%2)	24 (7,3)	11 (6,7)
Woche 32		
N-visit	301 (90,9)	152 (92,7)
N-obs (%1) (%2)	298 (99,0) (90,0)	149 (98,0) (90,9)
N-miss (%1) (%2)	3 (1,0) (0,9)	3 (2,0) (1,8)
N-miss (%2)	30 (9,1)	12 (7,3)
Woche 36		
N-visit	299 (90,3)	151 (92,1)
N-obs (%1) (%2)	295 (98,7) (89,1)	146 (96,7) (89,0)
N-miss (%1) (%2)	4 (1,3) (1,2)	5 (3,3) (3,0)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
N-miss (%2)	32 (9,7)	13 (7,9)
Woche 40		
N-visit	295 (89,1)	149 (90,9)
N-obs (%1) (%2)	290 (98,3) (87,6)	145 (97,3) (88,4)
N-miss (%1) (%2)	5 (1,7) (1,5)	4 (2,7) (2,4)
N-miss (%2)	36 (10,9)	15 (9,1)
Woche 44		
N-visit	292 (88,2)	146 (89,0)
N-obs (%1) (%2)	291 (99,7) (87,9)	142 (97,3) (86,6)
N-miss (%1) (%2)	1 (0,3) (0,3)	4 (2,7) (2,4)
N-miss (%2)	39 (11,8)	18 (11,0)
Woche 48		
N-visit	287 (86,7)	146 (89,0)
N-obs (%1) (%2)	283 (98,6) (85,5)	140 (95,9) (85,4)
N-miss (%1) (%2)	4 (1,4) (1,2)	6 (4,1) (3,7)
N-miss (%2)	44 (13,3)	18 (11,0)
Woche 52		
N-visit	286 (86,4)	144 (87,8)
N-obs (%1) (%2)	282 (98,6) (85,2)	138 (95,8) (84,1)
N-miss (%1) (%2)	4 (1,4) (1,2)	6 (4,2) (3,7)
N-miss (%2)	45 (13,6)	20 (12,2)
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; PRO: Patient Reported Outcome, defined as 2 of the patient-reported items of the CDAI (SF and AP); RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_pro2cmp_itta.rf

Dataset Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adef_gba

/lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Anhang 4-G.3.4.2.2 Symptomatik**Darm- und systemische Symptome IBDQ**

Die Rücklaufquoten sind Anhang 4-G.3.4.2.4 zu entnehmen.

Stuhlfrequenz – CDAI-SF

Angaben zur Vollständigkeit der Daten für Stool frequency zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
Stool frequency		
Baseline		
N-obs (%2)	330 (99,7)	164 (100,0)
N-miss (%2)	1 (0,3)	0 (0,0)
Woche 2		
N-visit	331 (100,0)	164 (100,0)
N-obs (%1) (%2)	328 (99,1) (99,1)	161 (98,2) (98,2)
N-miss (%1) (%2)	3 (0,9) (0,9)	3 (1,8) (1,8)
N-miss (%2)	0 (0,0)	0 (0,0)
Woche 4		
N-visit	331 (100,0)	163 (99,4)
N-obs (%1) (%2)	325 (98,2) (98,2)	159 (97,5) (97,0)
N-miss (%1) (%2)	6 (1,8) (1,8)	4 (2,5) (2,4)
N-miss (%2)	0 (0,0)	1 (0,6)
Woche 6		
N-visit	326 (98,5)	158 (96,3)
N-obs (%1) (%2)	320 (98,2) (96,7)	157 (99,4) (95,7)
N-miss (%1) (%2)	6 (1,8) (1,8)	1 (0,6) (0,6)
N-miss (%2)	5 (1,5)	6 (3,7)
Woche 8		
N-visit	322 (97,3)	158 (96,3)
N-obs (%1) (%2)	317 (98,4) (95,8)	156 (98,7) (95,1)
N-miss (%1) (%2)	5 (1,6) (1,5)	2 (1,3) (1,2)
N-miss (%2)	9 (2,7)	6 (3,7)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
Woche 12		
N-visit	319 (96,4)	157 (95,7)
N-obs (%1) (%2)	316 (99,1) (95,5)	157 (100,0) (95,7)
N-miss (%1) (%2)	3 (0,9) (0,9)	0 (0,0) (0,0)
N-miss (%2)	12 (3,6)	7 (4,3)
Woche 16		
N-visit	314 (94,9)	156 (95,1)
N-obs (%1) (%2)	311 (99,0) (94,0)	152 (97,4) (92,7)
N-miss (%1) (%2)	3 (1,0) (0,9)	4 (2,6) (2,4)
N-miss (%2)	17 (5,1)	8 (4,9)
Woche 20		
N-visit	311 (94,0)	156 (95,1)
N-obs (%1) (%2)	307 (98,7) (92,7)	156 (100,0) (95,1)
N-miss (%1) (%2)	4 (1,3) (1,2)	0 (0,0) (0,0)
N-miss (%2)	20 (6,0)	8 (4,9)
Woche 24		
N-visit	309 (93,4)	155 (94,5)
N-obs (%1) (%2)	304 (98,4) (91,8)	151 (97,4) (92,1)
N-miss (%1) (%2)	5 (1,6) (1,5)	4 (2,6) (2,4)
N-miss (%2)	22 (6,6)	9 (5,5)
Woche 28		
N-visit	307 (92,7)	153 (93,3)
N-obs (%1) (%2)	302 (98,4) (91,2)	147 (96,1) (89,6)
N-miss (%1) (%2)	5 (1,6) (1,5)	6 (3,9) (3,7)
N-miss (%2)	24 (7,3)	11 (6,7)
Woche 32		
N-visit	301 (90,9)	152 (92,7)
N-obs (%1) (%2)	298 (99,0) (90,0)	149 (98,0) (90,9)
N-miss (%1) (%2)	3 (1,0) (0,9)	3 (2,0) (1,8)
N-miss (%2)	30 (9,1)	12 (7,3)
Woche 36		
N-visit	299 (90,3)	151 (92,1)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
N-obs (%1) (%2)	295 (98,7) (89,1)	146 (96,7) (89,0)
N-miss (%1) (%2)	4 (1,3) (1,2)	5 (3,3) (3,0)
N-miss (%2)	32 (9,7)	13 (7,9)
Woche 40		
N-visit	295 (89,1)	149 (90,9)
N-obs (%1) (%2)	290 (98,3) (87,6)	145 (97,3) (88,4)
N-miss (%1) (%2)	5 (1,7) (1,5)	4 (2,7) (2,4)
N-miss (%2)	36 (10,9)	15 (9,1)
Woche 44		
N-visit	292 (88,2)	146 (89,0)
N-obs (%1) (%2)	291 (99,7) (87,9)	142 (97,3) (86,6)
N-miss (%1) (%2)	1 (0,3) (0,3)	4 (2,7) (2,4)
N-miss (%2)	39 (11,8)	18 (11,0)
Woche 48		
N-visit	287 (86,7)	146 (89,0)
N-obs (%1) (%2)	283 (98,6) (85,5)	140 (95,9) (85,4)
N-miss (%1) (%2)	4 (1,4) (1,2)	6 (4,1) (3,7)
N-miss (%2)	44 (13,3)	18 (11,0)
Woche 52		
N-visit	286 (86,4)	144 (87,8)
N-obs (%1) (%2)	282 (98,6) (85,2)	138 (95,8) (84,1)
N-miss (%1) (%2)	4 (1,4) (1,2)	6 (4,2) (3,7)
N-miss (%2)	45 (13,6)	20 (12,2)
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_sfcmp_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adef_gba

/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Imperativer Stuhldrang - Urgency NRS

Angaben zur Vollständigkeit der Daten für Urgency NRS zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
Urgency NRS		
Baseline		
N-obs (%2)	330 (99,7)	164 (100,0)
N-miss (%2)	1 (0,3)	0 (0,0)
Woche 2		
N-visit	331 (100,0)	164 (100,0)
N-obs (%1) (%2)	328 (99,1) (99,1)	161 (98,2) (98,2)
N-miss (%1) (%2)	3 (0,9) (0,9)	3 (1,8) (1,8)
N-miss (%2)	0 (0,0)	0 (0,0)
Woche 4		
N-visit	331 (100,0)	163 (99,4)
N-obs (%1) (%2)	325 (98,2) (98,2)	159 (97,5) (97,0)
N-miss (%1) (%2)	6 (1,8) (1,8)	4 (2,5) (2,4)
N-miss (%2)	0 (0,0)	1 (0,6)
Woche 6		
N-visit	326 (98,5)	158 (96,3)
N-obs (%1) (%2)	320 (98,2) (96,7)	157 (99,4) (95,7)
N-miss (%1) (%2)	6 (1,8) (1,8)	1 (0,6) (0,6)
N-miss (%2)	5 (1,5)	6 (3,7)
Woche 8		
N-visit	322 (97,3)	158 (96,3)
N-obs (%1) (%2)	317 (98,4) (95,8)	156 (98,7) (95,1)
N-miss (%1) (%2)	5 (1,6) (1,5)	2 (1,3) (1,2)
N-miss (%2)	9 (2,7)	6 (3,7)
Woche 12		
N-visit	319 (96,4)	157 (95,7)
N-obs (%1) (%2)	316 (99,1) (95,5)	157 (100,0) (95,7)
N-miss (%1) (%2)	3 (0,9) (0,9)	0 (0,0) (0,0)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
N-miss (%2)	12 (3,6)	7 (4,3)
Woche 16		
N-visit	314 (94,9)	156 (95,1)
N-obs (%1) (%2)	311 (99,0) (94,0)	152 (97,4) (92,7)
N-miss (%1) (%2)	3 (1,0) (0,9)	4 (2,6) (2,4)
N-miss (%2)	17 (5,1)	8 (4,9)
Woche 20		
N-visit	311 (94,0)	156 (95,1)
N-obs (%1) (%2)	307 (98,7) (92,7)	156 (100,0) (95,1)
N-miss (%1) (%2)	4 (1,3) (1,2)	0 (0,0) (0,0)
N-miss (%2)	20 (6,0)	8 (4,9)
Woche 24		
N-visit	309 (93,4)	155 (94,5)
N-obs (%1) (%2)	304 (98,4) (91,8)	151 (97,4) (92,1)
N-miss (%1) (%2)	5 (1,6) (1,5)	4 (2,6) (2,4)
N-miss (%2)	22 (6,6)	9 (5,5)
Woche 28		
N-visit	307 (92,7)	153 (93,3)
N-obs (%1) (%2)	302 (98,4) (91,2)	147 (96,1) (89,6)
N-miss (%1) (%2)	5 (1,6) (1,5)	6 (3,9) (3,7)
N-miss (%2)	24 (7,3)	11 (6,7)
Woche 32		
N-visit	301 (90,9)	152 (92,7)
N-obs (%1) (%2)	298 (99,0) (90,0)	149 (98,0) (90,9)
N-miss (%1) (%2)	3 (1,0) (0,9)	3 (2,0) (1,8)
N-miss (%2)	30 (9,1)	12 (7,3)
Woche 36		
N-visit	299 (90,3)	151 (92,1)
N-obs (%1) (%2)	295 (98,7) (89,1)	146 (96,7) (89,0)
N-miss (%1) (%2)	4 (1,3) (1,2)	5 (3,3) (3,0)
N-miss (%2)	32 (9,7)	13 (7,9)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
Woche 40		
N-visit	295 (89,1)	149 (90,9)
N-obs (%1) (%2)	290 (98,3) (87,6)	145 (97,3) (88,4)
N-miss (%1) (%2)	5 (1,7) (1,5)	4 (2,7) (2,4)
N-miss (%2)	36 (10,9)	15 (9,1)
Woche 44		
N-visit	292 (88,2)	146 (89,0)
N-obs (%1) (%2)	291 (99,7) (87,9)	142 (97,3) (86,6)
N-miss (%1) (%2)	1 (0,3) (0,3)	4 (2,7) (2,4)
N-miss (%2)	39 (11,8)	18 (11,0)
Woche 48		
N-visit	287 (86,7)	146 (89,0)
N-obs (%1) (%2)	283 (98,6) (85,5)	140 (95,9) (85,4)
N-miss (%1) (%2)	4 (1,4) (1,2)	6 (4,1) (3,7)
N-miss (%2)	44 (13,3)	18 (11,0)
Woche 52		
N-visit	286 (86,4)	144 (87,8)
N-obs (%1) (%2)	282 (98,6) (85,2)	138 (95,8) (84,1)
N-miss (%1) (%2)	4 (1,4) (1,2)	6 (4,2) (3,7)
N-miss (%2)	45 (13,6)	20 (12,2)
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; NRS: Numeric Rating Scale; RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_urcgm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adef_gba

/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Abdominelle Schmerzen – CDAI-AP

Angaben zur Vollständigkeit der Daten für Abdominal pain zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
Abdominal pain		
Baseline		
N-obs (%2)	330 (99,7)	164 (100,0)
N-miss (%2)	1 (0,3)	0 (0,0)
Woche 2		
N-visit	331 (100,0)	164 (100,0)
N-obs (%1) (%2)	328 (99,1) (99,1)	161 (98,2) (98,2)
N-miss (%1) (%2)	3 (0,9) (0,9)	3 (1,8) (1,8)
N-miss (%2)	0 (0,0)	0 (0,0)
Woche 4		
N-visit	331 (100,0)	163 (99,4)
N-obs (%1) (%2)	325 (98,2) (98,2)	159 (97,5) (97,0)
N-miss (%1) (%2)	6 (1,8) (1,8)	4 (2,5) (2,4)
N-miss (%2)	0 (0,0)	1 (0,6)
Woche 6		
N-visit	326 (98,5)	158 (96,3)
N-obs (%1) (%2)	320 (98,2) (96,7)	157 (99,4) (95,7)
N-miss (%1) (%2)	6 (1,8) (1,8)	1 (0,6) (0,6)
N-miss (%2)	5 (1,5)	6 (3,7)
Woche 8		
N-visit	322 (97,3)	158 (96,3)
N-obs (%1) (%2)	317 (98,4) (95,8)	156 (98,7) (95,1)
N-miss (%1) (%2)	5 (1,6) (1,5)	2 (1,3) (1,2)
N-miss (%2)	9 (2,7)	6 (3,7)
Woche 12		
N-visit	319 (96,4)	157 (95,7)
N-obs (%1) (%2)	316 (99,1) (95,5)	157 (100,0) (95,7)
N-miss (%1) (%2)	3 (0,9) (0,9)	0 (0,0) (0,0)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
N-miss (%2)	12 (3,6)	7 (4,3)
Woche 16		
N-visit	314 (94,9)	156 (95,1)
N-obs (%1) (%2)	311 (99,0) (94,0)	152 (97,4) (92,7)
N-miss (%1) (%2)	3 (1,0) (0,9)	4 (2,6) (2,4)
N-miss (%2)	17 (5,1)	8 (4,9)
Woche 20		
N-visit	311 (94,0)	156 (95,1)
N-obs (%1) (%2)	307 (98,7) (92,7)	156 (100,0) (95,1)
N-miss (%1) (%2)	4 (1,3) (1,2)	0 (0,0) (0,0)
N-miss (%2)	20 (6,0)	8 (4,9)
Woche 24		
N-visit	309 (93,4)	155 (94,5)
N-obs (%1) (%2)	304 (98,4) (91,8)	151 (97,4) (92,1)
N-miss (%1) (%2)	5 (1,6) (1,5)	4 (2,6) (2,4)
N-miss (%2)	22 (6,6)	9 (5,5)
Woche 28		
N-visit	307 (92,7)	153 (93,3)
N-obs (%1) (%2)	302 (98,4) (91,2)	147 (96,1) (89,6)
N-miss (%1) (%2)	5 (1,6) (1,5)	6 (3,9) (3,7)
N-miss (%2)	24 (7,3)	11 (6,7)
Woche 32		
N-visit	301 (90,9)	152 (92,7)
N-obs (%1) (%2)	298 (99,0) (90,0)	149 (98,0) (90,9)
N-miss (%1) (%2)	3 (1,0) (0,9)	3 (2,0) (1,8)
N-miss (%2)	30 (9,1)	12 (7,3)
Woche 36		
N-visit	299 (90,3)	151 (92,1)
N-obs (%1) (%2)	295 (98,7) (89,1)	146 (96,7) (89,0)
N-miss (%1) (%2)	4 (1,3) (1,2)	5 (3,3) (3,0)
N-miss (%2)	32 (9,7)	13 (7,9)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
Woche 40		
N-visit	295 (89,1)	149 (90,9)
N-obs (%1) (%2)	290 (98,3) (87,6)	145 (97,3) (88,4)
N-miss (%1) (%2)	5 (1,7) (1,5)	4 (2,7) (2,4)
N-miss (%2)	36 (10,9)	15 (9,1)
Woche 44		
N-visit	292 (88,2)	146 (89,0)
N-obs (%1) (%2)	291 (99,7) (87,9)	142 (97,3) (86,6)
N-miss (%1) (%2)	1 (0,3) (0,3)	4 (2,7) (2,4)
N-miss (%2)	39 (11,8)	18 (11,0)
Woche 48		
N-visit	287 (86,7)	146 (89,0)
N-obs (%1) (%2)	283 (98,6) (85,5)	140 (95,9) (85,4)
N-miss (%1) (%2)	4 (1,4) (1,2)	6 (4,1) (3,7)
N-miss (%2)	44 (13,3)	18 (11,0)
Woche 52		
N-visit	286 (86,4)	144 (87,8)
N-obs (%1) (%2)	282 (98,6) (85,2)	138 (95,8) (84,1)
N-miss (%1) (%2)	4 (1,4) (1,2)	6 (4,2) (3,7)
N-miss (%2)	45 (13,6)	20 (12,2)
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_apcmp_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Fatigue – FACIT Fatigue

Angaben zur Vollständigkeit der Daten für FACIT-Fatigue zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
FACIT-Fatigue		
Baseline		
N-obs (%2)	328 (99,1)	164 (100,0)
N-miss (%2)	3 (0,9)	0 (0,0)
Woche 12		
N-visit	319 (96,4)	157 (95,7)
N-obs (%1) (%2)	314 (98,4) (94,9)	156 (99,4) (95,1)
N-miss (%1) (%2)	5 (1,6) (1,5)	1 (0,6) (0,6)
N-miss (%2)	12 (3,6)	7 (4,3)
Woche 52		
N-visit	286 (86,4)	144 (87,8)
N-obs (%1) (%2)	279 (97,6) (84,3)	142 (98,6) (86,6)
N-miss (%1) (%2)	7 (2,4) (2,1)	2 (1,4) (1,2)
N-miss (%2)	45 (13,6)	20 (12,2)
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: FACIT: Functional Assessment of Chronic Illness Therapy-Fatigue; ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_facitcmp_itta.rtf

Dataset Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adefl_gba
/lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Depressionen – QIDS-SR16

Angaben zur Vollständigkeit der Daten für QIDS-SR16 Total Score zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
QIDS-SR16 Total Score		
Baseline		
N-obs (%2)	331 (100,0)	164 (100,0)
N-miss (%2)	0 (0,0)	0 (0,0)
Woche 12		
N-visit	319 (96,4)	157 (95,7)
N-obs (%1) (%2)	315 (98,7) (95,2)	156 (99,4) (95,1)
N-miss (%1) (%2)	4 (1,3) (1,2)	1 (0,6) (0,6)
N-miss (%2)	12 (3,6)	7 (4,3)
Woche 24		
N-visit	309 (93,4)	155 (94,5)
N-obs (%1) (%2)	304 (98,4) (91,8)	151 (97,4) (92,1)
N-miss (%1) (%2)	5 (1,6) (1,5)	4 (2,6) (2,4)
N-miss (%2)	22 (6,6)	9 (5,5)
Woche 36		
N-visit	299 (90,3)	151 (92,1)
N-obs (%1) (%2)	292 (97,7) (88,2)	149 (98,7) (90,9)
N-miss (%1) (%2)	7 (2,3) (2,1)	2 (1,3) (1,2)
N-miss (%2)	32 (9,7)	13 (7,9)
Woche 52		
N-visit	286 (86,4)	144 (87,8)
N-obs (%1) (%2)	280 (97,9) (84,6)	143 (99,3) (87,2)
N-miss (%1) (%2)	6 (2,1) (1,8)	1 (0,7) (0,6)
N-miss (%2)	45 (13,6)	20 (12,2)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; QIDS-SR16: Quick Inventory of Depressive Symptomatology - Self Report (16 items); RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_qidscmp_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adefl_gba
/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Anhang 4-G.3.4.2.3 Gesundheitszustand**Gesundheitszustand – EQ-5D VAS**

Angaben zur Vollständigkeit der Daten für EQ-5D VAS zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
EQ-5D VAS		
Baseline		
N-obs (%2)	328 (99,1)	164 (100,0)
N-miss (%2)	3 (0,9)	0 (0,0)
Woche 12		
N-visit	319 (96,4)	157 (95,7)
N-obs (%1) (%2)	315 (98,7) (95,2)	156 (99,4) (95,1)
N-miss (%1) (%2)	4 (1,3) (1,2)	1 (0,6) (0,6)
N-miss (%2)	12 (3,6)	7 (4,3)
Woche 52		
N-visit	286 (86,4)	144 (87,8)
N-obs (%1) (%2)	279 (97,6) (84,3)	142 (98,6) (86,6)
N-miss (%1) (%2)	7 (2,4) (2,1)	2 (1,4) (1,2)
N-miss (%2)	45 (13,6)	20 (12,2)
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: EQ-5D: Fragebogen der EuroQol-Gruppe zur Lebensqualität auf 5 Dimensionen; ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; VAS: Visuelle Analogskala. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_vascmp_itta.rtf

Dataset Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adef_gba

/lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Gesundheitszustand – PGRS

Angaben zur Vollständigkeit der Daten für Patient Global Rating of severity (PGRS) zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
PGRS		
Baseline		
N-obs (%2)	330 (99,7)	164 (100,0)
N-miss (%2)	1 (0,3)	0 (0,0)
Woche 2		
N-visit	331 (100,0)	164 (100,0)
N-obs (%1) (%2)	328 (99,1) (99,1)	161 (98,2) (98,2)
N-miss (%1) (%2)	3 (0,9) (0,9)	3 (1,8) (1,8)
N-miss (%2)	0 (0,0)	0 (0,0)
Woche 4		
N-visit	331 (100,0)	163 (99,4)
N-obs (%1) (%2)	325 (98,2) (98,2)	159 (97,5) (97,0)
N-miss (%1) (%2)	6 (1,8) (1,8)	4 (2,5) (2,4)
N-miss (%2)	0 (0,0)	1 (0,6)
Woche 6		
N-visit	326 (98,5)	158 (96,3)
N-obs (%1) (%2)	320 (98,2) (96,7)	157 (99,4) (95,7)
N-miss (%1) (%2)	6 (1,8) (1,8)	1 (0,6) (0,6)
N-miss (%2)	5 (1,5)	6 (3,7)
Woche 8		
N-visit	322 (97,3)	158 (96,3)
N-obs (%1) (%2)	317 (98,4) (95,8)	156 (98,7) (95,1)
N-miss (%1) (%2)	5 (1,6) (1,5)	2 (1,3) (1,2)
N-miss (%2)	9 (2,7)	6 (3,7)
Woche 12		
N-visit	319 (96,4)	157 (95,7)
N-obs (%1) (%2)	316 (99,1) (95,5)	156 (99,4) (95,1)
N-miss (%1) (%2)	3 (0,9) (0,9)	1 (0,6) (0,6)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
N-miss (%2)	12 (3,6)	7 (4,3)
Woche 16		
N-visit	314 (94,9)	156 (95,1)
N-obs (%1) (%2)	311 (99,0) (94,0)	152 (97,4) (92,7)
N-miss (%1) (%2)	3 (1,0) (0,9)	4 (2,6) (2,4)
N-miss (%2)	17 (5,1)	8 (4,9)
Woche 20		
N-visit	311 (94,0)	156 (95,1)
N-obs (%1) (%2)	307 (98,7) (92,7)	156 (100,0) (95,1)
N-miss (%1) (%2)	4 (1,3) (1,2)	0 (0,0) (0,0)
N-miss (%2)	20 (6,0)	8 (4,9)
Woche 24		
N-visit	309 (93,4)	155 (94,5)
N-obs (%1) (%2)	304 (98,4) (91,8)	151 (97,4) (92,1)
N-miss (%1) (%2)	5 (1,6) (1,5)	4 (2,6) (2,4)
N-miss (%2)	22 (6,6)	9 (5,5)
Woche 28		
N-visit	307 (92,7)	153 (93,3)
N-obs (%1) (%2)	302 (98,4) (91,2)	147 (96,1) (89,6)
N-miss (%1) (%2)	5 (1,6) (1,5)	6 (3,9) (3,7)
N-miss (%2)	24 (7,3)	11 (6,7)
Woche 32		
N-visit	301 (90,9)	152 (92,7)
N-obs (%1) (%2)	298 (99,0) (90,0)	149 (98,0) (90,9)
N-miss (%1) (%2)	3 (1,0) (0,9)	3 (2,0) (1,8)
N-miss (%2)	30 (9,1)	12 (7,3)
Woche 36		
N-visit	299 (90,3)	151 (92,1)
N-obs (%1) (%2)	295 (98,7) (89,1)	146 (96,7) (89,0)
N-miss (%1) (%2)	4 (1,3) (1,2)	5 (3,3) (3,0)
N-miss (%2)	32 (9,7)	13 (7,9)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
Woche 40		
N-visit	295 (89,1)	149 (90,9)
N-obs (%1) (%2)	290 (98,3) (87,6)	145 (97,3) (88,4)
N-miss (%1) (%2)	5 (1,7) (1,5)	4 (2,7) (2,4)
N-miss (%2)	36 (10,9)	15 (9,1)
Woche 44		
N-visit	292 (88,2)	146 (89,0)
N-obs (%1) (%2)	291 (99,7) (87,9)	142 (97,3) (86,6)
N-miss (%1) (%2)	1 (0,3) (0,3)	4 (2,7) (2,4)
N-miss (%2)	39 (11,8)	18 (11,0)
Woche 48		
N-visit	287 (86,7)	146 (89,0)
N-obs (%1) (%2)	283 (98,6) (85,5)	140 (95,9) (85,4)
N-miss (%1) (%2)	4 (1,4) (1,2)	6 (4,1) (3,7)
N-miss (%2)	44 (13,3)	18 (11,0)
Woche 52		
N-visit	286 (86,4)	144 (87,8)
N-obs (%1) (%2)	282 (98,6) (85,2)	138 (95,8) (84,1)
N-miss (%1) (%2)	4 (1,4) (1,2)	6 (4,2) (3,7)
N-miss (%2)	45 (13,6)	20 (12,2)
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; PGRS: Patient Global Rating of Severity; RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_pgrscmp_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba
 /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Gesundheitszustand – PGIC

Angaben zur Vollständigkeit der Daten für Patient Reported Impression of Change (PGIC) zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
PGIC		
Woche 4		
N-visit	331 (100,0)	163 (99,4)
N-obs (%1) (%2)	324 (97,9) (97,9)	161 (98,8) (98,2)
N-miss (%1) (%2)	7 (2,1) (2,1)	2 (1,2) (1,2)
N-miss (%2)	0 (0,0)	1 (0,6)
Woche 8		
N-visit	322 (97,3)	158 (96,3)
N-obs (%1) (%2)	319 (99,1) (96,4)	156 (98,7) (95,1)
N-miss (%1) (%2)	3 (0,9) (0,9)	2 (1,3) (1,2)
N-miss (%2)	9 (2,7)	6 (3,7)
Woche 12		
N-visit	319 (96,4)	157 (95,7)
N-obs (%1) (%2)	315 (98,7) (95,2)	156 (99,4) (95,1)
N-miss (%1) (%2)	4 (1,3) (1,2)	1 (0,6) (0,6)
N-miss (%2)	12 (3,6)	7 (4,3)
Woche 52		
N-visit	286 (86,4)	144 (87,8)
N-obs (%1) (%2)	279 (97,6) (84,3)	141 (97,9) (86,0)
N-miss (%1) (%2)	7 (2,4) (2,1)	3 (2,1) (1,8)
N-miss (%2)	45 (13,6)	20 (12,2)
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; PGIC: Patient Global Impression of Change; RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_pgiccmp_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba
 /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv 19DEC2024 / 12:52

Gesundheitszustand – WPAI-CD (Aktivitätsbeeinträchtigung)

Angaben zur Vollständigkeit der Daten für WPAI (Activity impairment) zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population, Participants with baseline employment status of Yes)

Endpunkt Zeitpunkt	Mirikizumab (N=202)	Ustekinumab (N=91)
WPAI (Activity impairment)		
Baseline		
N-obs (%2)	202 (100,0)	91 (100,0)
N-miss (%2)	0 (0,0)	0 (0,0)
Woche 12		
N-visit	195 (96,5)	87 (95,6)
N-obs (%1) (%2)	192 (98,5) (95,0)	87 (100,0) (95,6)
N-miss (%1) (%2)	3 (1,5) (1,5)	0 (0,0) (0,0)
N-miss (%2)	7 (3,5)	4 (4,4)
Woche 52		
N-visit	177 (87,6)	81 (89,0)
N-obs (%1) (%2)	174 (98,3) (86,1)	80 (98,8) (87,9)
N-miss (%1) (%2)	3 (1,7) (1,5)	1 (1,2) (1,1)
N-miss (%2)	25 (12,4)	10 (11,0)
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; WPAI: Work Productivity and Activity Impairment Questionnaire. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_wpaicmp_empl_itta.rtf

Dataset Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

/lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Allgemeinbefinden - CDAI-GWP

Angaben zur Vollständigkeit der Daten für General well being zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
General well being		
Baseline		
N-obs (%2)	330 (99,7)	164 (100,0)
N-miss (%2)	1 (0,3)	0 (0,0)
Woche 2		
N-visit	331 (100,0)	164 (100,0)
N-obs (%1) (%2)	328 (99,1) (99,1)	161 (98,2) (98,2)
N-miss (%1) (%2)	3 (0,9) (0,9)	3 (1,8) (1,8)
N-miss (%2)	0 (0,0)	0 (0,0)
Woche 4		
N-visit	331 (100,0)	163 (99,4)
N-obs (%1) (%2)	325 (98,2) (98,2)	159 (97,5) (97,0)
N-miss (%1) (%2)	6 (1,8) (1,8)	4 (2,5) (2,4)
N-miss (%2)	0 (0,0)	1 (0,6)
Woche 6		
N-visit	326 (98,5)	158 (96,3)
N-obs (%1) (%2)	320 (98,2) (96,7)	157 (99,4) (95,7)
N-miss (%1) (%2)	6 (1,8) (1,8)	1 (0,6) (0,6)
N-miss (%2)	5 (1,5)	6 (3,7)
Woche 8		
N-visit	322 (97,3)	158 (96,3)
N-obs (%1) (%2)	317 (98,4) (95,8)	156 (98,7) (95,1)
N-miss (%1) (%2)	5 (1,6) (1,5)	2 (1,3) (1,2)
N-miss (%2)	9 (2,7)	6 (3,7)
Woche 12		
N-visit	319 (96,4)	157 (95,7)
N-obs (%1) (%2)	316 (99,1) (95,5)	157 (100,0) (95,7)
N-miss (%1) (%2)	3 (0,9) (0,9)	0 (0,0) (0,0)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
N-miss (%2)	12 (3,6)	7 (4,3)
Woche 16		
N-visit	314 (94,9)	156 (95,1)
N-obs (%1) (%2)	311 (99,0) (94,0)	152 (97,4) (92,7)
N-miss (%1) (%2)	3 (1,0) (0,9)	4 (2,6) (2,4)
N-miss (%2)	17 (5,1)	8 (4,9)
Woche 20		
N-visit	311 (94,0)	156 (95,1)
N-obs (%1) (%2)	307 (98,7) (92,7)	156 (100,0) (95,1)
N-miss (%1) (%2)	4 (1,3) (1,2)	0 (0,0) (0,0)
N-miss (%2)	20 (6,0)	8 (4,9)
Woche 24		
N-visit	309 (93,4)	155 (94,5)
N-obs (%1) (%2)	304 (98,4) (91,8)	151 (97,4) (92,1)
N-miss (%1) (%2)	5 (1,6) (1,5)	4 (2,6) (2,4)
N-miss (%2)	22 (6,6)	9 (5,5)
Woche 28		
N-visit	307 (92,7)	153 (93,3)
N-obs (%1) (%2)	302 (98,4) (91,2)	147 (96,1) (89,6)
N-miss (%1) (%2)	5 (1,6) (1,5)	6 (3,9) (3,7)
N-miss (%2)	24 (7,3)	11 (6,7)
Woche 32		
N-visit	301 (90,9)	152 (92,7)
N-obs (%1) (%2)	298 (99,0) (90,0)	149 (98,0) (90,9)
N-miss (%1) (%2)	3 (1,0) (0,9)	3 (2,0) (1,8)
N-miss (%2)	30 (9,1)	12 (7,3)
Woche 36		
N-visit	299 (90,3)	151 (92,1)
N-obs (%1) (%2)	295 (98,7) (89,1)	146 (96,7) (89,0)
N-miss (%1) (%2)	4 (1,3) (1,2)	5 (3,3) (3,0)
N-miss (%2)	32 (9,7)	13 (7,9)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
Woche 40		
N-visit	295 (89,1)	149 (90,9)
N-obs (%1) (%2)	290 (98,3) (87,6)	145 (97,3) (88,4)
N-miss (%1) (%2)	5 (1,7) (1,5)	4 (2,7) (2,4)
N-miss (%2)	36 (10,9)	15 (9,1)
Woche 44		
N-visit	292 (88,2)	146 (89,0)
N-obs (%1) (%2)	291 (99,7) (87,9)	142 (97,3) (86,6)
N-miss (%1) (%2)	1 (0,3) (0,3)	4 (2,7) (2,4)
N-miss (%2)	39 (11,8)	18 (11,0)
Woche 48		
N-visit	287 (86,7)	146 (89,0)
N-obs (%1) (%2)	283 (98,6) (85,5)	140 (95,9) (85,4)
N-miss (%1) (%2)	4 (1,4) (1,2)	6 (4,1) (3,7)
N-miss (%2)	44 (13,3)	18 (11,0)
Woche 52		
N-visit	286 (86,4)	144 (87,8)
N-obs (%1) (%2)	282 (98,6) (85,2)	138 (95,8) (84,1)
N-miss (%1) (%2)	4 (1,4) (1,2)	6 (4,2) (3,7)
N-miss (%2)	45 (13,6)	20 (12,2)
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_gwbcmp_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Anhang 4-G.3.4.2.4 Gesundheitsbezogene Lebensqualität**Krankheitsspezifische Lebensqualität**

Angaben zur Vollständigkeit der Daten für IBDQ zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
IBDQ Total Score		
Baseline		
N-obs (%2)	328 (99,1)	164 (100,0)
N-miss (%2)	3 (0,9)	0 (0,0)
Woche 12		
N-visit	319 (96,4)	157 (95,7)
N-obs (%1) (%2)	315 (98,7) (95,2)	156 (99,4) (95,1)
N-miss (%1) (%2)	4 (1,3) (1,2)	1 (0,6) (0,6)
N-miss (%2)	12 (3,6)	7 (4,3)
Woche 52		
N-visit	286 (86,4)	144 (87,8)
N-obs (%1) (%2)	279 (97,6) (84,3)	142 (98,6) (86,6)
N-miss (%1) (%2)	7 (2,4) (2,1)	2 (1,4) (1,2)
N-miss (%2)	45 (13,6)	20 (12,2)
IBDQ Bowel Symptoms		
Baseline		
N-obs (%2)	328 (99,1)	164 (100,0)
N-miss (%2)	3 (0,9)	0 (0,0)
Woche 12		
N-visit	319 (96,4)	157 (95,7)
N-obs (%1) (%2)	315 (98,7) (95,2)	156 (99,4) (95,1)
N-miss (%1) (%2)	4 (1,3) (1,2)	1 (0,6) (0,6)
N-miss (%2)	12 (3,6)	7 (4,3)
Woche 52		
N-visit	286 (86,4)	144 (87,8)
N-obs (%1) (%2)	279 (97,6) (84,3)	142 (98,6) (86,6)
N-miss (%1) (%2)	7 (2,4) (2,1)	2 (1,4) (1,2)
N-miss (%2)	45 (13,6)	20 (12,2)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
IBDQ Emotional Function		
Baseline		
N-obs (%2)	328 (99,1)	164 (100,0)
N-miss (%2)	3 (0,9)	0 (0,0)
Woche 12		
N-visit	319 (96,4)	157 (95,7)
N-obs (%1) (%2)	315 (98,7) (95,2)	156 (99,4) (95,1)
N-miss (%1) (%2)	4 (1,3) (1,2)	1 (0,6) (0,6)
N-miss (%2)	12 (3,6)	7 (4,3)
Woche 52		
N-visit	286 (86,4)	144 (87,8)
N-obs (%1) (%2)	279 (97,6) (84,3)	142 (98,6) (86,6)
N-miss (%1) (%2)	7 (2,4) (2,1)	2 (1,4) (1,2)
N-miss (%2)	45 (13,6)	20 (12,2)
IBDQ Social Function		
Baseline		
N-obs (%2)	328 (99,1)	164 (100,0)
N-miss (%2)	3 (0,9)	0 (0,0)
Woche 12		
N-visit	319 (96,4)	157 (95,7)
N-obs (%1) (%2)	315 (98,7) (95,2)	156 (99,4) (95,1)
N-miss (%1) (%2)	4 (1,3) (1,2)	1 (0,6) (0,6)
N-miss (%2)	12 (3,6)	7 (4,3)
Woche 52		
N-visit	286 (86,4)	144 (87,8)
N-obs (%1) (%2)	279 (97,6) (84,3)	142 (98,6) (86,6)
N-miss (%1) (%2)	7 (2,4) (2,1)	2 (1,4) (1,2)
N-miss (%2)	45 (13,6)	20 (12,2)
IBDQ Systemic Symptoms		
Baseline		
N-obs (%2)	328 (99,1)	164 (100,0)
N-miss (%2)	3 (0,9)	0 (0,0)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
Woche 12		
N-visit	319 (96,4)	157 (95,7)
N-obs (%1) (%2)	315 (98,7) (95,2)	156 (99,4) (95,1)
N-miss (%1) (%2)	4 (1,3) (1,2)	1 (0,6) (0,6)
N-miss (%2)	12 (3,6)	7 (4,3)
Woche 52		
N-visit	286 (86,4)	144 (87,8)
N-obs (%1) (%2)	279 (97,6) (84,3)	142 (98,6) (86,6)
N-miss (%1) (%2)	7 (2,4) (2,1)	2 (1,4) (1,2)
N-miss (%2)	45 (13,6)	20 (12,2)
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_ibdqcmp_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Gesundheitsbezogene Lebensqualität

Angaben zur Vollständigkeit der Daten für SF-36 zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
SF-36 MCS Score		
Baseline		
N-obs (%2)	328 (99,1)	164 (100,0)
N-miss (%2)	3 (0,9)	0 (0,0)
Woche 12		
N-visit	319 (96,4)	157 (95,7)
N-obs (%1) (%2)	315 (98,7) (95,2)	156 (99,4) (95,1)
N-miss (%1) (%2)	4 (1,3) (1,2)	1 (0,6) (0,6)
N-miss (%2)	12 (3,6)	7 (4,3)
Woche 52		
N-visit	286 (86,4)	144 (87,8)
N-obs (%1) (%2)	279 (97,6) (84,3)	142 (98,6) (86,6)
N-miss (%1) (%2)	7 (2,4) (2,1)	2 (1,4) (1,2)
N-miss (%2)	45 (13,6)	20 (12,2)
SF-36 PCS Score		
Baseline		
N-obs (%2)	328 (99,1)	164 (100,0)
N-miss (%2)	3 (0,9)	0 (0,0)
Woche 12		
N-visit	319 (96,4)	157 (95,7)
N-obs (%1) (%2)	315 (98,7) (95,2)	156 (99,4) (95,1)
N-miss (%1) (%2)	4 (1,3) (1,2)	1 (0,6) (0,6)
N-miss (%2)	12 (3,6)	7 (4,3)
Woche 52		
N-visit	286 (86,4)	144 (87,8)
N-obs (%1) (%2)	279 (97,6) (84,3)	142 (98,6) (86,6)
N-miss (%1) (%2)	7 (2,4) (2,1)	2 (1,4) (1,2)
N-miss (%2)	45 (13,6)	20 (12,2)

Endpunkt Zeitpunkt	Mirikizumab (N=331)	Ustekinumab (N=164)
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; MCS: Mental Health Component Summary Score; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; PCS: Physical Health Component Summary Score; RCT: randomisierte, kontrollierte Studie; SF-36: 36-Item Short Form Health Survey. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_sf36cmp_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Anhang 4-G.3.4.3 Ergebnisse für die Veränderung der kontinuierlichen Endpunkte bis Woche 52 in RCT VIVID-1 in Teilpopulation A

Anhang 4-G.3.4.3.1 Klinische Remission

Ergebnisse für die Veränderung des PRO (AP+SF) von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
PRO (AP+SF)					
Woche 2	330 21,55 (5,87)	328 -4,16 (0,32)	164 21,71 (6,26)	159 -4,64 (0,46)	0,48 [-0,59;1,56] 0,378 0,08 [-0,11;0,27]
Woche 4	330 21,55 (5,87)	325 -6,16 (0,37)	164 21,71 (6,26)	157 -6,88 (0,52)	0,72 [-0,52;1,95] 0,254 0,11 [-0,08;0,30]
Woche 6	330 21,55 (5,87)	319 -7,81 (0,38)	164 21,71 (6,26)	157 -8,59 (0,54)	0,78 [-0,51;2,06] 0,237 0,11 [-0,08;0,30]
Woche 8	330 21,55 (5,87)	316 -8,65 (0,39)	164 21,71 (6,26)	156 -9,25 (0,55)	0,60 [-0,71;1,92] 0,370 0,09 [-0,11;0,28]
Woche 12	330 21,55 (5,87)	315 -9,61 (0,41)	164 21,71 (6,26)	157 -10,51 (0,58)	0,91 [-0,47;2,29] 0,197 0,12 [-0,07;0,32]
Woche 16	330 21,55 (5,87)	310 -11,05 (0,39)	164 21,71 (6,26)	152 -11,30 (0,55)	0,25 [-1,05;1,55] 0,707 0,04 [-0,16;0,23]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Woche 20	330 21,55 (5,87)	306 -12,12 (0,39)	164 21,71 (6,26)	156 -11,93 (0,55)	-0,19 [-1,49;1,11] 0,776 -0,03 [-0,22;0,17]
Woche 24	330 21,55 (5,87)	304 -12,72 (0,39)	164 21,71 (6,26)	151 -11,99 (0,55)	-0,73 [-2,03;0,57] 0,270 -0,11 [-0,30;0,09]
Woche 28	330 21,55 (5,87)	301 -12,81 (0,38)	164 21,71 (6,26)	147 -12,54 (0,54)	-0,27 [-1,55;1,01] 0,677 -0,04 [-0,24;0,16]
Woche 32	330 21,55 (5,87)	297 -13,46 (0,39)	164 21,71 (6,26)	149 -12,28 (0,54)	-1,18 [-2,47;0,10] 0,072 -0,18 [-0,38;0,02]
Woche 36	330 21,55 (5,87)	294 -13,63 (0,38)	164 21,71 (6,26)	146 -12,58 (0,54)	-1,06 [-2,33;0,22] 0,105 -0,16 [-0,36;0,04]
Woche 40	330 21,55 (5,87)	290 -13,91 (0,38)	164 21,71 (6,26)	145 -12,50 (0,53)	-1,42 [-2,68;-0,15] 0,028 -0,22 [-0,42;-0,02]
Woche 44	330 21,55 (5,87)	291 -13,97 (0,38)	164 21,71 (6,26)	142 -13,09 (0,53)	-0,88 [-2,13;0,38] 0,170 -0,14 [-0,34;0,06]
Woche 48	330 21,55 (5,87)	283 -14,20 (0,38)	164 21,71 (6,26)	140 -13,38 (0,53)	-0,82 [-2,09;0,44] 0,203 -0,13 [-0,33;0,07]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Woche 52	330 21,55 (5,87)	282 -14,29 (0,38)	164 21,71 (6,26)	138 -13,41 (0,53)	-0,88 [-2,15;0,38] 0,172 -0,14 [-0,34;0,06]
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; PRO: Patient Reported Outcome, defined as 2 of the patient-reported items of the CDAI (SF and AP); RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score (<12 , ≥ 12), entweder Baseline SF $\geq$ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz- Struktur).					

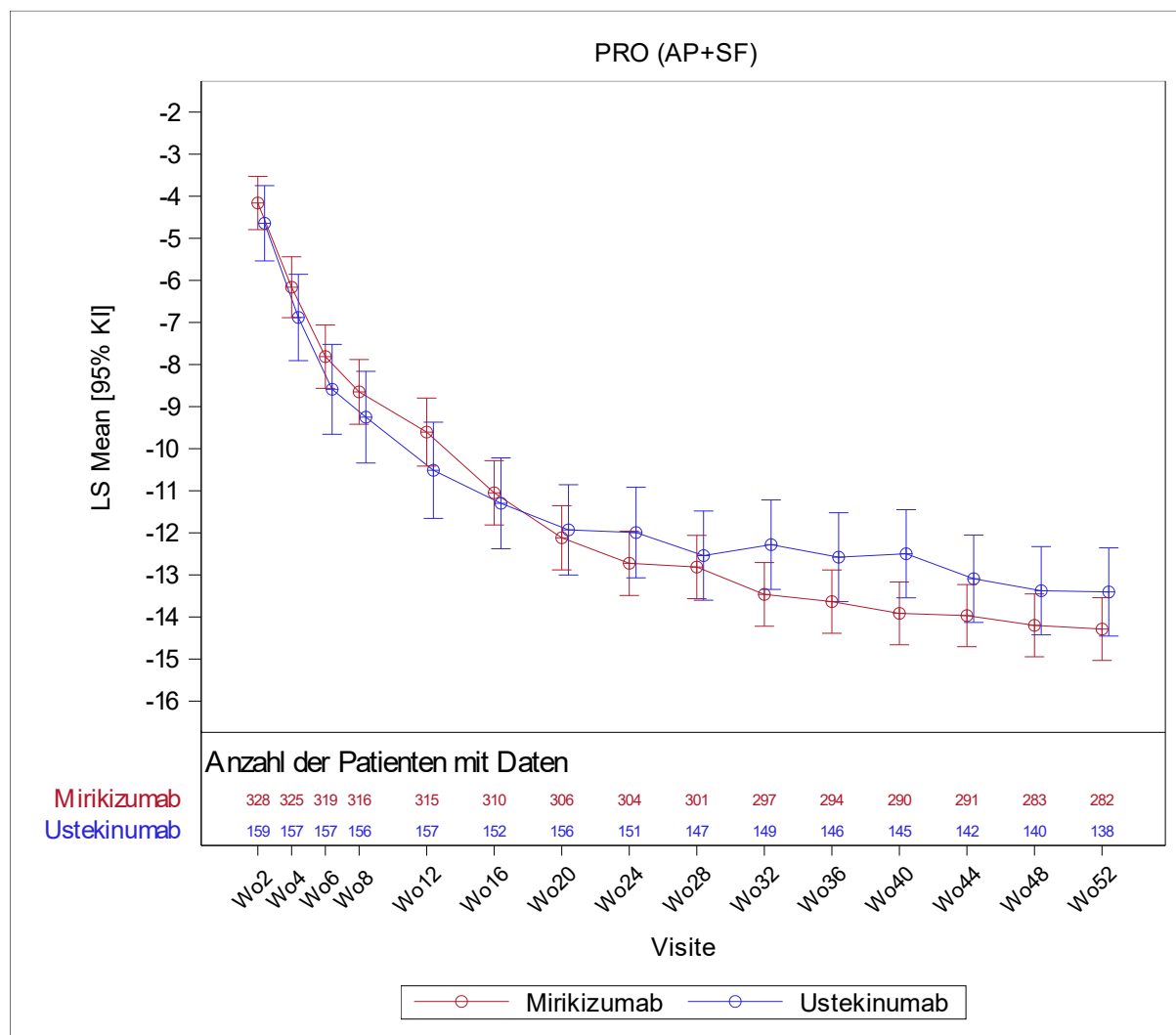
Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_pro2rm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des PRO (AP+SF) bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)



Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; PRO: Patient Reported Outcome, defined as 2 of the patient-reported items of the CDAI (SF and AP); RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/f_pro2rm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Anhang 4-G.3.4.3.2 Symptomatik**Darm- und systemische Symptome - IBDQ**

Die Ergebnisse sind Anhang 4-G.3.4.3.4 zu entnehmen.

Stuhlfrequenz – CDAI-SF

Ergebnisse für die Veränderung des Stool frequency von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Stool frequency					
Woche 2	330 5,44 (2,49)	328 -1,15 (0,10)	164 5,53 (2,53)	159 -1,22 (0,15)	0,06 [-0,29;0,41] 0,724 0,03 [-0,16;0,22]
Woche 4	330 5,44 (2,49)	325 -1,71 (0,12)	164 5,53 (2,53)	157 -1,89 (0,16)	0,18 [-0,21;0,57] 0,370 0,09 [-0,10;0,28]
Woche 6	330 5,44 (2,49)	319 -2,16 (0,12)	164 5,53 (2,53)	157 -2,38 (0,17)	0,22 [-0,19;0,62] 0,296 0,10 [-0,09;0,29]
Woche 8	330 5,44 (2,49)	316 -2,40 (0,12)	164 5,53 (2,53)	156 -2,57 (0,18)	0,17 [-0,25;0,59] 0,423 0,08 [-0,11;0,27]
Woche 12	330 5,44 (2,49)	315 -2,59 (0,13)	164 5,53 (2,53)	157 -2,89 (0,18)	0,30 [-0,13;0,72] 0,169 0,13 [-0,06;0,32]
Woche 16	330 5,44 (2,49)	310 -3,03 (0,12)	164 5,53 (2,53)	152 -3,09 (0,17)	0,06 [-0,34;0,46] 0,774 0,03 [-0,17;0,22]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Woche 20	330 5,44 (2,49)	306 -3,24 (0,12)	164 5,53 (2,53)	156 -3,30 (0,17)	0,06 [-0,34;0,46] 0,759 0,03 [-0,16;0,22]
Woche 24	330 5,44 (2,49)	304 -3,44 (0,12)	164 5,53 (2,53)	151 -3,29 (0,17)	-0,14 [-0,55;0,26] 0,481 -0,07 [-0,26;0,13]
Woche 28	330 5,44 (2,49)	301 -3,41 (0,12)	164 5,53 (2,53)	147 -3,37 (0,17)	-0,03 [-0,43;0,36] 0,864 -0,02 [-0,21;0,18]
Woche 32	330 5,44 (2,49)	297 -3,63 (0,12)	164 5,53 (2,53)	149 -3,29 (0,17)	-0,35 [-0,74;0,05] 0,086 -0,17 [-0,37;0,03]
Woche 36	330 5,44 (2,49)	294 -3,63 (0,12)	164 5,53 (2,53)	146 -3,34 (0,16)	-0,30 [-0,69;0,10] 0,139 -0,15 [-0,35;0,05]
Woche 40	330 5,44 (2,49)	290 -3,71 (0,12)	164 5,53 (2,53)	145 -3,30 (0,16)	-0,41 [-0,81;-0,02] 0,040 -0,21 [-0,41;-0,01]
Woche 44	330 5,44 (2,49)	291 -3,72 (0,11)	164 5,53 (2,53)	142 -3,52 (0,16)	-0,19 [-0,57;0,19] 0,321 -0,10 [-0,30;0,10]
Woche 48	330 5,44 (2,49)	283 -3,80 (0,11)	164 5,53 (2,53)	140 -3,55 (0,16)	-0,25 [-0,63;0,13] 0,197 -0,13 [-0,33;0,07]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Woche 52	330 5,44 (2,49)	282 -3,80 (0,11)	164 5,53 (2,53)	138 -3,54 (0,16)	-0,26 [-0,64;0,13] 0,187 -0,13 [-0,34;0,07]
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score ($<12, \geq 12$), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).					

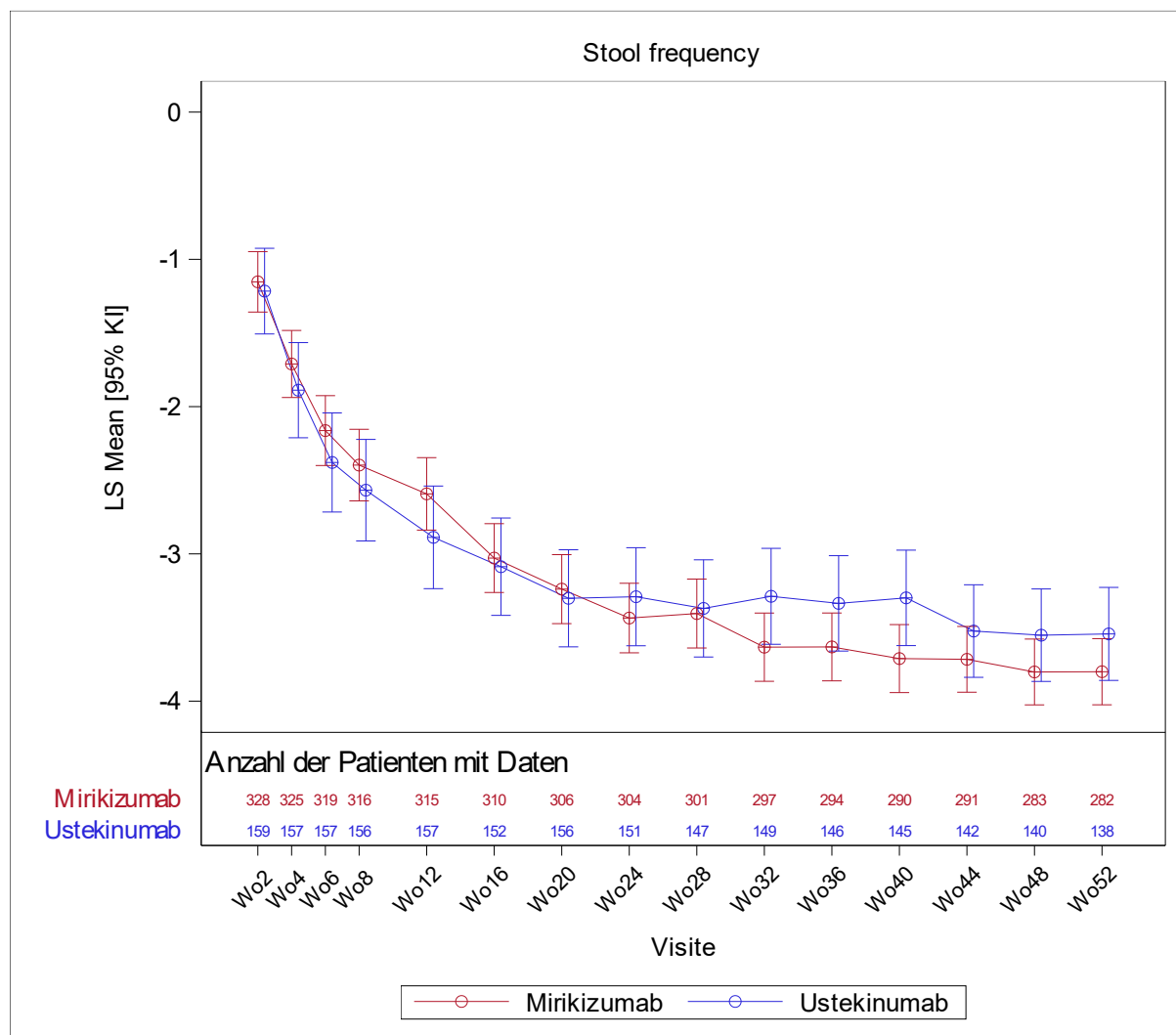
Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_sfrm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des Stool frequency bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)



Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/f_sfrm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Imperativer Stuhldrang – Urgency NRS

Ergebnisse für die Veränderung des Urgency NRS von Baseline bis Woche 52 in RCT
VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Urgency NRS					
Woche 2	330 6,47 (2,10)	328 -1,00 (0,09)	164 6,57 (2,03)	159 -1,17 (0,13)	0,16 [-0,15;0,48] 0,312 0,10 [-0,09;0,29]
Woche 4	330 6,47 (2,10)	325 -1,42 (0,11)	164 6,57 (2,03)	157 -1,65 (0,16)	0,24 [-0,14;0,61] 0,217 0,12 [-0,07;0,31]
Woche 6	330 6,47 (2,10)	319 -1,93 (0,12)	164 6,57 (2,03)	157 -2,11 (0,18)	0,18 [-0,24;0,60] 0,390 0,08 [-0,11;0,27]
Woche 8	330 6,47 (2,10)	316 -2,13 (0,13)	164 6,57 (2,03)	156 -2,30 (0,18)	0,17 [-0,27;0,60] 0,452 0,07 [-0,12;0,26]
Woche 12	330 6,47 (2,10)	315 -2,42 (0,14)	164 6,57 (2,03)	157 -2,60 (0,19)	0,19 [-0,27;0,65] 0,424 0,08 [-0,11;0,27]
Woche 16	330 6,47 (2,10)	310 -2,85 (0,14)	164 6,57 (2,03)	152 -2,70 (0,19)	-0,16 [-0,62;0,30] 0,501 -0,07 [-0,26;0,13]
Woche 20	330 6,47 (2,10)	306 -3,18 (0,14)	164 6,57 (2,03)	156 -2,86 (0,19)	-0,32 [-0,78;0,14] 0,172 -0,13 [-0,33;0,06]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Woche 24	330 6,47 (2,10)	304 -3,29 (0,14)	164 6,57 (2,03)	151 -2,85 (0,19)	-0,44 [-0,90;0,02] 0,061 -0,18 [-0,38;0,01]
Woche 28	330 6,47 (2,10)	301 -3,39 (0,13)	164 6,57 (2,03)	147 -3,01 (0,19)	-0,38 [-0,83;0,07] 0,097 -0,17 [-0,36;0,03]
Woche 32	330 6,47 (2,10)	297 -3,53 (0,14)	164 6,57 (2,03)	149 -3,02 (0,19)	-0,51 [-0,97;-0,05] 0,029 -0,22 [-0,41;-0,02]
Woche 36	330 6,47 (2,10)	294 -3,52 (0,14)	164 6,57 (2,03)	146 -3,02 (0,19)	-0,50 [-0,96;-0,04] 0,034 -0,21 [-0,41;-0,01]
Woche 40	330 6,47 (2,10)	290 -3,61 (0,13)	164 6,57 (2,03)	145 -3,05 (0,19)	-0,57 [-1,02;-0,11] 0,015 -0,25 [-0,45;-0,05]
Woche 44	330 6,47 (2,10)	291 -3,61 (0,13)	164 6,57 (2,03)	142 -3,16 (0,19)	-0,44 [-0,89;0,00] 0,051 -0,20 [-0,40;0,00]
Woche 48	330 6,47 (2,10)	283 -3,62 (0,13)	164 6,57 (2,03)	140 -3,33 (0,19)	-0,29 [-0,74;0,17] 0,214 -0,13 [-0,33;0,08]
Woche 52	330 6,47 (2,10)	282 -3,68 (0,14)	164 6,57 (2,03)	138 -3,35 (0,19)	-0,33 [-0,79;0,13] 0,156 -0,15 [-0,35;0,06]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline	Veränderung ggü. Baseline	Baseline	Veränderung ggü. Baseline	MWD
	N MW (SD)	N LS Mean (SE) ^a	N MW (SD)	N LS Mean (SE) ^a	[95 % KI] p-Wert ^a Hedges'g [95 % KI]
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; NRS: Numeric Rating Scale; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score (<12, ≥ 12), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).					

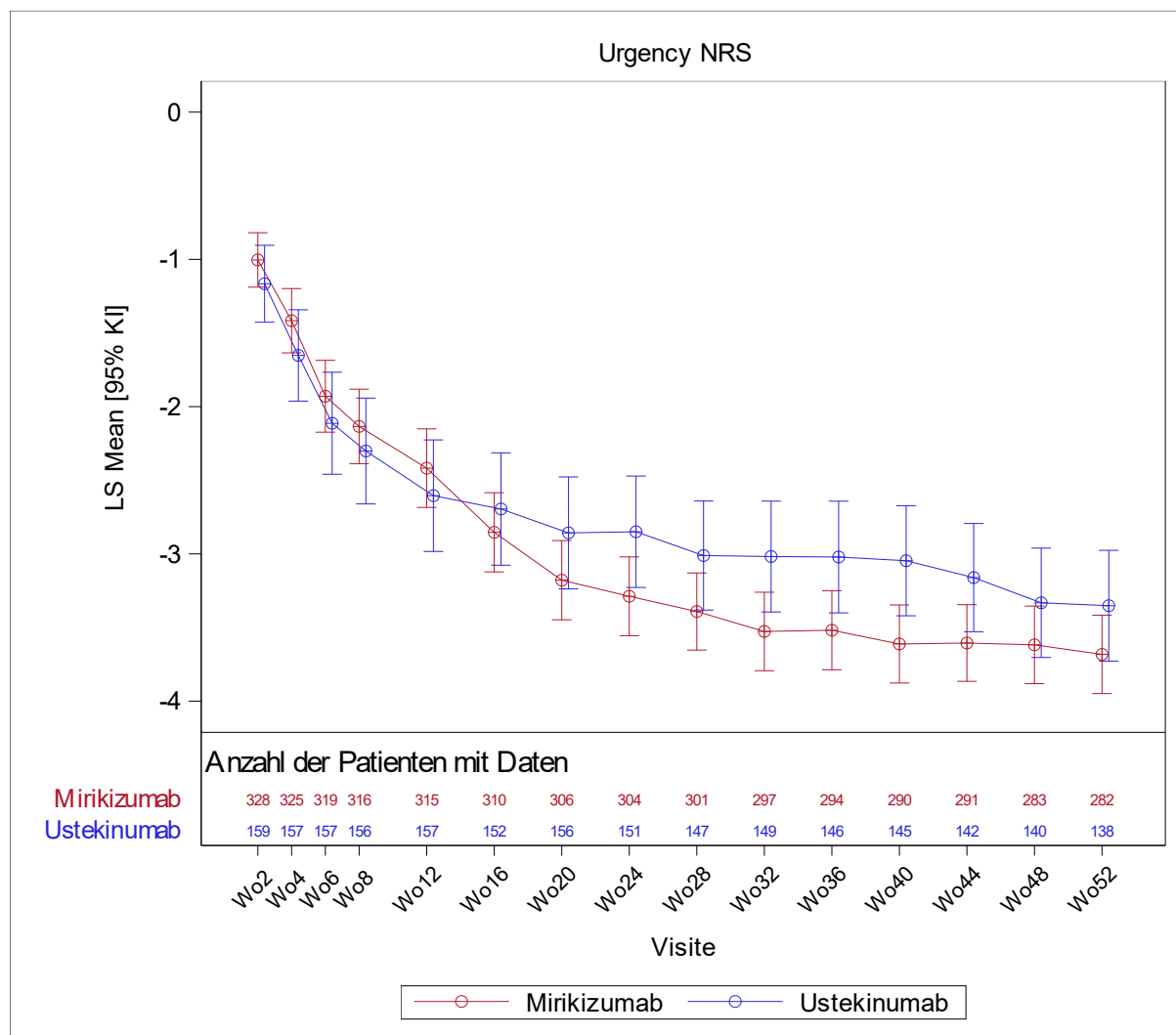
Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_urgrm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des Urgency NRS bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)



Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; NRS: Numeric Rating Scale; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/f_urgrm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adefeff_gba

19DEC2024 / 13:38

Abdominelle Schmerzen - CDAI-AP

Ergebnisse für die Veränderung des Abdominal pain von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline	Veränderung	Baseline	Veränderung	MWD
	N MW (SD)	ggü. Baseline N LS Mean (SE) ^a	N MW (SD)	ggü. Baseline N LS Mean (SE) ^a	[95 % KI] p-Wert ^a Hedges'g [95 % KI]
Abdominal pain					
Woche 2	330 2,14 (0,59)	328 -0,37 (0,03)	164 2,13 (0,58)	159 -0,44 (0,04)	0,07 [-0,03;0,17] 0,164 0,13 [-0,06;0,32]
Woche 4	330 2,14 (0,59)	325 -0,55 (0,04)	164 2,13 (0,58)	157 -0,62 (0,05)	0,07 [-0,05;0,19] 0,240 0,11 [-0,08;0,30]
Woche 6	330 2,14 (0,59)	319 -0,70 (0,04)	164 2,13 (0,58)	157 -0,77 (0,05)	0,07 [-0,06;0,20] 0,288 0,10 [-0,09;0,29]
Woche 8	330 2,14 (0,59)	316 -0,77 (0,04)	164 2,13 (0,58)	156 -0,82 (0,05)	0,05 [-0,08;0,18] 0,445 0,07 [-0,12;0,27]
Woche 12	330 2,14 (0,59)	315 -0,89 (0,04)	164 2,13 (0,58)	157 -0,95 (0,06)	0,06 [-0,08;0,20] 0,368 0,09 [-0,10;0,28]
Woche 16	330 2,14 (0,59)	310 -1,00 (0,04)	164 2,13 (0,58)	152 -1,03 (0,06)	0,03 [-0,11;0,16] 0,717 0,04 [-0,16;0,23]
Woche 20	330 2,14 (0,59)	306 -1,13 (0,04)	164 2,13 (0,58)	156 -1,07 (0,06)	-0,06 [-0,20;0,07] 0,354 -0,09 [-0,28;0,10]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Woche 24	330 2,14 (0,59)	304 -1,17 (0,04)	164 2,13 (0,58)	151 -1,08 (0,06)	-0,09 [-0,23;0,04] 0,187 -0,13 [-0,33;0,07]
Woche 28	330 2,14 (0,59)	301 -1,20 (0,04)	164 2,13 (0,58)	147 -1,16 (0,06)	-0,04 [-0,17;0,10] 0,578 -0,06 [-0,25;0,14]
Woche 32	330 2,14 (0,59)	297 -1,24 (0,04)	164 2,13 (0,58)	149 -1,14 (0,06)	-0,10 [-0,23;0,04] 0,159 -0,14 [-0,34;0,06]
Woche 36	330 2,14 (0,59)	294 -1,28 (0,04)	164 2,13 (0,58)	146 -1,19 (0,06)	-0,09 [-0,23;0,05] 0,190 -0,13 [-0,33;0,07]
Woche 40	330 2,14 (0,59)	290 -1,30 (0,04)	164 2,13 (0,58)	145 -1,18 (0,06)	-0,12 [-0,25;0,01] 0,079 -0,18 [-0,38;0,02]
Woche 44	330 2,14 (0,59)	291 -1,31 (0,04)	164 2,13 (0,58)	142 -1,21 (0,06)	-0,10 [-0,23;0,03] 0,144 -0,15 [-0,35;0,05]
Woche 48	330 2,14 (0,59)	283 -1,32 (0,04)	164 2,13 (0,58)	140 -1,26 (0,06)	-0,07 [-0,20;0,07] 0,350 -0,10 [-0,30;0,11]
Woche 52	330 2,14 (0,59)	282 -1,34 (0,04)	164 2,13 (0,58)	138 -1,27 (0,06)	-0,07 [-0,21;0,06] 0,295 -0,11 [-0,31;0,10]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline	Veränderung ggü. Baseline	Baseline	Veränderung ggü. Baseline	MWD
	N MW (SD)	N LS Mean (SE) ^a	N MW (SD)	N LS Mean (SE) ^a	[95 % KI] p-Wert ^a Hedges'g [95 % KI]
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score ($<12, \geq 12$), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).					

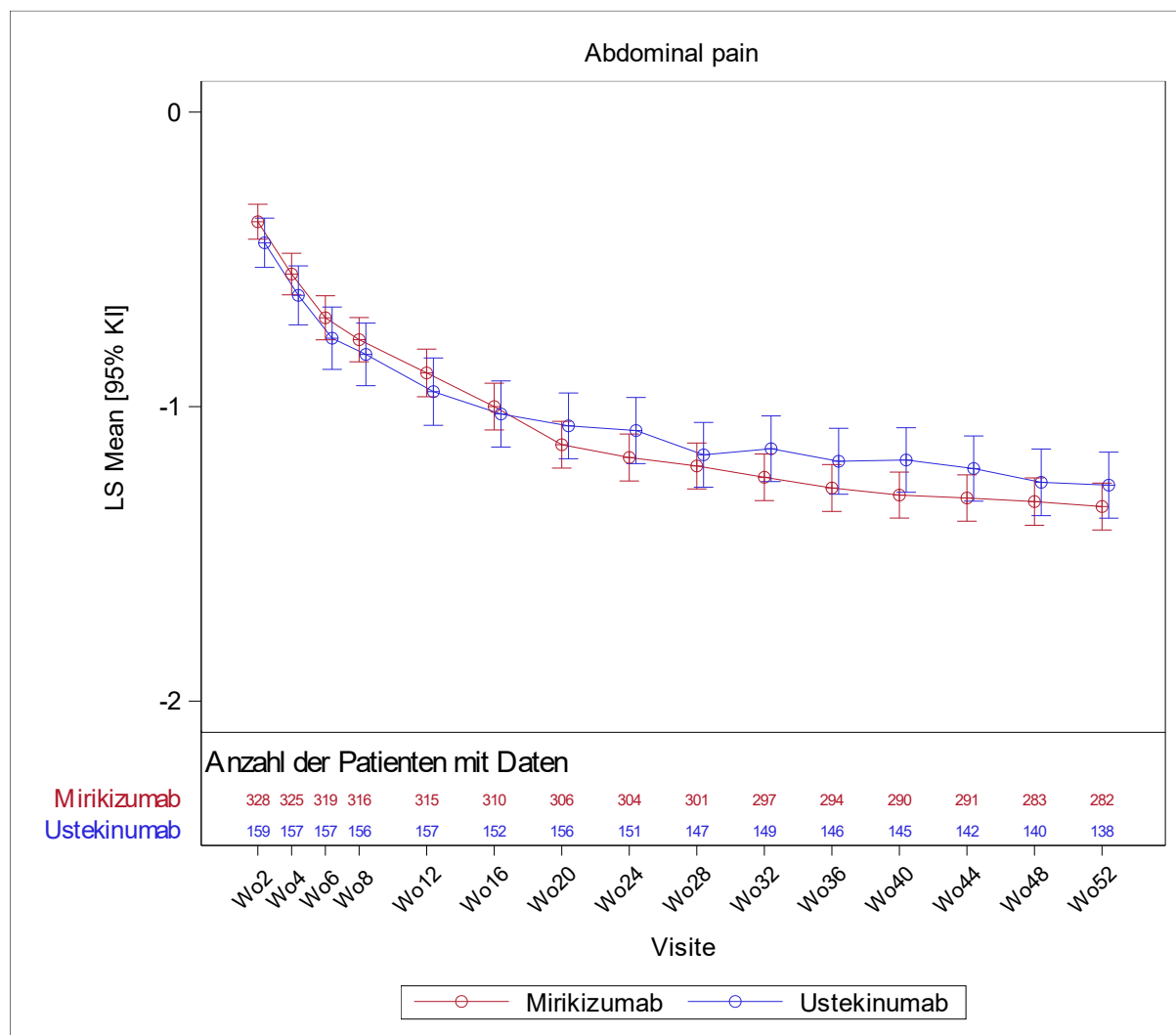
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Output Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_aprm_itta.rtf

Dataset Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des Abdominal pain bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)



Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/f_aprm_ita.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Fatigue – FACIT Fatigue

Ergebnisse für die Veränderung des FACIT-Fatigue von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
FACIT-Fatigue					
Woche 12	328 31,88 (11,28)	311 6,59 (0,49)	164 29,97 (12,07)	156 7,11 (0,68)	-0,52 [-2,14;1,10] 0,527 -0,06 [-0,25;0,13]
Woche 52	328 31,88 (11,28)	278 8,88 (0,49)	164 29,97 (12,07)	142 9,01 (0,68)	-0,13 [-1,75;1,49] 0,877 -0,02 [-0,22;0,19]
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; FACIT: Functional Assessment of Chronic Illness Therapy-Fatigue; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score (<12 , ≥ 12), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).					

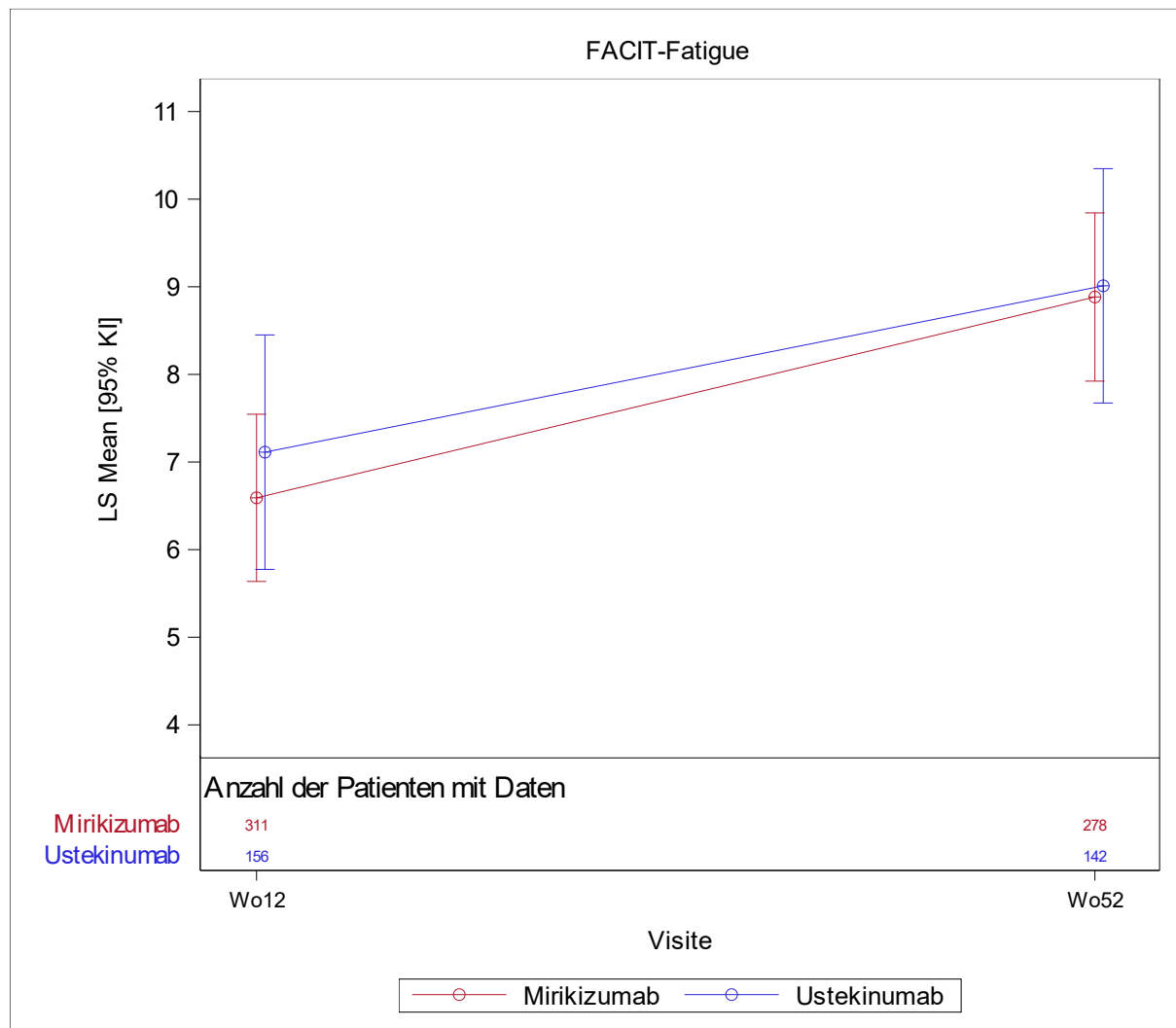
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Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_facitrm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adef_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des FACIT-Fatigue bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)



Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: FACIT: Functional Assessment of Chronic Illness Therapy-Fatigue; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/f_facitrm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Depressionen – QIDS-SR16

Ergebnisse für die Veränderung des QIDS-SR16 Total Score von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline	Veränderung	Baseline	Veränderung	MWD
	N MW (SD)	ggü. Baseline N LS Mean (SE) ^a	N MW (SD)	ggü. Baseline N LS Mean (SE) ^a	[95% KI] p-Wert ^a Hedges'g [95% KI]
QIDS-SR16 Total Score					
Woche 12	331 6,37 (4,51)	315 -1,73 (0,18)	164 7,15 (4,83)	156 -1,98 (0,25)	0,25 [-0,34;0,84] 0,399 0,08 [-0,11;0,27]
Woche 24	331 6,37 (4,51)	304 -2,25 (0,18)	164 7,15 (4,83)	151 -2,24 (0,26)	-0,00 [-0,61;0,61] 0,994 -0,00 [-0,20;0,19]
Woche 36	331 6,37 (4,51)	292 -2,35 (0,19)	164 7,15 (4,83)	149 -2,45 (0,26)	0,11 [-0,52;0,73] 0,738 0,03 [-0,16;0,23]
Woche 52	331 6,37 (4,51)	280 -2,49 (0,18)	164 7,15 (4,83)	143 -2,69 (0,25)	0,20 [-0,39;0,80] 0,502 0,07 [-0,13;0,27]

Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; QIDS-SR16: Quick Inventory of Depressive Symptomatology - Self Report (16 items); RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score (<12, ≥12), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).

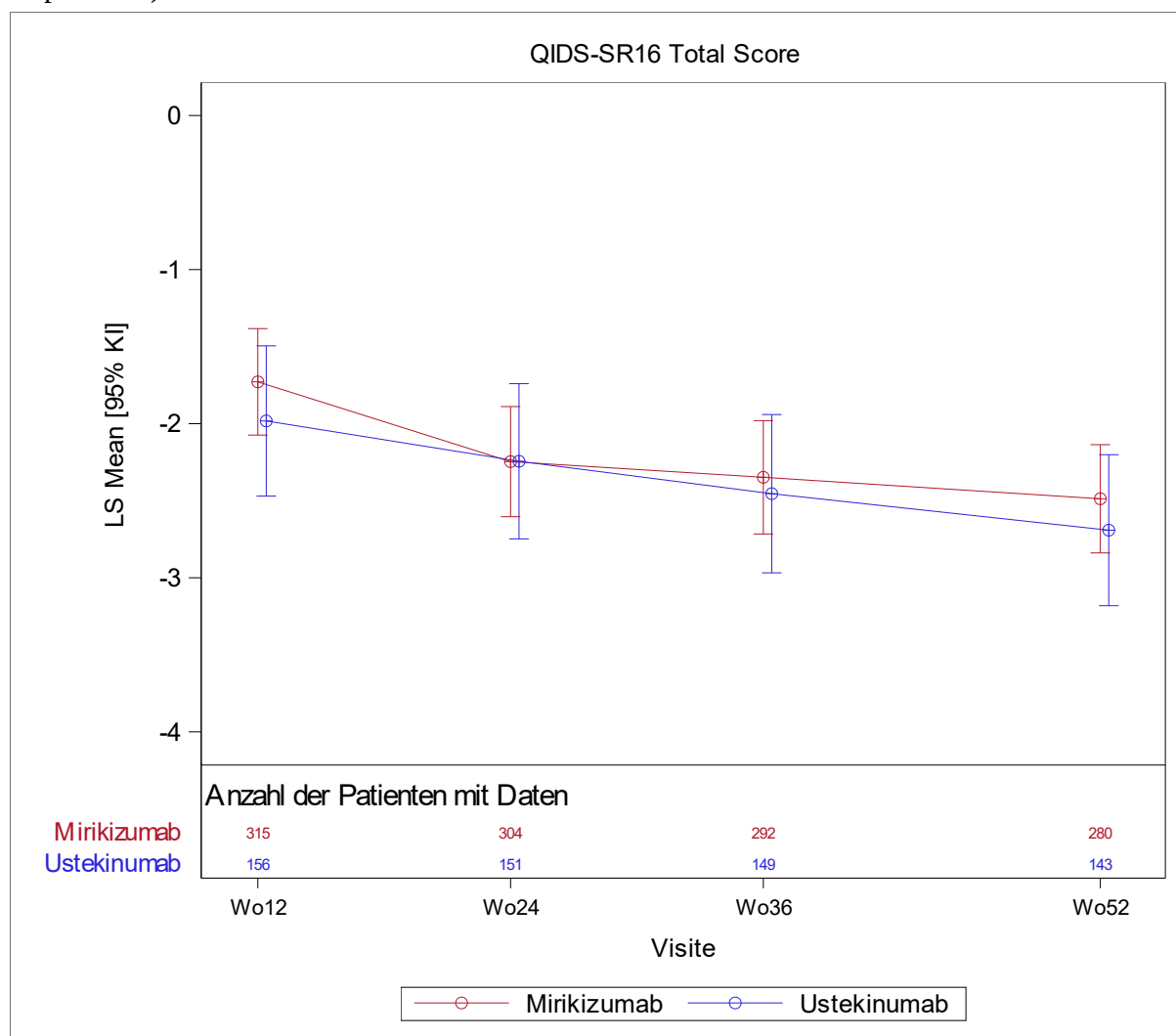
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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des QIDS-SR16 Total Score bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)



Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; QIDS-SR16: Quick Inventory of Depressive Symptomatology - Self Report (16 items); RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Anhang 4-G.3.4.3.3 Gesundheitszustand**Gesundheitszustand – EQ-5D VAS**

Ergebnisse für die Veränderung des EQ-5D VAS von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline	Veränderung ggü. Baseline	Baseline	Veränderung ggü. Baseline	MWD
	N MW (SD)	N LS Mean (SE) ^a	N MW (SD)	N LS Mean (SE) ^a	[95 % KI] p-Wert ^a Hedges'g [95 % KI]
EQ-5D VAS					
Woche 12	328 54,30 (19,34)	312 14,36 (1,03)	164 53,54 (18,48)	156 15,31 (1,45)	-0,96 [-4,40;2,49] 0,586 -0,05 [-0,24;0,14]
Woche 52	328 54,30 (19,34)	278 21,45 (1,01)	164 53,54 (18,48)	142 20,29 (1,40)	1,16 [-2,19;4,50] 0,496 0,07 [-0,13;0,27]
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; EQ-5D: Fragebogen der EuroQol-Gruppe zur Lebensqualität auf 5 Dimensionen; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; VAS: Visuelle Analogskala; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score ($<12, \geq 12$), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).					

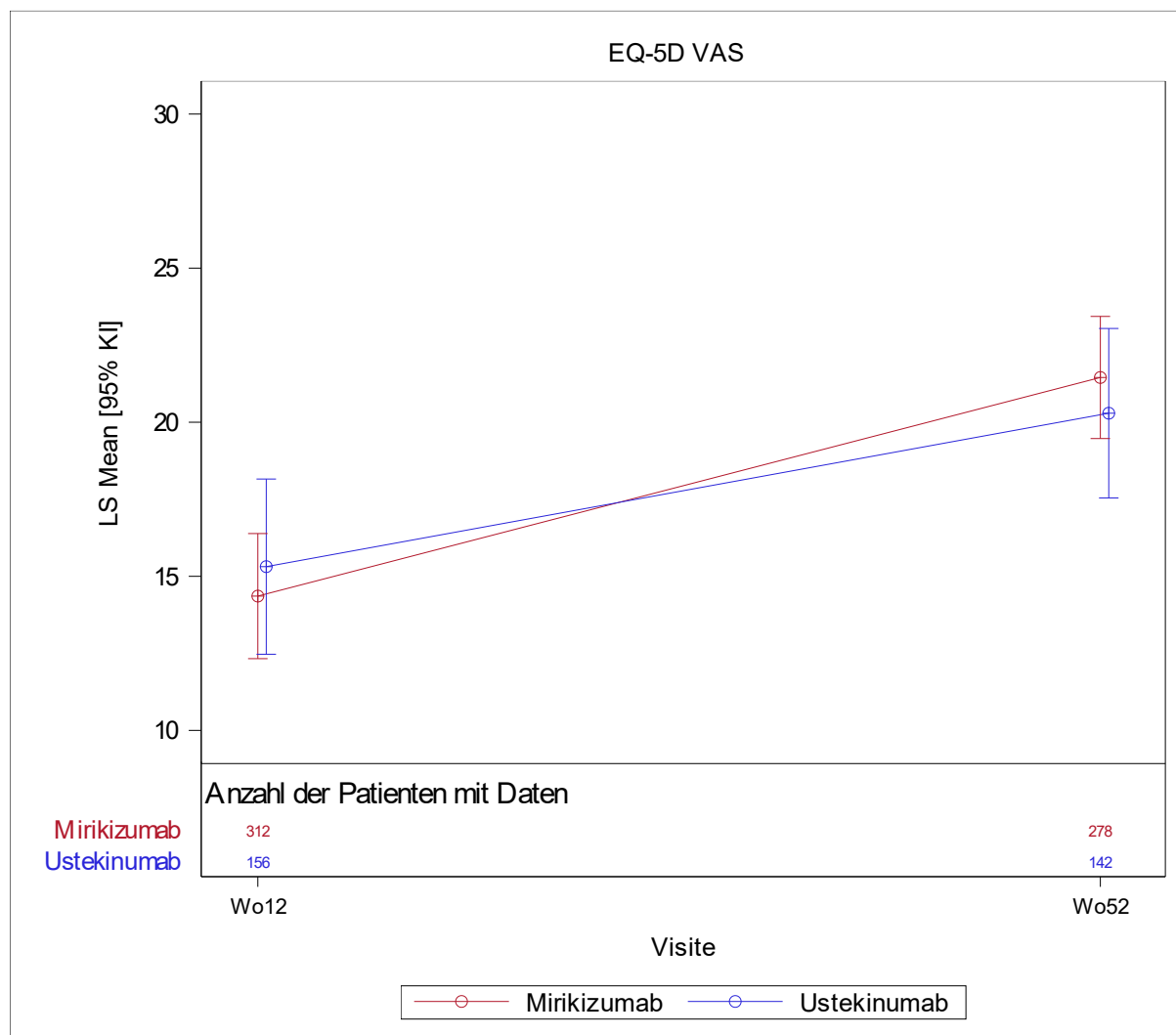
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Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_vasrm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des EQ-5D VAS bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)



Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: EQ-5D: Fragebogen der EuroQol-Gruppe zur Lebensqualität auf 5 Dimensionen; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; VAS: Visuelle Analogskala; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/f_vasrm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Gesundheitszustand – PGRS

Ergebnisse für die Veränderung des Patient Global Rating of severity (PGRS) von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
PGRS					
Woche 2	330 4,46 (0,77)	328 -0,53 (0,04)	164 4,45 (0,84)	159 -0,63 (0,06)	0,10 [-0,04;0,24] 0,178 0,13 [-0,06;0,32]
Woche 4	330 4,46 (0,77)	325 -0,82 (0,05)	164 4,45 (0,84)	157 -0,86 (0,07)	0,04 [-0,13;0,21] 0,637 0,05 [-0,15;0,24]
Woche 6	330 4,46 (0,77)	319 -1,06 (0,06)	164 4,45 (0,84)	157 -1,13 (0,08)	0,07 [-0,13;0,26] 0,497 0,07 [-0,13;0,26]
Woche 8	330 4,46 (0,77)	316 -1,19 (0,06)	164 4,45 (0,84)	156 -1,22 (0,08)	0,04 [-0,16;0,24] 0,710 0,04 [-0,16;0,23]
Woche 12	330 4,46 (0,77)	315 -1,33 (0,06)	164 4,45 (0,84)	156 -1,37 (0,09)	0,04 [-0,17;0,25] 0,716 0,04 [-0,16;0,23]
Woche 16	330 4,46 (0,77)	310 -1,51 (0,06)	164 4,45 (0,84)	152 -1,50 (0,09)	-0,01 [-0,22;0,21] 0,949 -0,01 [-0,20;0,19]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Woche 20	330 4,46 (0,77)	306 -1,70 (0,06)	164 4,45 (0,84)	156 -1,59 (0,09)	-0,11 [-0,32;0,10] 0,312 -0,10 [-0,29;0,09]
Woche 24	330 4,46 (0,77)	304 -1,74 (0,06)	164 4,45 (0,84)	151 -1,61 (0,09)	-0,14 [-0,35;0,07] 0,200 -0,13 [-0,32;0,07]
Woche 28	330 4,46 (0,77)	301 -1,80 (0,06)	164 4,45 (0,84)	147 -1,71 (0,09)	-0,08 [-0,30;0,13] 0,442 -0,08 [-0,27;0,12]
Woche 32	330 4,46 (0,77)	297 -1,86 (0,07)	164 4,45 (0,84)	149 -1,72 (0,09)	-0,14 [-0,36;0,08] 0,208 -0,13 [-0,32;0,07]
Woche 36	330 4,46 (0,77)	294 -1,91 (0,07)	164 4,45 (0,84)	146 -1,75 (0,09)	-0,16 [-0,38;0,06] 0,154 -0,14 [-0,34;0,06]
Woche 40	330 4,46 (0,77)	290 -1,96 (0,07)	164 4,45 (0,84)	145 -1,74 (0,09)	-0,22 [-0,44;-0,00] 0,048 -0,20 [-0,40;0,00]
Woche 44	330 4,46 (0,77)	291 -1,99 (0,06)	164 4,45 (0,84)	142 -1,78 (0,09)	-0,21 [-0,42;0,01] 0,060 -0,19 [-0,39;0,01]
Woche 48	330 4,46 (0,77)	283 -2,00 (0,07)	164 4,45 (0,84)	140 -1,84 (0,09)	-0,15 [-0,38;0,07] 0,179 -0,14 [-0,34;0,07]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Woche 52	330 4,46 (0,77)	282 -2,03 (0,07)	164 4,45 (0,84)	138 -1,86 (0,09)	-0,17 [-0,39;0,06] 0,143 -0,15 [-0,35;0,05]
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; PGRS: Patient Global Rating of Severity; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score ($<12, \geq 12$), entweder Baseline SF $\geq$ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz- Struktur).					

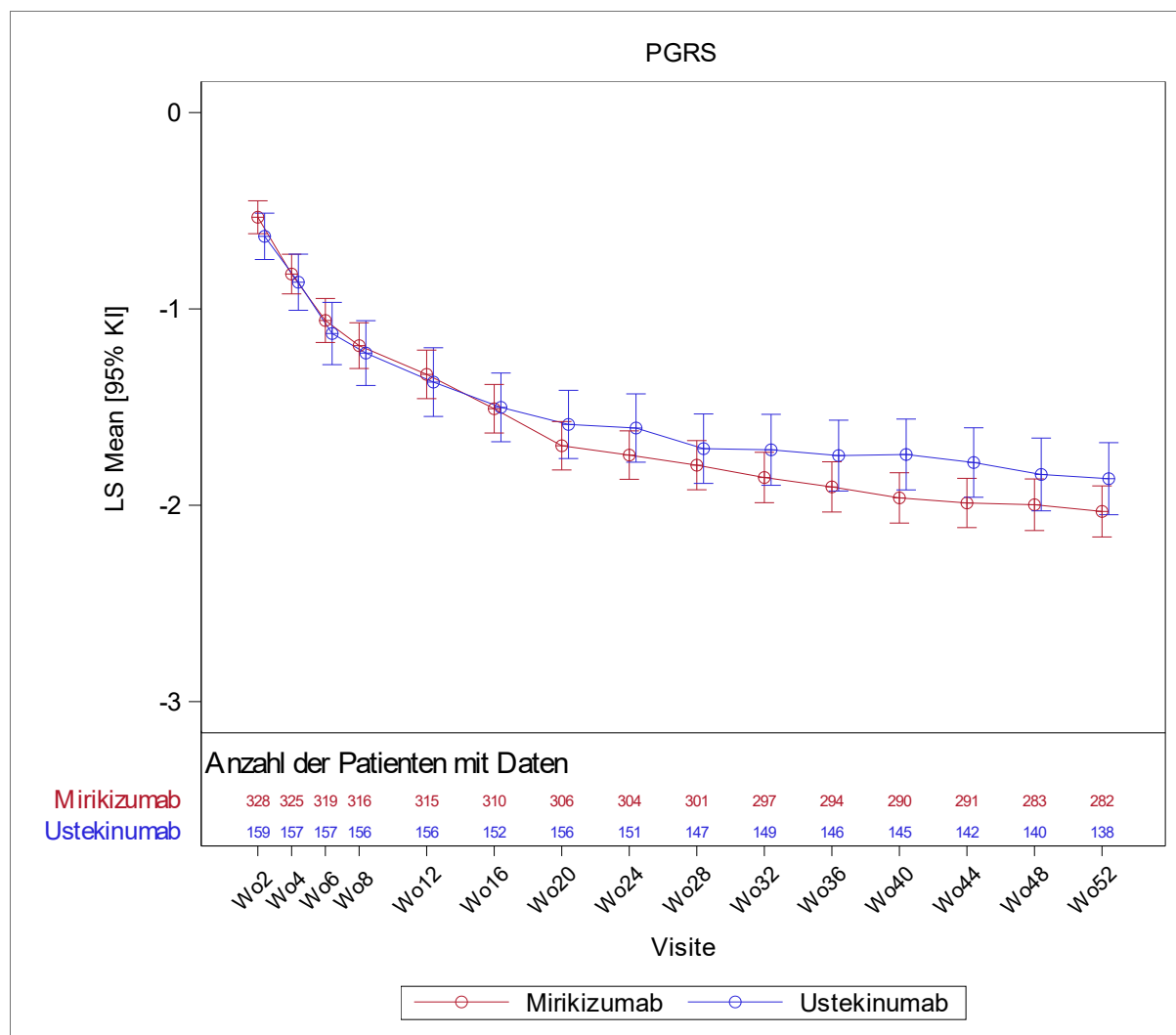
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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des Patient Global Rating of severity (PGRS) bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)



Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; PGRS: Patient Global Rating of Severity; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Gesundheitszustand – PGIC

Ergebnisse für Patient Reported Impression of Change (PGIC) von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
PGIC					
Woche 4	NE	324 3,10 (0,05)	NE	159 2,96 (0,07)	0,14 [-0,03;0,31] 0,106 0,15 [-0,04;0,34]
Woche 8	NE	319 2,67 (0,06)	NE	156 2,66 (0,08)	0,01 [-0,18;0,20] 0,919 0,01 [-0,18;0,20]
Woche 12	NE	315 2,54 (0,06)	NE	156 2,43 (0,08)	0,10 [-0,10;0,30] 0,309 0,10 [-0,09;0,29]
Woche 52	NE	279 1,93 (0,06)	NE	141 1,90 (0,08)	0,03 [-0,15;0,22] 0,725 0,04 [-0,17;0,24]

Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; NE: Nicht errechenbar/nicht erreicht; PGIC: Patient Global Impression of Change; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score (<12, ≥12), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).

PGIC umfasst die Werte einer 5-stufigen Skala von 1 ('viel besser') bis 5 ('viel schlechter').

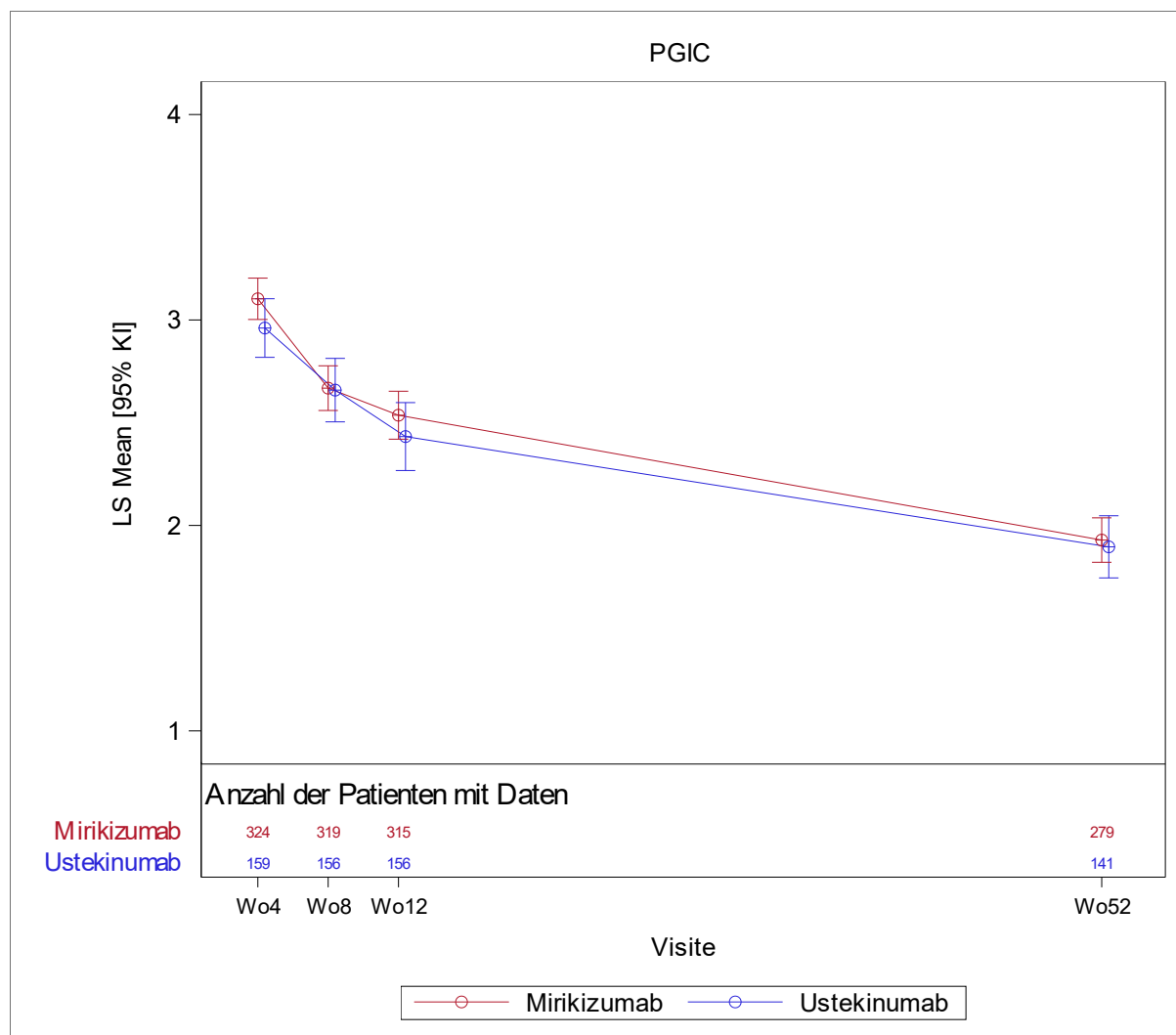
Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_pgicrm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des Patient Reported Impression of Change (PGIC) bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)



Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; PGIC: Patient Global Impression of Change; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/f_pgicrm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Gesundheitszustand – WPAI-CD (Aktivitätsbeeinträchtigung)

Ergebnisse für die Veränderung des WPAI (Activity impairment) von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population, Participants with baseline employment status of Yes)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
WPAI (Activity impairment)					
Woche 12	202 48,32 (23,27)	192 -20,68 (1,67)	91 47,47 (24,93)	87 -24,19 (2,48)	3,51 [-2,22;9,24] 0,229 0,15 [-0,10;0,41]
Woche 52	202 48,32 (23,27)	174 -27,96 (1,61)	91 47,47 (24,93)	80 -29,28 (2,39)	1,32 [-4,20;6,83] 0,639 0,06 [-0,20;0,33]
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus; WPAI: Work Productivity and Activity Impairment Questionnaire. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score (<12, ≥12), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz- Struktur).					

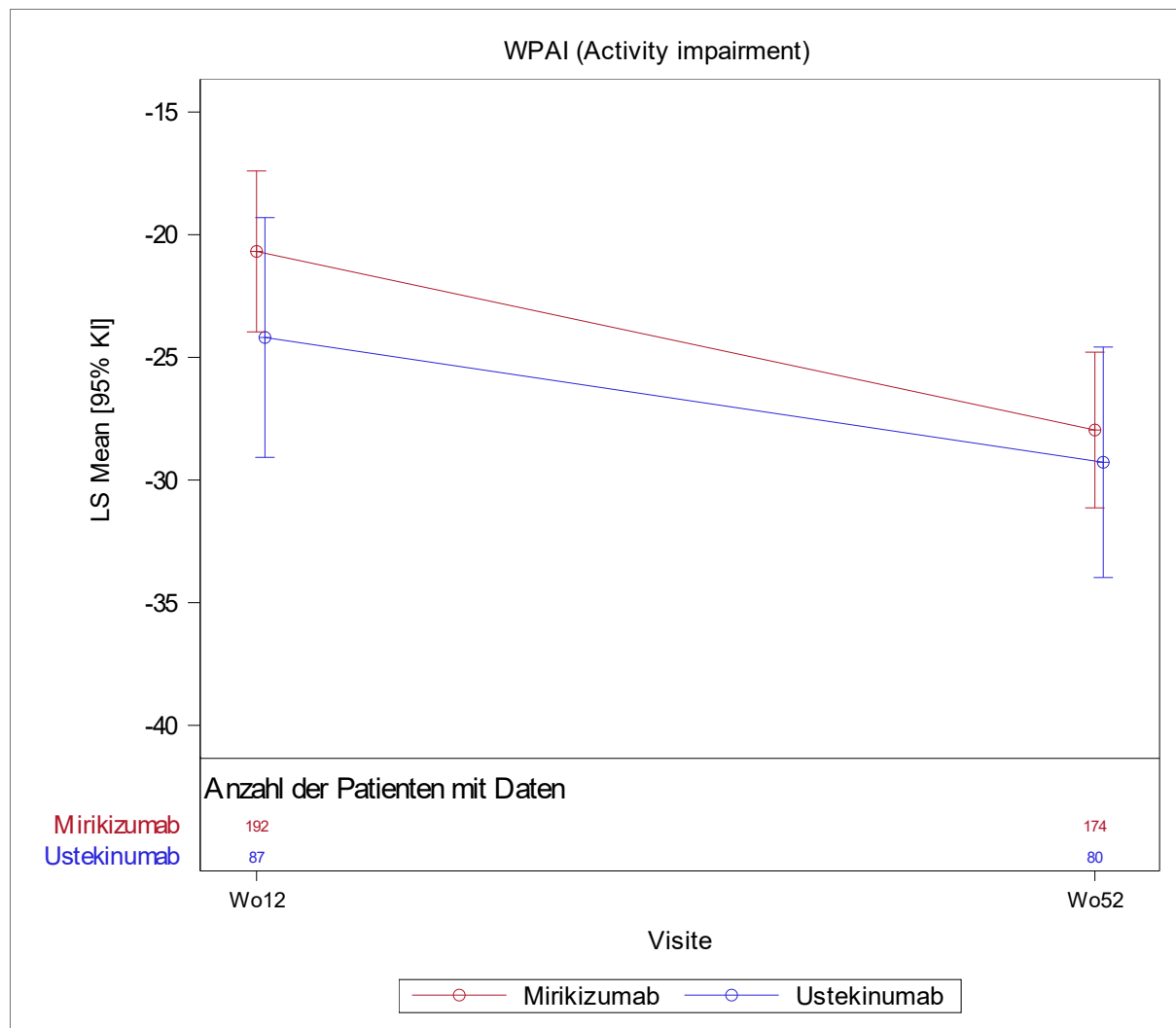
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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adef_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des WPAI (Activity impairment) bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population, Participants with baseline employment status of Yes)



Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; Wo: Woche; WPAI: Work Productivity and Activity Impairment Questionnaire.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/f_wpaim_empl_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Allgemeinbefinden - CDAI-GWP

Ergebnisse für die Veränderung des General well being von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
General well being					
Woche 2	330 2,24 (0,84)	328 -0,45 (0,04)	164 2,20 (0,96)	159 -0,56 (0,06)	0,11 [-0,02;0,24] 0,095 0,16 [-0,03;0,35]
Woche 4	330 2,24 (0,84)	325 -0,65 (0,04)	164 2,20 (0,96)	157 -0,79 (0,06)	0,14 [-0,01;0,28] 0,062 0,18 [-0,01;0,37]
Woche 6	330 2,24 (0,84)	319 -0,82 (0,04)	164 2,20 (0,96)	157 -0,96 (0,06)	0,14 [-0,01;0,29] 0,072 0,17 [-0,02;0,36]
Woche 8	330 2,24 (0,84)	316 -0,89 (0,05)	164 2,20 (0,96)	156 -1,02 (0,06)	0,13 [-0,03;0,28] 0,101 0,16 [-0,03;0,35]
Woche 12	330 2,24 (0,84)	315 -1,00 (0,05)	164 2,20 (0,96)	157 -1,11 (0,07)	0,10 [-0,06;0,27] 0,204 0,12 [-0,07;0,31]
Woche 16	330 2,24 (0,84)	310 -1,16 (0,05)	164 2,20 (0,96)	152 -1,18 (0,07)	0,02 [-0,14;0,18] 0,806 0,02 [-0,17;0,22]
Woche 20	330 2,24 (0,84)	306 -1,29 (0,05)	164 2,20 (0,96)	156 -1,21 (0,06)	-0,08 [-0,24;0,07] 0,296 -0,10 [-0,29;0,09]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Woche 24	330 2,24 (0,84)	304 -1,32 (0,05)	164 2,20 (0,96)	151 -1,22 (0,07)	-0,10 [-0,25;0,06] 0,213 -0,12 [-0,32;0,07]
Woche 28	330 2,24 (0,84)	301 -1,35 (0,05)	164 2,20 (0,96)	147 -1,30 (0,06)	-0,05 [-0,20;0,10] 0,511 -0,07 [-0,26;0,13]
Woche 32	330 2,24 (0,84)	297 -1,39 (0,05)	164 2,20 (0,96)	149 -1,29 (0,06)	-0,11 [-0,26;0,05] 0,175 -0,13 [-0,33;0,06]
Woche 36	330 2,24 (0,84)	294 -1,42 (0,05)	164 2,20 (0,96)	146 -1,31 (0,07)	-0,11 [-0,27;0,04] 0,156 -0,14 [-0,34;0,06]
Woche 40	330 2,24 (0,84)	290 -1,44 (0,05)	164 2,20 (0,96)	145 -1,30 (0,07)	-0,14 [-0,29;0,02] 0,083 -0,17 [-0,37;0,03]
Woche 44	330 2,24 (0,84)	291 -1,47 (0,05)	164 2,20 (0,96)	142 -1,37 (0,06)	-0,10 [-0,25;0,05] 0,206 -0,13 [-0,33;0,07]
Woche 48	330 2,24 (0,84)	283 -1,47 (0,05)	164 2,20 (0,96)	140 -1,39 (0,07)	-0,08 [-0,24;0,07] 0,295 -0,11 [-0,31;0,10]
Woche 52	330 2,24 (0,84)	282 -1,47 (0,05)	164 2,20 (0,96)	138 -1,43 (0,06)	-0,05 [-0,20;0,11] 0,561 -0,06 [-0,26;0,14]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline	Veränderung ggü. Baseline	Baseline	Veränderung ggü. Baseline	MWD
	N MW (SD)	N LS Mean (SE) ^a	N MW (SD)	N LS Mean (SE) ^a	[95 % KI] p-Wert ^a Hedges'g [95 % KI]
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score ($<12, \geq 12$), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).					

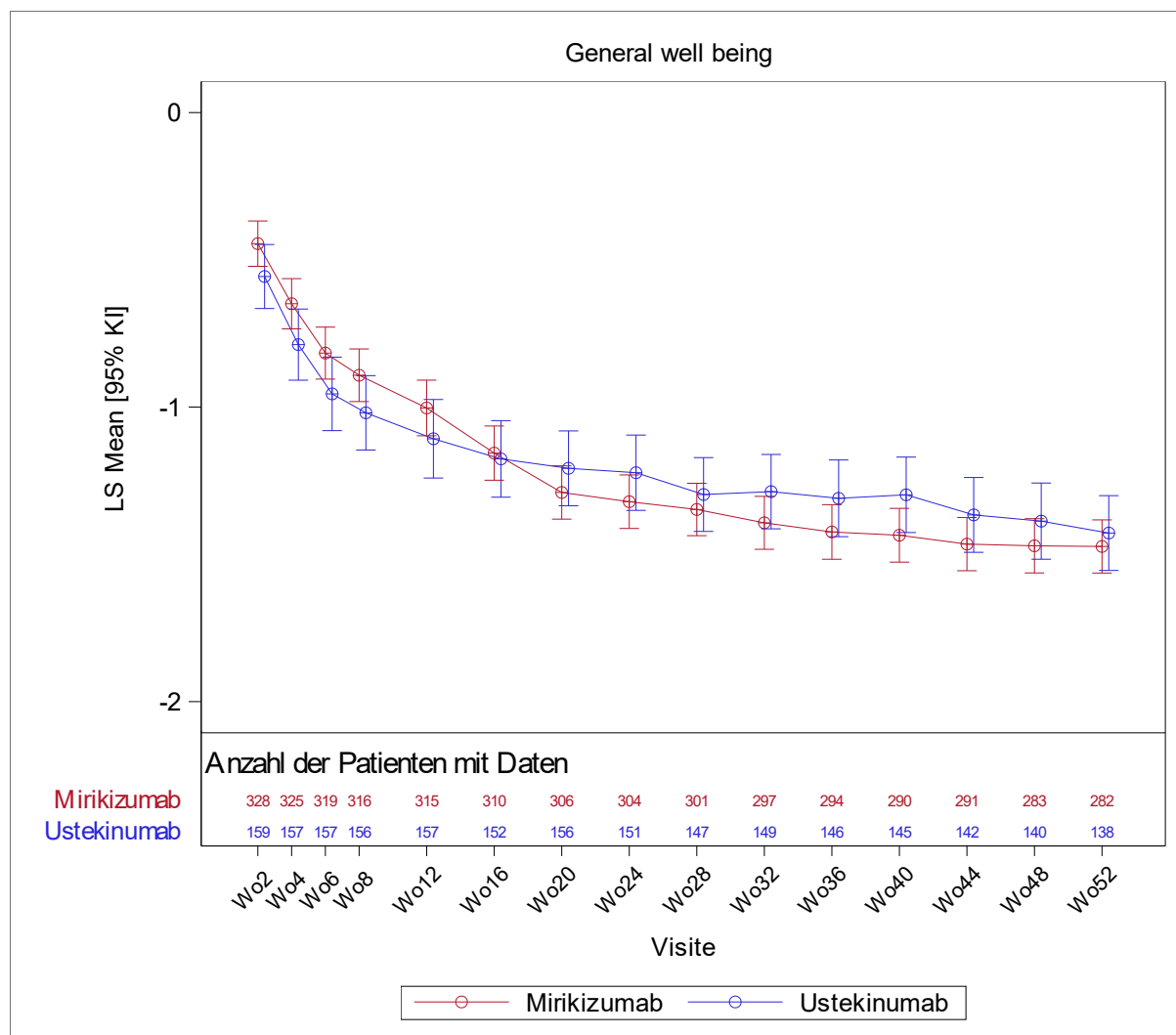
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Dataset Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des General well being bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)



Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

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19DEC2024 / 13:38

Anhang 4-G.3.4.3.4 Gesundheitsbezogene Lebensqualität**Krankheitsspezifische Lebensqualität - IBDQ**

Ergebnisse für die Veränderung des IBDQ von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
IBDQ Total Score					
Woche 12	328 128,04 (33,16)	312 40,77 (1,69)	164 123,74 (35,18)	156 42,38 (2,36)	-1,62 [-7,24;4,00] 0,572 -0,05 [-0,25;0,14]
Woche 52	328 128,04 (33,16)	278 53,41 (1,65)	164 123,74 (35,18)	142 50,52 (2,30)	2,89 [-2,59;8,37] 0,300 0,11 [-0,10;0,31]
IBDQ Bowel Symptoms					
Woche 12	328 38,21 (9,74)	312 14,57 (0,57)	164 37,33 (10,36)	156 15,26 (0,79)	-0,69 [-2,57;1,20] 0,474 -0,07 [-0,26;0,12]
Woche 52	328 38,21 (9,74)	278 18,95 (0,54)	164 37,33 (10,36)	142 17,28 (0,75)	1,67 [-0,13;3,47] 0,069 0,18 [-0,02;0,39]
IBDQ Emotional Function					
Woche 12	328 50,91 (14,12)	312 13,00 (0,64)	164 49,30 (14,94)	156 13,25 (0,90)	-0,25 [-2,40;1,89] 0,817 -0,02 [-0,21;0,17]
Woche 52	328 50,91 (14,12)	278 16,97 (0,65)	164 49,30 (14,94)	142 16,14 (0,90)	0,84 [-1,32;2,99] 0,446 0,08 [-0,12;0,28]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
IBDQ Social Function					
Woche 12	328 20,95 (7,04)	312 6,86 (0,33)	164 19,70 (7,72)	156 7,17 (0,46)	-0,32 [-1,41;0,78] 0,569 -0,05 [-0,25;0,14]
Woche 52	328 20,95 (7,04)	278 9,18 (0,31)	164 19,70 (7,72)	142 9,06 (0,44)	0,13 [-0,91;1,16] 0,809 0,02 [-0,18;0,23]
IBDQ Systemic Symptoms					
Woche 12	328 17,97 (5,75)	312 6,32 (0,30)	164 17,41 (5,88)	156 6,67 (0,42)	-0,35 [-1,35;0,64] 0,487 -0,07 [-0,26;0,13]
Woche 52	328 17,97 (5,75)	278 8,31 (0,31)	164 17,41 (5,88)	142 8,05 (0,43)	0,26 [-0,77;1,30] 0,620 0,05 [-0,15;0,25]
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score (<12, ≥12), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).					

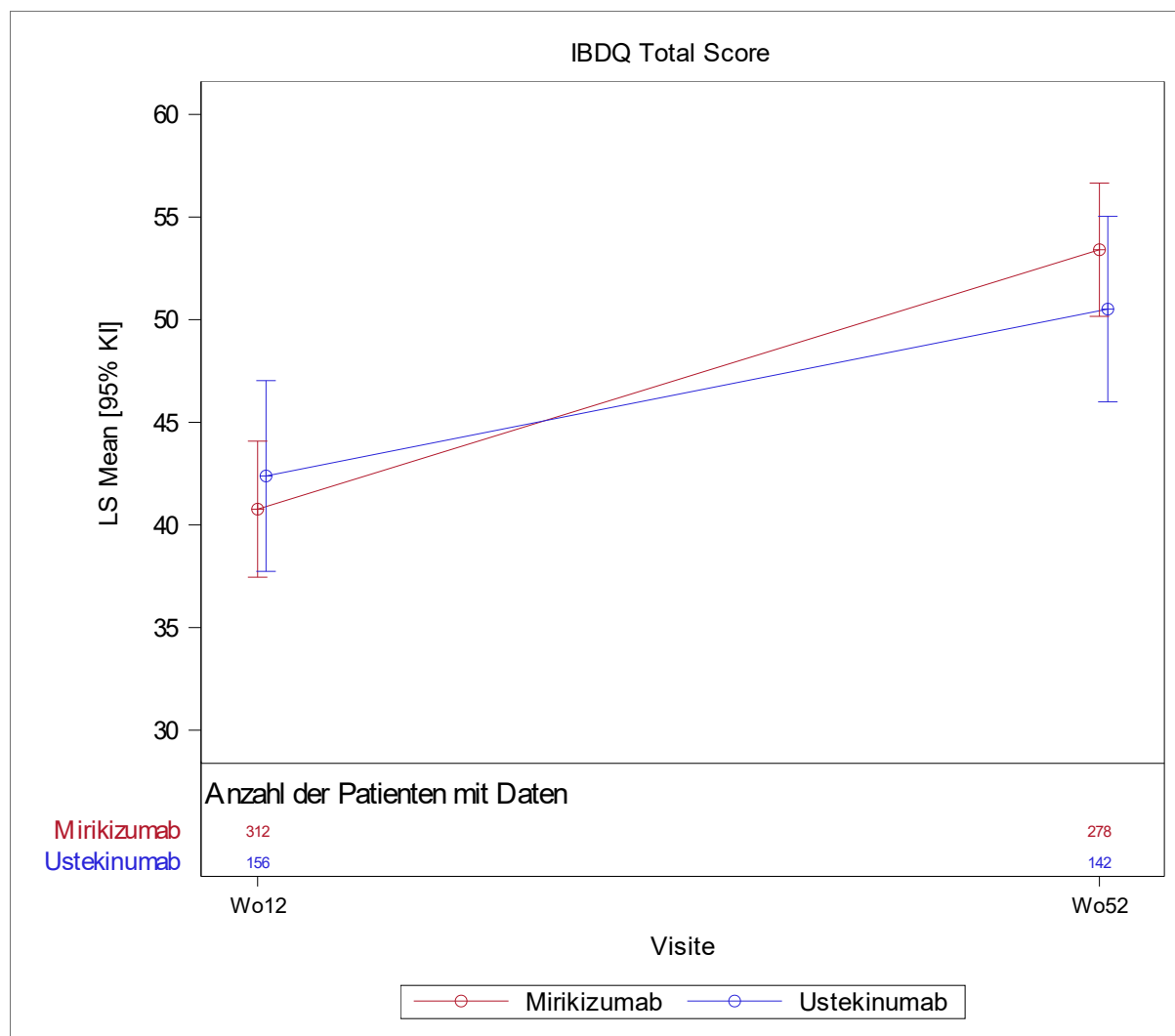
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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des IBDQ Total Score bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)



Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

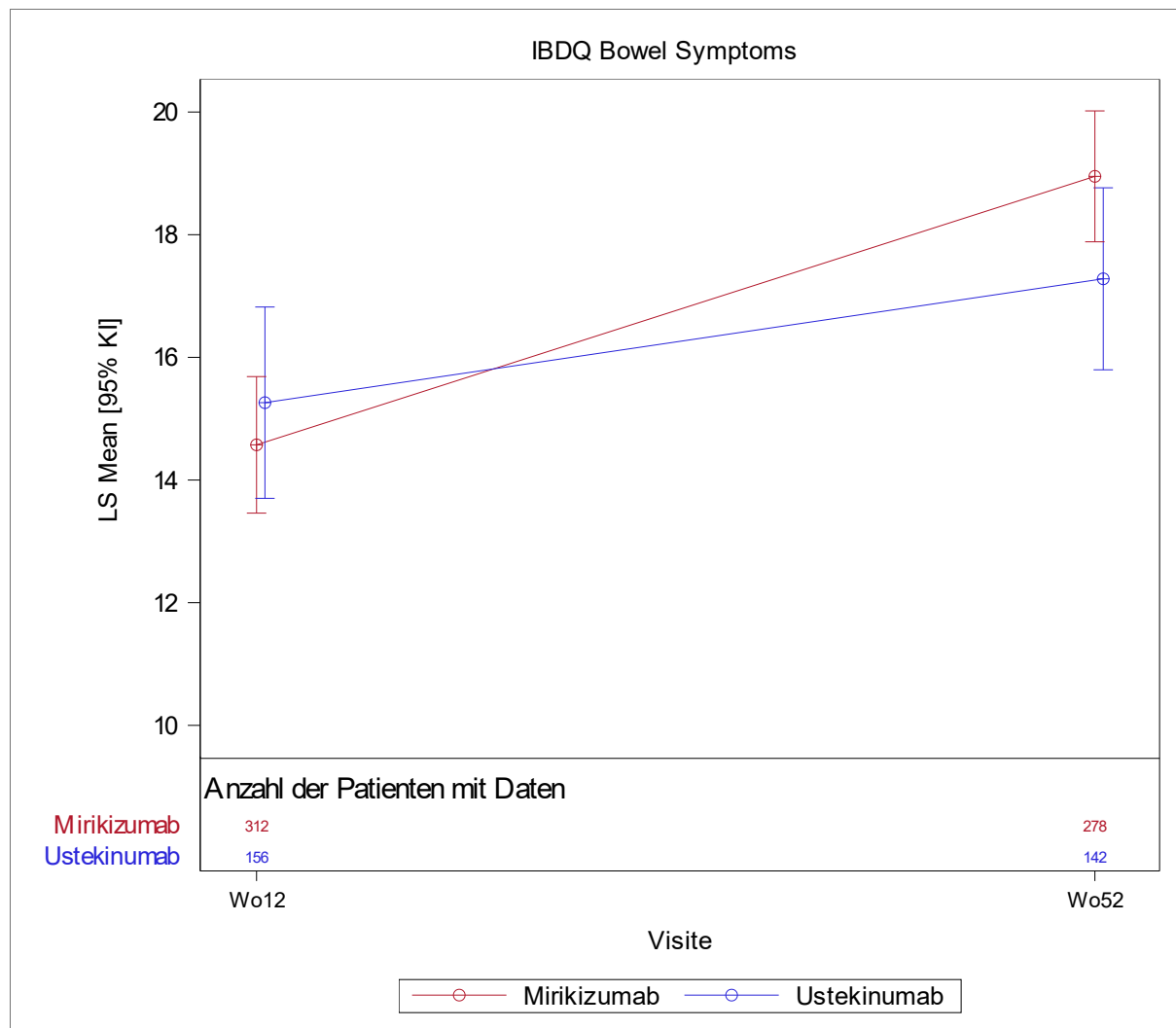
Abkürzungen: IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

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19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des IBDQ Bowel Symptoms bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)



Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

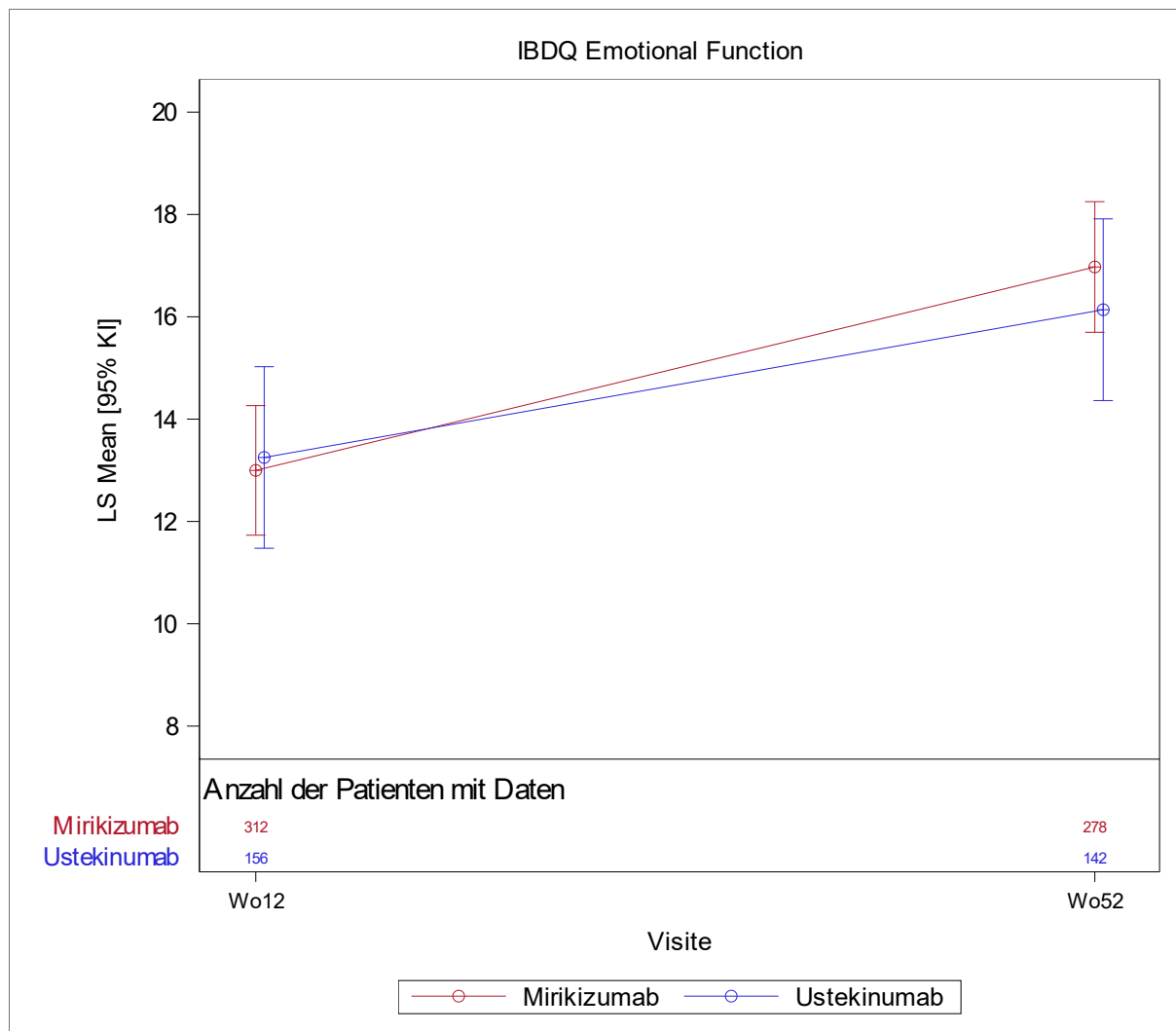
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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des IBDQ Emotional Function bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)



Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

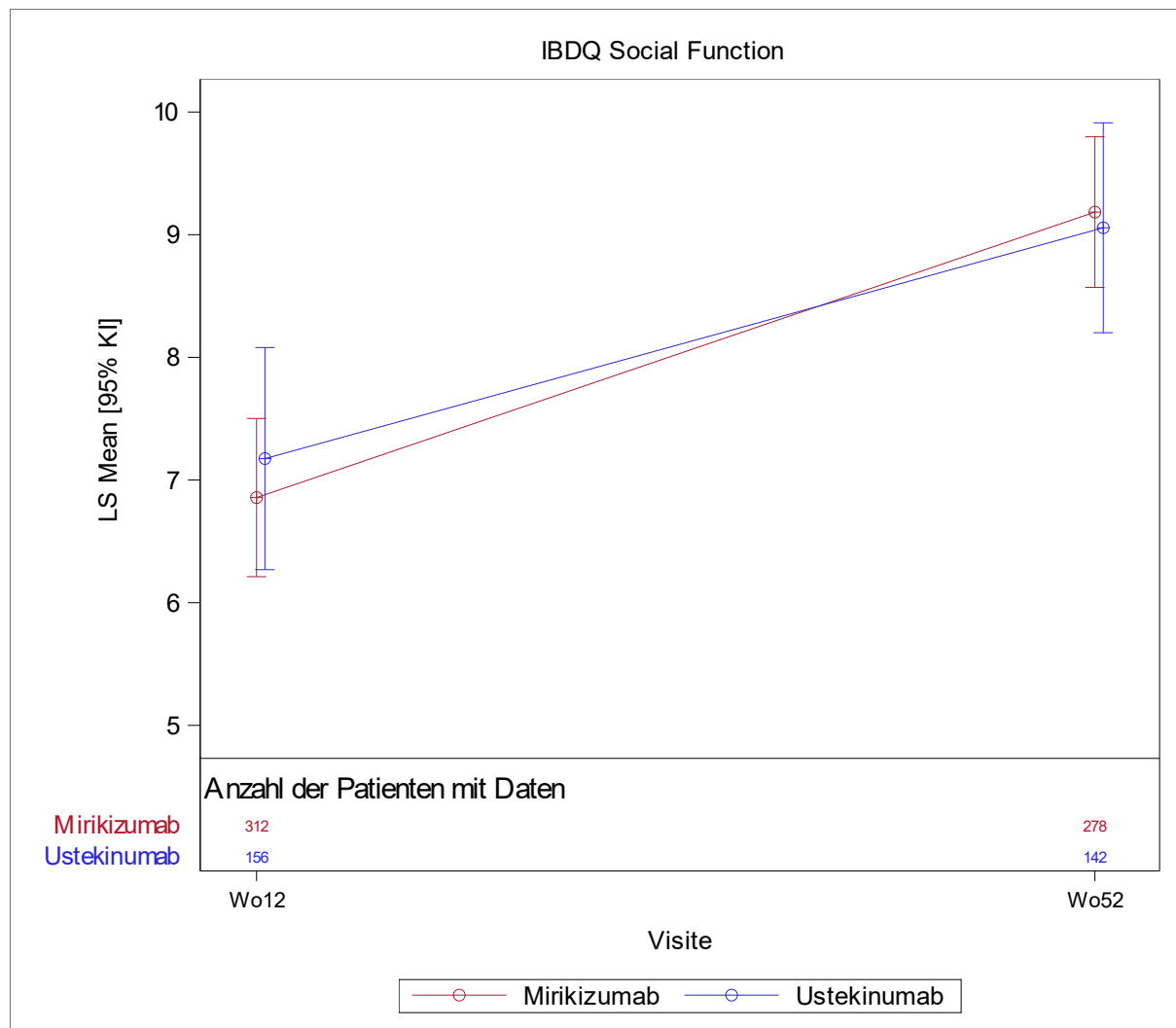
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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des IBDQ Social Function bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)



Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

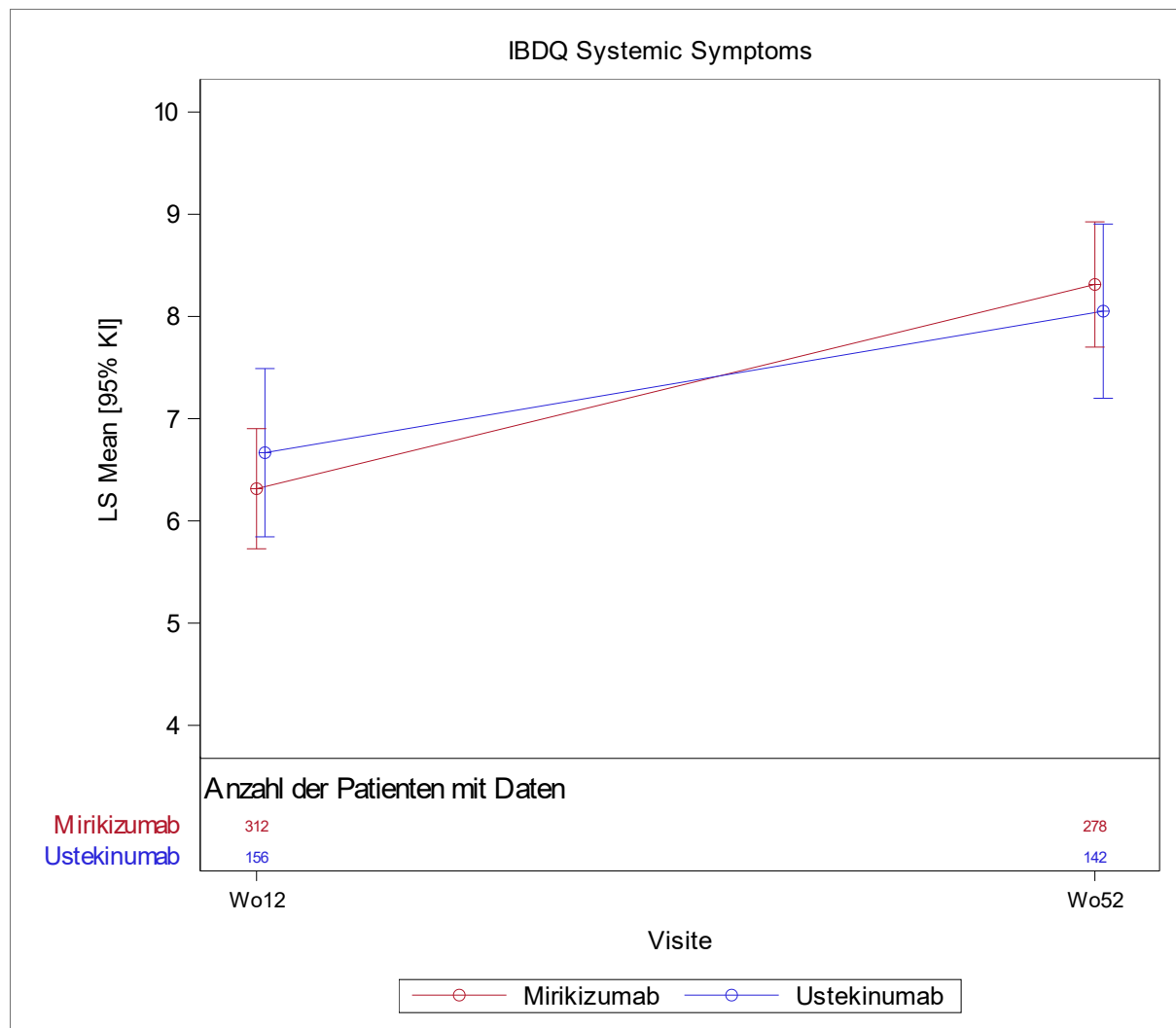
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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des IBDQ Systemic Symptoms bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)



Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/f_ibdqssrm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Gesundheitsbezogene Lebensqualität – SF-36

Ergebnisse für die Veränderung des SF-36 von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
SF-36 MCS Score					
Woche 12	328 43,38 (10,94)	312 5,64 (0,46)	164 42,26 (10,78)	156 6,75 (0,64)	-1,11 [-2,64;0,42] 0,154 -0,14 [-0,33;0,05]
Woche 52	328 43,38 (10,94)	278 7,19 (0,48)	164 42,26 (10,78)	142 7,26 (0,67)	-0,07 [-1,66;1,52] 0,929 -0,01 [-0,21;0,19]
SF-36 PCS Score					
Woche 12	328 39,96 (7,26)	312 7,40 (0,38)	164 40,00 (8,02)	156 7,71 (0,53)	-0,31 [-1,56;0,94] 0,622 -0,05 [-0,24;0,14]
Woche 52	328 39,96 (7,26)	278 10,16 (0,41)	164 40,00 (8,02)	142 9,69 (0,57)	0,46 [-0,91;1,83] 0,508 0,07 [-0,13;0,27]
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MCS: Mental Health Component Summary Score; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; PCS: Physical Health Component Summary Score; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF-36: 36-Item Short Form Health Survey; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score (<12, ≥ 12), entweder Baseline SF $\geq$ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz- Struktur).					

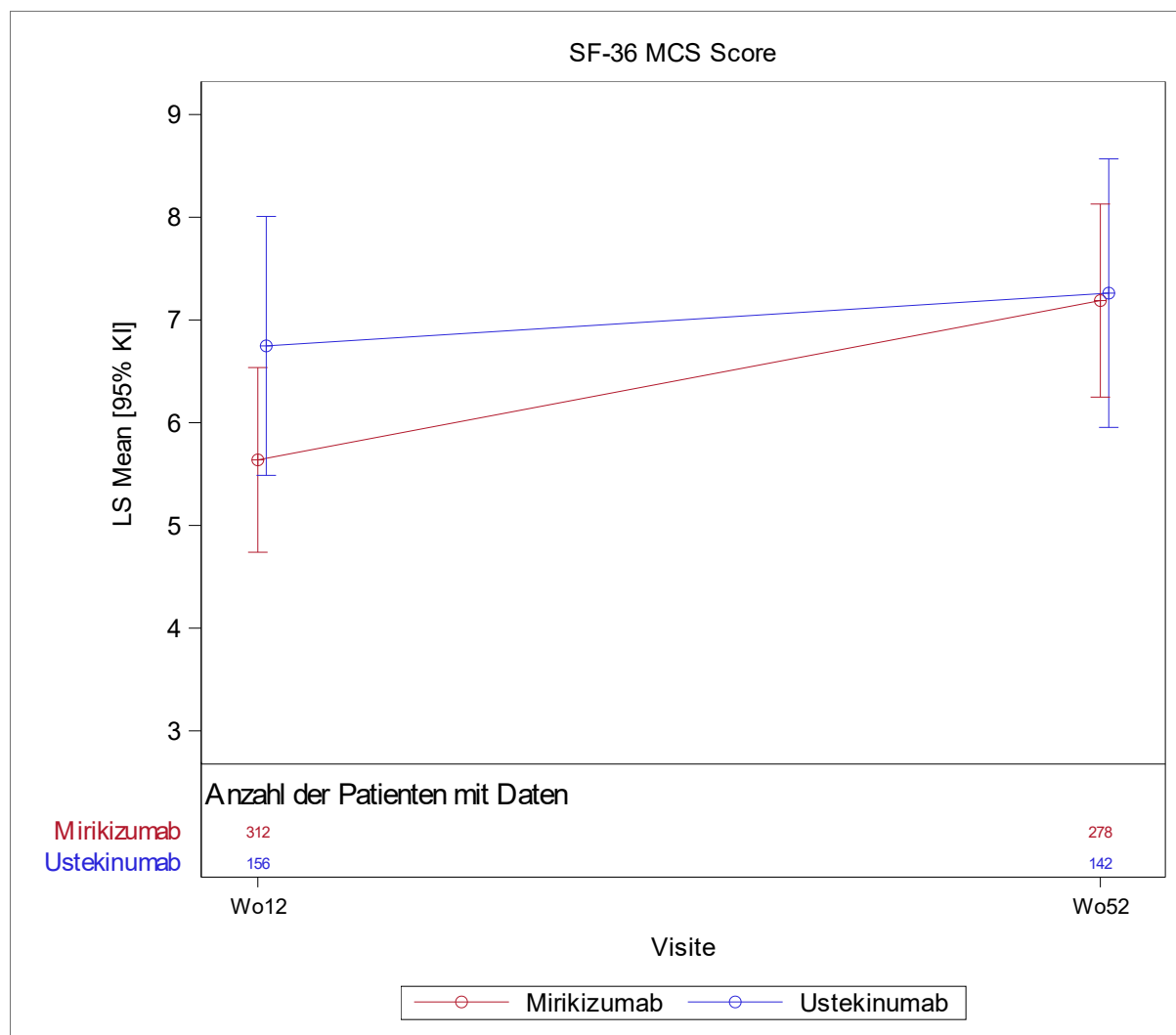
Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_sf36rm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adef_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des SF-36 MCS Score bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)



Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

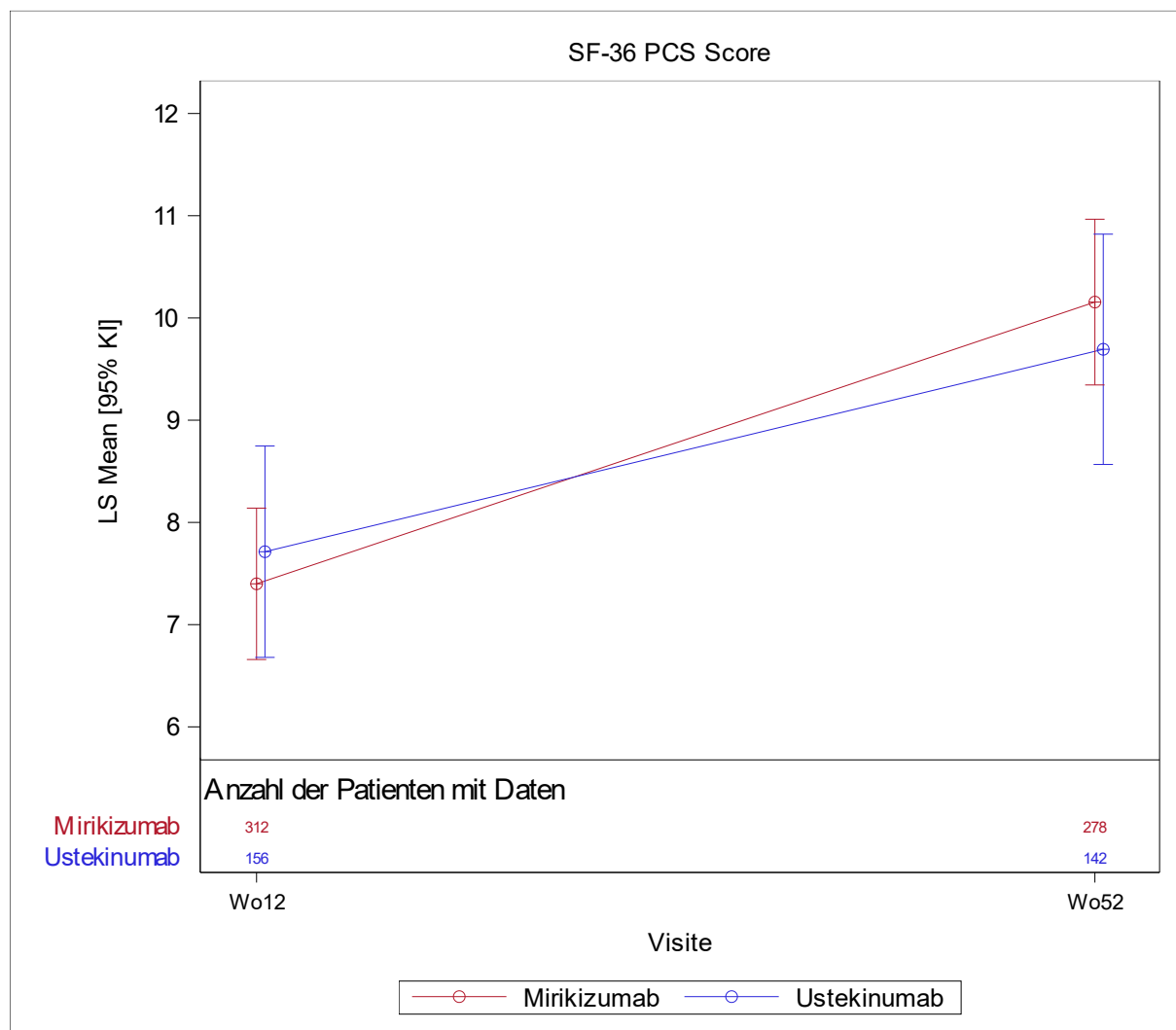
Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MCS: Mental Health Component Summary Score; RCT: randomisierte, kontrollierte Studie; SF-36: 36-Item Short Form Health Survey; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/f_sf36mcsrm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba
19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des SF-36 PCS Score bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)



Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; PCS: Physical Health Component Summary Score; RCT: randomisierte, kontrollierte Studie; SF-36: 36-Item Short Form Health Survey; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/f_sf36pcsrn_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Anhang 4-G.3.4.4 Verlaufsbeobachtungen der kontinuierlichen Endpunkte in RCT VIVID-1 in Teilpopulation A

Anhang 4-G.3.4.4.1 Klinische Remission

Zusammenfassende Statistik für PRO (AP+SF) in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)			Ustekinumab (N=164)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
PRO (AP+SF)						
Baseline	330	21,5 (5,9) 20,9 7; 58	NB	164	21,7 (6,3) 20,6 10; 39	NB
Woche 2	328	17,4 (7,3) 17,0 1; 42	-4,2 (5,6) -3,0 -31; 11	161	17,1 (7,3) 17,0 0; 42	-4,6 (6,2) -3,7 -36; 7
Woche 4	325	15,3 (7,5) 14,9 0; 43	-6,2 (6,4) -5,1 -25; 12	159	14,9 (7,8) 15,0 0; 41	-6,9 (7,4) -4,7 -36; 7
Woche 6	320	13,9 (7,7) 12,9 0; 41	-7,8 (6,9) -7,3 -29; 10	157	13,1 (7,5) 12,7 0; 37	-8,7 (7,8) -7,9 -37; 8
Woche 8	317	13,0 (7,9) 11,7 0; 40	-8,7 (6,9) -8,4 -31; 8	156	12,5 (7,7) 12,2 0; 43	-9,3 (8,0) -7,4 -37; 9
Woche 12	316	12,0 (7,9) 10,3 0; 39	-9,6 (7,6) -9,0 -31; 8	157	11,1 (7,5) 11,3 0; 48	-10,6 (8,4) -8,7 -37; 13
Woche 16	311	10,6 (7,4) 9,4 0; 34	-11,1 (7,8) -11,0 -35; 7	152	10,3 (6,8) 10,3 0; 29	-11,4 (7,8) -9,9 -37; 9
Woche 20	307	9,5 (7,3) 8,3 0; 35	-12,2 (8,0) -12,6 -43; 7	156	9,7 (6,7) 9,0 0; 27	-12,0 (7,8) -11,1 -37; 2
Woche 24	304	8,8 (7,0) 7,3 0; 33	-12,8 (8,0) -13,1 -49; 7	151	9,6 (6,9) 9,1 0; 31	-12,1 (7,9) -10,7 -37; 8
Woche 28	302	8,8 (7,0) 7,6 0; 37	-12,9 (8,0) -13,4 -45; 9	147	8,9 (6,5) 8,1 0; 28	-12,7 (7,7) -11,6 -37; 6

Endpunkt Zeitpunkt	Mirikizumab (N=331)			Ustekinumab (N=164)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
Woche 32	298	8,1 (6,7) 6,4 0; 32	-13,7 (8,0) -13,7 -51; 6	149	9,2 (6,9) 8,6 0; 27	-12,4 (7,9) -11,4 -37; 7
Woche 36	295	7,8 (6,6) 6,6 0; 32	-13,9 (8,0) -14,4 -48; 7	146	9,0 (6,8) 7,4 0; 28	-12,7 (8,0) -12,0 -37; 8
Woche 40	290	7,5 (6,4) 6,3 0; 31	-14,1 (7,8) -14,6 -50; 6	145	9,0 (6,8) 8,0 0; 33	-12,7 (7,7) -11,7 -36; 7
Woche 44	291	7,4 (6,5) 5,7 0; 31	-14,2 (7,7) -14,9 -56; 4	142	8,4 (6,5) 7,4 0; 26	-13,4 (8,1) -12,3 -37; 6
Woche 48	283	7,2 (6,4) 6,0 0; 32	-14,4 (7,9) -14,6 -51; 5	140	7,9 (6,7) 7,0 0; 28	-13,9 (7,9) -13,5 -37; 3
Woche 52	282	7,2 (6,4) 5,7 0; 31	-14,4 (8,0) -14,7 -52; 8	138	7,9 (6,6) 7,1 0; 28	-14,0 (7,6) -13,1 -37; 3
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; PRO: Patient Reported Outcome, defined as 2 of the patient-reported items of the CDAI (SF and AP); RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_pro2sm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba
19DEC2024 / 12:36

Anhang 4-G.3.4.4.2 Symptomatik**Darm- und systemische Symptome IBDQ**

Die Ergebnisse sind Anhang 4-G.3.4.4.4 zu entnehmen.

Stuhlfrequenz – CDAI-SF

Zusammenfassende Statistik für Stool frequency in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)			Ustekinumab (N=164)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
Stool frequency						
Baseline	330	5,4 (2,5) 5,3 0; 22	NB	164	5,5 (2,5) 5,3 0; 13	NB
Woche 2	328	4,3 (2,7) 4,1 0; 16	-1,2 (1,8) -0,7 -8; 5	161	4,3 (2,7) 4,1 0; 14	-1,2 (2,1) -0,9 -11; 4
Woche 4	325	3,7 (2,7) 3,4 0; 15	-1,7 (2,1) -1,3 -7; 5	159	3,6 (2,8) 3,3 0; 17	-1,9 (2,4) -1,4 -11; 4
Woche 6	320	3,3 (2,6) 3,0 0; 13	-2,1 (2,2) -1,9 -11; 6	157	3,1 (2,6) 2,9 0; 16	-2,4 (2,5) -2,1 -12; 3
Woche 8	317	3,1 (2,6) 2,6 0; 12	-2,4 (2,3) -2,1 -11; 3	156	3,0 (2,6) 2,2 0; 17	-2,6 (2,6) -2,2 -11; 4
Woche 12	316	2,9 (2,5) 2,3 0; 12	-2,6 (2,5) -2,3 -11; 3	157	2,6 (2,5) 2,0 0; 18	-2,9 (2,7) -2,6 -12; 5
Woche 16	311	2,5 (2,4) 1,9 0; 12	-3,0 (2,7) -2,8 -15; 4	152	2,4 (2,1) 2,1 0; 9	-3,2 (2,6) -3,0 -11; 1
Woche 20	307	2,3 (2,3) 1,6 0; 12	-3,3 (2,8) -3,1 -18; 3	156	2,2 (2,0) 1,6 0; 10	-3,4 (2,6) -3,1 -12; 1
Woche 24	304	2,0 (2,2) 1,1 0; 12	-3,5 (2,8) -3,3 -21; 2	151	2,2 (2,2) 1,7 0; 10	-3,4 (2,7) -3,3 -11; 4

Endpunkt Zeitpunkt	Mirikizumab (N=331)			Ustekinumab (N=164)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
Woche 28	302	2,1 (2,2) 1,3 0; 12	-3,4 (2,8) -3,3 -19; 4	147	2,1 (2,0) 1,4 0; 9	-3,4 (2,6) -3,3 -11; 2
Woche 32	298	1,8 (2,1) 1,0 0; 11	-3,7 (2,8) -3,7 -20; 3	149	2,2 (2,1) 1,7 0; 9	-3,4 (2,7) -3,1 -11; 4
Woche 36	295	1,8 (2,0) 1,0 0; 11	-3,7 (2,8) -3,6 -19; 3	146	2,2 (2,1) 1,6 0; 10	-3,4 (2,8) -3,1 -11; 5
Woche 40	290	1,7 (1,9) 1,0 0; 11	-3,8 (2,8) -3,9 -20; 3	145	2,2 (2,2) 1,7 0; 10	-3,4 (2,7) -2,9 -12; 4
Woche 44	291	1,7 (1,9) 1,0 0; 11	-3,8 (2,7) -3,9 -21; 2	142	1,9 (2,0) 1,3 0; 9	-3,6 (2,8) -3,4 -11; 4
Woche 48	283	1,6 (1,9) 1,0 0; 11	-3,9 (2,8) -3,9 -20; 2	140	1,9 (2,0) 1,1 0; 9	-3,7 (2,7) -3,6 -12; 1
Woche 52	282	1,6 (1,9) 1,0 0; 10	-3,9 (2,8) -3,9 -21; 4	138	1,9 (2,0) 1,2 0; 9	-3,8 (2,7) -3,5 -12; 1
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_sfs_m_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba
19DEC2024 / 12:36

Imperativer Stuhldrang - Urgency NRS

Zusammenfassende Statistik für Urgency NRS in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)			Ustekinumab (N=164)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
Urgency NRS						
Baseline	330	6,5 (2,1) 6,7 0; 10	NB	164	6,6 (2,0) 6,7 1; 10	NB
Woche 2	328	5,5 (2,4) 5,5 0; 10	-1,0 (1,7) -0,6 -7; 4	161	5,4 (2,4) 5,3 0; 10	-1,1 (1,8) -0,7 -8; 3
Woche 4	325	5,1 (2,5) 5,3 0; 10	-1,4 (1,9) -1,0 -7; 4	159	4,9 (2,6) 5,1 0; 10	-1,6 (2,2) -0,9 -10; 3
Woche 6	320	4,6 (2,6) 4,6 0; 10	-1,9 (2,2) -1,6 -10; 7	157	4,4 (2,7) 4,1 0; 10	-2,1 (2,5) -1,6 -10; 3
Woche 8	317	4,4 (2,6) 4,3 0; 10	-2,1 (2,3) -1,9 -9; 6	156	4,3 (2,8) 3,9 0; 10	-2,3 (2,6) -1,6 -10; 4
Woche 12	316	4,1 (2,6) 4,0 0; 10	-2,4 (2,5) -2,1 -10; 6	157	3,9 (2,7) 3,3 0; 10	-2,6 (2,7) -2,1 -10; 4
Woche 16	311	3,7 (2,6) 3,3 0; 10	-2,9 (2,5) -2,7 -10; 5	152	3,8 (2,8) 3,1 0; 10	-2,8 (2,7) -2,2 -10; 3
Woche 20	307	3,4 (2,5) 3,0 0; 10	-3,2 (2,6) -3,1 -9; 5	156	3,7 (2,8) 2,9 0; 10	-2,9 (2,7) -2,4 -10; 3
Woche 24	304	3,2 (2,5) 3,0 0; 10	-3,3 (2,6) -3,1 -10; 5	151	3,7 (2,7) 3,0 0; 10	-2,9 (2,7) -2,4 -10; 3
Woche 28	302	3,1 (2,4) 2,7 0; 10	-3,4 (2,5) -3,4 -10; 5	147	3,5 (2,7) 2,9 0; 10	-3,1 (2,7) -2,6 -10; 3
Woche 32	298	3,0 (2,4) 2,4 0; 10	-3,5 (2,6) -3,4 -10; 4	149	3,5 (2,7) 3,0 0; 10	-3,1 (2,8) -2,7 -10; 3

Endpunkt Zeitpunkt	Mirikizumab (N=331)			Ustekinumab (N=164)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
Woche 36	295	3,0 (2,5) 2,4 0; 10	-3,6 (2,6) -3,4 -10; 3	146	3,5 (2,7) 2,9 0; 10	-3,0 (2,8) -2,8 -10; 4
Woche 40	290	2,8 (2,3) 2,3 0; 10	-3,7 (2,5) -3,7 -10; 4	145	3,4 (2,6) 2,9 0; 10	-3,1 (2,8) -3,3 -10; 4
Woche 44	291	2,8 (2,4) 2,3 0; 10	-3,7 (2,5) -3,6 -9; 3	142	3,3 (2,5) 2,7 0; 10	-3,2 (2,7) -3,1 -10; 3
Woche 48	283	2,8 (2,4) 2,4 0; 10	-3,6 (2,6) -3,9 -10; 4	140	3,1 (2,4) 2,3 0; 10	-3,5 (2,8) -3,7 -10; 3
Woche 52	282	2,8 (2,4) 2,4 0; 10	-3,7 (2,6) -3,7 -10; 5	138	3,0 (2,5) 2,4 0; 10	-3,5 (2,7) -3,6 -10; 3
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; NRS: Numeric Rating Scale; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_urghsm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 12:36

Abdominelle Schmerzen – CDAI-AP

Zusammenfassende Statistik für Abdominal pain in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)			Ustekinumab (N=164)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
Abdominal pain						
Baseline	330	2,1 (0,6) 2,1 0; 3	NB	164	2,1 (0,6) 2,0 0; 3	NB
Woche 2	328	1,8 (0,7) 2,0 0; 3	-0,4 (0,5) -0,3 -3; 1	161	1,7 (0,7) 1,9 0; 3	-0,4 (0,6) -0,3 -3; 1
Woche 4	325	1,6 (0,7) 1,7 0; 3	-0,5 (0,7) -0,4 -3; 1	159	1,5 (0,8) 1,6 0; 3	-0,6 (0,7) -0,4 -3; 1
Woche 6	320	1,4 (0,8) 1,4 0; 3	-0,7 (0,7) -0,6 -3; 1	157	1,4 (0,8) 1,3 0; 3	-0,8 (0,7) -0,7 -3; 1
Woche 8	317	1,4 (0,7) 1,3 0; 3	-0,8 (0,7) -0,8 -3; 1	156	1,3 (0,8) 1,3 0; 3	-0,8 (0,8) -0,7 -3; 0
Woche 12	316	1,2 (0,8) 1,1 0; 3	-0,9 (0,8) -0,9 -3; 1	157	1,2 (0,8) 1,1 0; 3	-0,9 (0,8) -0,9 -3; 1
Woche 16	311	1,1 (0,8) 1,1 0; 3	-1,0 (0,8) -1,0 -3; 1	152	1,1 (0,8) 1,0 0; 3	-1,0 (0,8) -1,0 -3; 1
Woche 20	307	1,0 (0,7) 1,0 0; 3	-1,1 (0,8) -1,1 -3; 1	156	1,1 (0,8) 1,0 0; 3	-1,1 (0,8) -1,0 -3; 0
Woche 24	304	1,0 (0,7) 1,0 0; 3	-1,2 (0,8) -1,1 -3; 1	151	1,0 (0,8) 1,0 0; 3	-1,1 (0,8) -1,0 -3; 0
Woche 28	302	0,9 (0,7) 1,0 0; 3	-1,2 (0,8) -1,1 -3; 1	147	0,9 (0,7) 1,0 0; 3	-1,2 (0,8) -1,0 -3; 0
Woche 32	298	0,9 (0,7) 1,0 0; 3	-1,2 (0,8) -1,1 -3; 1	149	1,0 (0,7) 1,0 0; 2	-1,1 (0,8) -1,0 -3; 1

Endpunkt Zeitpunkt	Mirikizumab (N=331)			Ustekinumab (N=164)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
Woche 36	295	0,9 (0,7) 1,0 0; 3	-1,3 (0,8) -1,3 -3; 1	146	0,9 (0,7) 1,0 0; 2	-1,2 (0,8) -1,0 -3; 1
Woche 40	290	0,8 (0,7) 1,0 0; 3	-1,3 (0,8) -1,3 -3; 1	145	0,9 (0,7) 1,0 0; 2	-1,2 (0,8) -1,0 -3; 0
Woche 44	291	0,8 (0,7) 1,0 0; 3	-1,3 (0,8) -1,3 -3; 1	142	0,9 (0,7) 1,0 0; 2	-1,2 (0,8) -1,1 -3; 0
Woche 48	283	0,8 (0,7) 1,0 0; 3	-1,3 (0,8) -1,3 -3; 1	140	0,8 (0,7) 1,0 0; 3	-1,3 (0,8) -1,1 -3; 1
Woche 52	282	0,8 (0,7) 1,0 0; 3	-1,3 (0,8) -1,3 -3; 1	138	0,8 (0,7) 1,0 0; 2	-1,3 (0,8) -1,3 -3; 0
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_apsm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 12:36

Fatigue – FACIT Fatigue

Zusammenfassende Statistik für FACIT-Fatigue in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)			Ustekinumab (N=164)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
FACIT-Fatigue						
Baseline	328	31,9 (11,3) 33,0 2; 52	NB	164	30,0 (12,1) 31,0 1; 52	NB
Woche 12	314	38,2 (10,0) 40,0 5; 52	6,1 (10,7) 5,0 -24; 45	156	38,0 (9,7) 40,0 12; 52	7,4 (10,0) 6,0 -14; 40
Woche 52	279	40,5 (8,7) 43,0 8; 52	8,5 (11,2) 7,5 -26; 44	142	40,1 (9,0) 42,0 16; 52	9,3 (11,6) 8,0 -23; 40
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: FACIT: Functional Assessment of Chronic Illness Therapy -Fatigue; ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_facism_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 12:36

Depressionen – QIDS-SR16

Zusammenfassende Statistik für QIDS-SR16 Total Score in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)			Ustekinumab (N=164)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
QIDS-SR16 Total Score						
Baseline	331	6,4 (4,5) 5,0 0; 25	NB	164	7,2 (4,8) 6,0 0; 24	NB
Woche 12	315	4,7 (3,7) 4,0 0; 21	-1,6 (4,0) -1,0 -21; 17	156	4,7 (3,2) 4,0 0; 17	-2,2 (4,2) -1,0 -17; 9
Woche 24	304	4,2 (3,6) 3,0 0; 17	-2,1 (4,2) -1,0 -25; 10	151	4,4 (3,2) 4,0 0; 15	-2,5 (4,5) -2,0 -18; 7
Woche 36	292	4,1 (3,5) 3,0 0; 23	-2,3 (4,2) -2,0 -25; 11	149	4,2 (3,5) 4,0 0; 20	-2,7 (4,5) -2,0 -19; 7
Woche 52	280	3,9 (3,4) 3,0 0; 19	-2,5 (4,3) -2,0 -17; 9	143	3,9 (2,8) 4,0 0; 16	-2,9 (4,6) -2,0 -19; 7
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; QIDS-SR16: Quick Inventory of Depressive Symptomatology - Self Report (16 items); RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_qidssm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adef_gba

19DEC2024 / 12:36

Anhang 4-G.3.4.4.3 Gesundheitszustand**Gesundheitszustand – EQ-5D VAS**

Zusammenfassende Statistik für EQ-5D VAS in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)			Ustekinumab (N=164)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
EQ-5D VAS						
Baseline	328	54,3 (19,3) 54,0 0; 99	NB	164	53,5 (18,5) 52,0 5; 91	NB
Woche 12	315	68,7 (18,9) 70,0 8; 100	14,3 (22,2) 12,0 -62; 83	156	69,6 (18,4) 70,0 0; 100	15,2 (22,3) 13,0 -79; 72
Woche 52	279	76,1 (16,6) 80,0 19; 100	21,4 (23,2) 20,0 -41; 90	142	74,7 (17,5) 79,0 7; 100	20,2 (22,8) 20,0 -62; 72
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: EQ-5D: Fragebogen der EuroQol-Gruppe zur Lebensqualität auf 5 Dimensionen; ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; VAS: Visuelle Analogskala.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_vassm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adef_gba
19DEC2024 / 12:36

Gesundheitszustand – PGRS

Zusammenfassende Statistik für Patient Global Rating of severity (PGRS) in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)			Ustekinumab (N=164)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
PGRS						
Baseline	330	4,5 (0,8) 4,4 1; 6	NB	164	4,5 (0,8) 4,4 2; 6	NB
Woche 2	328	3,9 (1,0) 4,0 1; 6	-0,5 (0,7) -0,4 -4; 1	161	3,8 (1,0) 4,0 1; 6	-0,6 (0,8) -0,4 -5; 1
Woche 4	325	3,6 (1,0) 3,9 1; 6	-0,8 (0,9) -0,7 -4; 1	159	3,6 (1,1) 3,9 1; 6	-0,8 (1,0) -0,6 -5; 1
Woche 6	320	3,4 (1,1) 3,4 1; 6	-1,0 (1,0) -0,9 -4; 1	157	3,3 (1,2) 3,4 1; 6	-1,1 (1,1) -0,9 -5; 2
Woche 8	317	3,3 (1,1) 3,3 1; 6	-1,2 (1,0) -1,0 -4; 1	156	3,3 (1,1) 3,3 1; 6	-1,2 (1,2) -0,9 -5; 1
Woche 12	316	3,1 (1,2) 3,0 1; 6	-1,3 (1,2) -1,1 -4; 1	156	3,1 (1,2) 3,1 1; 6	-1,4 (1,2) -1,0 -5; 1
Woche 16	311	2,9 (1,2) 3,0 1; 6	-1,5 (1,2) -1,4 -5; 1	152	3,0 (1,2) 3,0 1; 6	-1,5 (1,2) -1,1 -5; 1
Woche 20	307	2,8 (1,1) 2,9 1; 6	-1,7 (1,2) -1,7 -5; 1	156	2,9 (1,2) 3,0 1; 6	-1,6 (1,3) -1,3 -5; 1
Woche 24	304	2,7 (1,1) 2,6 1; 6	-1,7 (1,2) -1,7 -5; 1	151	2,9 (1,2) 3,0 1; 5	-1,6 (1,3) -1,3 -5; 1
Woche 28	302	2,7 (1,1) 2,6 1; 6	-1,8 (1,2) -1,7 -5; 1	147	2,7 (1,2) 2,9 1; 6	-1,7 (1,3) -1,4 -5; 1
Woche 32	298	2,6 (1,1) 2,4 1; 6	-1,9 (1,2) -1,9 -5; 2	149	2,7 (1,2) 2,7 1; 6	-1,7 (1,3) -1,6 -5; 1

Endpunkt Zeitpunkt	Mirikizumab (N=331)			Ustekinumab (N=164)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
Woche 36	295	2,5 (1,1) 2,4 1; 6	-1,9 (1,2) -2,0 -5; 1	146	2,7 (1,2) 2,8 1; 5	-1,7 (1,4) -1,6 -5; 1
Woche 40	290	2,5 (1,1) 2,3 1; 6	-2,0 (1,2) -2,0 -5; 1	145	2,7 (1,2) 2,7 1; 6	-1,7 (1,3) -1,7 -5; 2
Woche 44	291	2,4 (1,1) 2,3 1; 6	-2,0 (1,2) -2,0 -5; 1	142	2,6 (1,1) 2,7 1; 5	-1,8 (1,3) -1,8 -5; 1
Woche 48	283	2,4 (1,1) 2,3 1; 6	-2,0 (1,2) -2,0 -5; 1	140	2,6 (1,2) 2,6 1; 5	-1,9 (1,4) -1,9 -5; 2
Woche 52	282	2,4 (1,1) 2,2 1; 6	-2,1 (1,2) -2,0 -5; 1	138	2,6 (1,2) 2,6 1; 5	-1,9 (1,3) -1,9 -5; 1
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; PGRS: Patient Global Rating of Severity; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_pgrssm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 12:36

Gesundheitszustand – PGIC

Zusammenfassende Statistik für Patient Reported Impression of Change (PGIC) in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)		Ustekinumab (N=164)	
	n	MW (SD) Median Min; Max	n	MW (SD) Median Min; Max
PGIC				
Woche 4	324	3,1 (0,9) 3,0 1; 7	161	3,0 (1,0) 3,0 1; 6
Woche 8	319	2,7 (1,0) 3,0 1; 7	156	2,7 (1,0) 3,0 1; 6
Woche 12	315	2,6 (1,1) 2,0 1; 7	156	2,4 (1,0) 2,0 1; 6
Woche 52	279	1,9 (1,0) 2,0 1; 6	141	1,9 (0,8) 2,0 1; 5
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; PGIC: Patient Global Impression of Change; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.				

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_pgicsm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 12:36

Gesundheitszustand – WPAI-CD (Aktivitätsbeeinträchtigung)

Zusammenfassende Statistik für WPAI (Activity impairment) in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population, Participants with baseline employment status of Yes)

Endpunkt Zeitpunkt	Mirikizumab (N=202)			Ustekinumab (N=91)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
WPAI (Activity impairment)						
Baseline	202	48,3 (23,3) 50,0 0; 100	NB	91	47,5 (24,9) 50,0 0; 100	NB
Woche 12	192	28,3 (23,8) 20,0 0; 100	-20,5 (25,1) -20,0 -100; 30	87	24,1 (23,2) 20,0 0; 100	-22,0 (32,0) -20,0 -100; 80
Woche 52	174	20,6 (21,9) 20,0 0; 80	-28,7 (26,6) -30,0 -90; 50	80	19,1 (21,2) 10,0 0; 100	-28,5 (28,4) -30,0 -90; 50
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; WPAI: Work Productivity and Activity Impairment Questionnaire.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_wpaism_empl_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 12:36

Allgemeinbefinden - CDAI-GWP

Zusammenfassende Statistik für General well being in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)			Ustekinumab (N=164)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
General well being						
Baseline	330	2,2 (0,8) 2,1 0; 4	NB	164	2,2 (1,0) 2,2 0; 4	NB
Woche 2	328	1,8 (0,9) 2,0 0; 4	-0,4 (0,7) -0,3 -3; 2	161	1,7 (1,0) 1,7 0; 4	-0,5 (0,7) -0,4 -4; 2
Woche 4	325	1,6 (0,9) 1,6 0; 4	-0,6 (0,8) -0,6 -3; 2	159	1,4 (1,0) 1,3 0; 4	-0,7 (0,9) -0,6 -4; 1
Woche 6	320	1,4 (0,9) 1,1 0; 4	-0,8 (0,9) -0,7 -3; 2	157	1,3 (0,9) 1,1 0; 4	-0,9 (0,9) -0,7 -4; 1
Woche 8	317	1,3 (0,9) 1,1 0; 4	-0,9 (0,9) -0,9 -3; 2	156	1,2 (0,9) 1,0 0; 4	-1,0 (1,0) -0,9 -4; 1
Woche 12	316	1,2 (0,9) 1,0 0; 4	-1,0 (1,0) -1,0 -3; 2	157	1,1 (0,9) 1,0 0; 4	-1,1 (1,0) -1,0 -4; 1
Woche 16	311	1,1 (0,9) 1,0 0; 4	-1,2 (0,9) -1,0 -4; 1	152	1,0 (0,9) 1,0 0; 3	-1,2 (1,0) -1,0 -4; 1
Woche 20	307	0,9 (0,9) 0,9 0; 4	-1,3 (0,9) -1,3 -4; 1	156	1,0 (0,9) 1,0 0; 4	-1,2 (1,1) -1,0 -4; 2
Woche 24	304	0,9 (0,9) 0,9 0; 4	-1,3 (1,0) -1,3 -4; 1	151	1,0 (0,8) 1,0 0; 3	-1,2 (1,0) -1,0 -4; 1
Woche 28	302	0,9 (0,8) 0,9 0; 4	-1,3 (1,0) -1,4 -4; 1	147	0,9 (0,8) 1,0 0; 4	-1,3 (1,0) -1,0 -4; 1
Woche 32	298	0,8 (0,8) 0,7 0; 4	-1,4 (1,0) -1,4 -4; 1	149	0,9 (0,8) 1,0 0; 3	-1,3 (1,1) -1,1 -4; 1

Endpunkt Zeitpunkt	Mirikizumab (N=331)			Ustekinumab (N=164)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
Woche 36	295	0,8 (0,9) 0,7 0; 4	-1,4 (1,0) -1,4 -4; 1	146	0,9 (0,9) 0,9 0; 3	-1,3 (1,1) -1,1 -4; 2
Woche 40	290	0,8 (0,9) 0,6 0; 4	-1,4 (1,0) -1,4 -4; 1	145	0,9 (0,8) 1,0 0; 3	-1,3 (1,0) -1,1 -4; 1
Woche 44	291	0,8 (0,9) 0,4 0; 4	-1,5 (1,0) -1,4 -4; 1	142	0,8 (0,8) 0,9 0; 3	-1,4 (1,0) -1,3 -4; 1
Woche 48	283	0,8 (0,8) 0,6 0; 4	-1,5 (1,0) -1,6 -4; 1	140	0,8 (0,8) 0,9 0; 3	-1,4 (1,1) -1,3 -4; 2
Woche 52	282	0,8 (0,8) 0,6 0; 4	-1,5 (1,0) -1,6 -4; 1	138	0,7 (0,8) 0,6 0; 3	-1,4 (1,0) -1,4 -4; 1
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_gwbsm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 12:36

Anhang 4-G.3.4.4.4 Gesundheitsbezogene Lebensqualität**Krankheitsspezifische Lebensqualität**

Zusammenfassende Statistik für IBDQ in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)			Ustekinumab (N=164)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
IBDQ Total Score						
Baseline	328	128,0 (33,2) 129,0 39; 209	NB	164	123,7 (35,2) 126,0 42; 204	NB
Woche 12	315	167,9 (32,5) 174,0 66; 223	39,9 (34,2) 39,0 -41; 164	156	168,4 (34,0) 174,0 79; 222	42,9 (34,4) 35,0 -23; 139
Woche 52	279	181,1 (29,1) 187,0 53; 221	52,9 (35,6) 52,5 -34; 151	142	177,7 (30,4) 182,0 61; 224	52,2 (36,9) 50,5 -33; 147
IBDQ Bowel Symptoms						
Baseline	328	38,2 (9,7) 39,0 12; 66	NB	164	37,3 (10,4) 38,0 14; 69	NB
Woche 12	315	52,5 (10,6) 55,0 19; 70	14,4 (11,5) 15,0 -22; 52	156	53,1 (10,5) 54,5 25; 70	15,3 (11,4) 13,5 -12; 45
Woche 52	279	57,1 (9,2) 59,0 18; 70	18,8 (11,4) 19,0 -9; 49	142	55,4 (9,8) 57,0 25; 70	17,7 (12,2) 17,5 -12; 47
IBDQ Emotional Function						
Baseline	328	50,9 (14,1) 52,0 13; 82	NB	164	49,3 (14,9) 51,0 12; 80	NB
Woche 12	315	63,6 (12,9) 67,0 23; 84	12,7 (13,0) 11,0 -15; 61	156	63,5 (13,6) 65,0 28; 84	13,5 (13,6) 10,0 -11; 54
Woche 52	279	67,8 (11,6) 69,0 18; 84	16,9 (14,3) 16,0 -26; 56	142	66,8 (12,1) 69,0 25; 84	16,7 (14,6) 15,0 -16; 55

Endpunkt Zeitpunkt	Mirikizumab (N=331)			Ustekinumab (N=164)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
IBDQ Social Function						
Baseline	328	20,9 (7,0) 21,0 5; 35	NB	164	19,7 (7,7) 19,0 6; 34	NB
Woche 12	315	27,7 (6,5) 29,0 6; 35	6,6 (6,9) 6,0 -12; 29	156	27,6 (6,8) 29,0 9; 35	7,5 (6,8) 7,0 -9; 24
Woche 52	279	30,0 (5,8) 32,0 6; 35	9,0 (7,3) 8,0 -9; 29	142	29,6 (5,6) 31,5 5; 35	9,6 (7,0) 9,0 -6; 28
IBDQ Systemic Symptoms						
Baseline	328	18,0 (5,8) 18,0 5; 33	NB	164	17,4 (5,9) 17,5 6; 30	NB
Woche 12	315	24,1 (5,8) 25,0 7; 35	6,1 (6,1) 6,0 -11; 22	156	24,4 (5,9) 25,0 9; 35	6,6 (6,0) 6,0 -8; 24
Woche 52	279	26,1 (5,4) 27,0 9; 35	8,2 (6,5) 8,0 -10; 26	142	25,9 (5,7) 26,5 6; 35	8,1 (6,7) 8,0 -6; 24
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ggü: gegenüber; IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_ibdqsm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adefl_gba
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Gesundheitsbezogene Lebensqualität

Zusammenfassende Statistik für SF-36 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=331)			Ustekinumab (N=164)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
SF-36 MCS Score						
Baseline	328	43,4 (10,9) 44,5 11; 63	NB	164	42,3 (10,8) 44,1 13; 63	NB
Woche 12	315	48,9 (9,6) 51,1 16; 64	5,5 (9,4) 4,3 -20; 42	156	49,7 (9,4) 51,5 21; 64	7,0 (9,9) 5,9 -18; 35
Woche 52	279	50,5 (8,5) 52,6 6; 66	7,1 (10,6) 5,5 -20; 40	142	50,4 (9,1) 53,3 14; 63	7,6 (10,9) 6,4 -16; 39
SF-36 PCS Score						
Baseline	328	40,0 (7,3) 39,9 18; 60	NB	164	40,0 (8,0) 40,0 23; 59	NB
Woche 12	315	47,4 (7,5) 48,2 22; 61	7,3 (7,5) 7,0 -16; 35	156	47,8 (7,8) 49,1 27; 62	7,5 (7,2) 6,5 -10; 27
Woche 52	279	50,2 (7,6) 51,7 22; 70	10,2 (8,0) 10,3 -14; 32	142	49,9 (8,0) 51,8 22; 63	9,5 (7,9) 9,4 -6; 28
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; MCS: Mental Health Component Summary Score; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; PCS: Physical Health Component Summary Score; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SF-36: 36-Item Short Form Health Survey.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_sf36sm_itta.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

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Anhang 4-G.3.5 Unerwünschte Ereignisse (UE) nach SOC/PT in RCT VIVID-1 in Teilpopulation A

Anteil der Patienten mit unerwünschten Ereignissen nach SOC/PT bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (Safety-Population)

SOC Preferred term	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
TEAEs occurred in ≥10% or in ≥10 patients and 1% in any treatment arm within analysis population					
Infections and infestations	131/331 (39,6)	51/164 (31,1)	1,27 [0,98; 1,66]	1,45 [0,98; 2,16]	8,48 [-0,35; 17,31]
				0,075	
COVID-19	51/331 (15,4)	15/164 (9,1)	1,68 [0,98; 2,90]	1,81 [0,98; 3,33]	6,26 [0,38; 12,14]
				0,067	
Nasopharyngitis	18/331 (5,4)	6/164 (3,7)	1,49 [0,60; 3,67]	1,51 [0,59; 3,89]	1,78 [-1,99; 5,55]
				0,506	
Upper respiratory tract infection	16/331 (4,8)	11/164 (6,7)	0,72 [0,34; 1,52]	0,71 [0,32; 1,56]	-1,87 [-6,35; 2,60]
				0,405	
Gastrointestinal disorders	98/331 (29,6)	40/164 (24,4)	1,21 [0,88; 1,67]	1,30 [0,85; 2,00]	5,22 [-2,99; 13,43]
				0,242	
Diarrhoea	15/331 (4,5)	2/164 (1,2)	3,72 [0,86; 16,06]	3,84 [0,87; 17,02]	3,31 [0,51; 6,11]
				0,067	
Crohn's disease	14/331 (4,2)	9/164 (5,5)	0,77 [0,34; 1,74]	0,76 [0,32; 1,80]	-1,26 [-5,36; 2,85]
				0,507	
Abdominal pain	13/331 (3,9)	4/164 (2,4)	1,61 [0,53; 4,86]	1,64 [0,52; 5,10]	1,49 [-1,67; 4,64]
				0,447	

SOC Preferred term	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Vomiting	10/331 (3,0)	0/164 (0,0)	10,44 [0,62; >100]	10,74 [0,63; >100]	3,02 [1,18; 4,87]
			0,035		
General disorders and administration site conditions	49/331 (14,8)	21/164 (12,8)	1,16 [0,72; 1,86]	1,18 [0,68; 2,05]	2,00 [-4,39; 8,39]
			0,586		
Fatigue	11/331 (3,3)	3/164 (1,8)	1,82 [0,51; 6,42]	1,84 [0,51; 6,71]	1,49 [-1,32; 4,31]
			0,405		
Injection site pain	10/331 (3,0)	3/164 (1,8)	1,65 [0,46; 5,92]	1,67 [0,45; 6,16]	1,19 [-1,57; 3,95]
			0,559		
Investigations	45/331 (13,6)	21/164 (12,8)	1,06 [0,66; 1,72]	1,07 [0,61; 1,87]	0,79 [-5,52; 7,10]
			0,889		
Alanine aminotransferase increased	11/331 (3,3)	1/164 (0,6)	5,45 [0,71; 41,85]	5,60 [0,72; 43,78]	2,71 [0,44; 4,98]
			0,116		
Weight increased	10/331 (3,0)	3/164 (1,8)	1,65 [0,46; 5,92]	1,67 [0,45; 6,16]	1,19 [-1,57; 3,95]
			0,559		
Skin and subcutaneous tissue disorders	44/331 (13,3)	15/164 (9,1)	1,45 [0,83; 2,53]	1,52 [0,82; 2,83]	4,15 [-1,58; 9,88]
			0,238		
Musculoskeletal and connective tissue disorders	40/331 (12,1)	11/164 (6,7)	1,80 [0,95; 3,42]	1,91 [0,95; 3,83]	5,38 [0,18; 10,57]
			0,083		
Arthralgia	18/331 (5,4)	1/164 (0,6)	8,92 [1,20; 66,23]	9,37 [1,24; 70,84]	4,83 [2,11; 7,55]
			0,006		

SOC Preferred term	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Nervous system disorders	37/331 (11,2)	14/164 (8,5)	1,31 [0,73; 2,35]	1,35 [0,71; 2,57]	2,64 [-2,82; 8,10]
			0,433		
Headache	22/331 (6,6)	9/164 (5,5)	1,21 [0,57; 2,57]	1,23 [0,55; 2,73]	1,16 [-3,24; 5,56]
			0,697		
Blood and lymphatic system disorders	36/331 (10,9)	15/164 (9,1)	1,19 [0,67; 2,11]	1,21 [0,64; 2,28]	1,73 [-3,81; 7,27]
			0,639		
Anaemia	21/331 (6,3)	7/164 (4,3)	1,49 [0,65; 3,42]	1,52 [0,63; 3,65]	2,08 [-1,98; 6,13]
			0,413		
Vascular disorders	20/331 (6,0)	4/164 (2,4)	2,48 [0,86; 7,13]	2,57 [0,86; 7,65]	3,60 [0,12; 7,09]
			0,117		
Hypertension	14/331 (4,2)	1/164 (0,6)	6,94 [0,92; 52,30]	7,20 [0,94; 55,23]	3,62 [1,15; 6,09]
			0,026		
Injury, poisoning and procedural complications	17/331 (5,1)	7/164 (4,3)	1,20 [0,51; 2,84]	1,21 [0,49; 2,99]	0,87 [-3,03; 4,77]
			0,825		
Metabolism and nutrition disorders	16/331 (4,8)	10/164 (6,1)	0,79 [0,37; 1,71]	0,78 [0,35; 1,76]	-1,26 [-5,59; 3,07]
			0,530		
Respiratory, thoracic and mediastinal disorders	15/331 (4,5)	8/164 (4,9)	0,93 [0,40; 2,15]	0,93 [0,38; 2,23]	-0,35 [-4,33; 3,64]
			0,825		
Surgical and medical procedures	14/331 (4,2)	2/164 (1,2)	3,47 [0,80; 15,08]	3,58 [0,80; 15,93]	3,01 [0,27; 5,75]
			0,104		

SOC Preferred term	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Hepatobiliary disorders	11/331 (3,3)	5/164 (3,0)	1,09 [0,39; 3,09]	1,09 [0,37; 3,20]	0,27 [-2,99; 3,54]
			1,000		
Immune system disorders	10/331 (3,0)	4/164 (2,4)	1,24 [0,39; 3,89]	1,25 [0,38; 4,03]	0,58 [-2,41; 3,58]
			1,000		
Renal and urinary disorders	7/331 (2,1)	10/164 (6,1)	0,35 [0,13; 0,89]	0,33 [0,12; 0,89]	-3,98 [-7,96; -0,01]
			0,033		
Severe TEAEs occurred in ≥5% or in ≥10 patients and 1% in any treatment arm within analysis population					
Gastrointestinal disorders	10/331 (3,0)	4/164 (2,4)	1,24 [0,39; 3,89]	1,25 [0,38; 4,03]	0,58 [-2,41; 3,58]
			1,000		
Serious TEAEs occurred in ≥5% or in ≥10 patients and 1% in any treatment arm within analysis population					
Gastrointestinal disorders	13/331 (3,9)	6/164 (3,7)	1,07 [0,42; 2,77]	1,08 [0,40; 2,89]	0,27 [-3,29; 3,82]
			1,000		
Datenschnitt: 23. August 2023; Conventional-failed Safety Population. Abkürzungen: KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit mindestens einem Ereignis; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; SOC: System Organ Class. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_aespt.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_aespt_safa.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
23SEP2024 / 05:00

Ergebnisse für den Anteil der Patienten mit Behandlungsabbruch aufgrund unerwünschter Ereignisse nach SOC/PT bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (Safety-Population)

SOC Preferred term	Mirikizumab Pat. mit Ereignis n/N (%)	Ustekinumab Pat. mit Ereignis n/N (%)
Gastrointestinal disorders	6/331 (1,8)	2/164 (1,2)
Crohn's disease	3/331 (0,9)	2/164 (1,2)
Small intestinal obstruction	2/331 (0,6)	0/164 (0,0)
Large intestine polyp	1/331 (0,3)	0/164 (0,0)
Immune system disorders	4/331 (1,2)	0/164 (0,0)
Infusion related hypersensitivity reaction	3/331 (0,9)	0/164 (0,0)
Hypersensitivity	1/331 (0,3)	0/164 (0,0)
Infections and infestations	2/331 (0,6)	1/164 (0,6)
Abdominal abscess	1/331 (0,3)	0/164 (0,0)
Urosepsis	1/331 (0,3)	0/164 (0,0)
Sepsis	0/331 (0,0)	1/164 (0,6)
Surgical and medical procedures	2/331 (0,6)	0/164 (0,0)
Colectomy	1/331 (0,3)	0/164 (0,0)
Ileectomy	1/331 (0,3)	0/164 (0,0)
General disorders and administration site conditions	1/331 (0,3)	0/164 (0,0)
Injection site pain	1/331 (0,3)	0/164 (0,0)
Hepatobiliary disorders	1/331 (0,3)	0/164 (0,0)
Non-alcoholic fatty liver	1/331 (0,3)	0/164 (0,0)
Nervous system disorders	1/331 (0,3)	0/164 (0,0)
Headache	1/331 (0,3)	0/164 (0,0)
Psychiatric disorders	1/331 (0,3)	0/164 (0,0)
Depression	1/331 (0,3)	0/164 (0,0)
Renal and urinary disorders	1/331 (0,3)	0/164 (0,0)
Haematuria	1/331 (0,3)	0/164 (0,0)
Skin and subcutaneous tissue disorders	1/331 (0,3)	0/164 (0,0)
Urticaria	1/331 (0,3)	0/164 (0,0)
Cardiac disorders	0/331 (0,0)	1/164 (0,6)
Angina pectoris	0/331 (0,0)	1/164 (0,6)

SOC Preferred term	Mirikizumab	Ustekinumab
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)
Datenschnitt: 23. August 2023; Conventional-failed Safety Population. Abkürzungen: n: Anzahl der Patienten; N: Anzahl der Patienten in der Analyse; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; SOC: System Organ Class.		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_aeldstspt.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_aeldstspt_safa.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba

/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/adae

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Anhang 4-G.3.6 Ergebnisse der Subgruppenanalysen mit nicht statistisch signifikantem Interaktionsterm in der Gesamtpopulation in RCT VIVID-1 in Teilpopulation A

Anhang 4-G.3.6.1 Morbidität

Anhang 4-G.3.6.1.1 Klinische Remission

Subgruppen für Clinical remission by PRO, defined as SF $\leq$ 3 and AP $\leq$ 1 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Subgruppe			p-Wert ^a		
Age 1 (p-value of the interaction test: 0,884)					
<65 years	178/322 (55,3)	81/160 (50,6)	1,09 [0,91; 1,31]	1,21 [0,82; 1,76]	4,65 [-4,81; 14,12]
			0,383		
≥65 years	4/9 (44,4)	2/4 (50,0)	0,89 [0,26; 3,02]	0,80 [0,08; 8,47]	-5,56 [-64,33; 53,22]
			1,000		
Age 2 (p-value of the interaction test: 0,955)					
<40 years	120/210 (57,1)	53/101 (52,5)	1,09 [0,87; 1,36]	1,21 [0,75; 1,94]	4,67 [-7,15; 16,49]
			0,466		
≥40 years	62/121 (51,2)	30/63 (47,6)	1,08 [0,79; 1,47]	1,16 [0,63; 2,13]	3,62 [-11,59; 18,83]
			0,756		
Sex (p-value of the interaction test: 0,464)					
Male	111/178 (62,4)	46/83 (55,4)	1,13 [0,90; 1,41]	1,33 [0,79; 2,26]	6,94 [-5,91; 19,78]
			0,342		
Female	71/153 (46,4)	37/81 (45,7)	1,02 [0,76; 1,36]	1,03 [0,60; 1,77]	0,73 [-12,69; 14,15]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Race (p-value of the interaction test: 0,097)					
White	139/268 (51,9)	71/137 (51,8)	1,00 [0,82; 1,22]	1,00 [0,66; 1,51]	0,04 [-10,24; 10,33]
				1,000	
Other	42/62 (67,7)	12/26 (46,2)	1,47 [0,94; 2,30]	2,45 [0,96; 6,25]	21,59 [-0,83; 44,01]
				0,092	
Geographic region 1 (p-value of the interaction test: 0,124)					
Europe	122/224 (54,5)	64/121 (52,9)	1,03 [0,84; 1,27]	1,07 [0,68; 1,66]	1,57 [-9,46; 12,60]
				0,821	
North America	10/31 (32,3)	6/13 (46,2)	0,70 [0,32; 1,52]	0,56 [0,15; 2,09]	-13,90 [-45,60; 17,81]
				0,496	
Other	50/76 (65,8)	13/30 (43,3)	1,52 [0,98; 2,36]	2,51 [1,06; 5,97]	22,46 [1,76; 43,15]
				0,048	
Geographic region 2 (p-value of the interaction test: 0,203)					
Asia	37/58 (63,8)	9/23 (39,1)	1,63 [0,94; 2,81]	2,74 [1,01; 7,41]	24,66 [1,19; 48,13]
				0,051	
Central America/South America	9/11 (81,8)	4/7 (57,1)	1,43 [0,71; 2,88]	3,38 [0,40; 28,74]	24,68 [-18,49; 67,84]
				0,326	
Europe and ROW	126/231 (54,5)	64/121 (52,9)	1,03 [0,84; 1,27]	1,07 [0,69; 1,66]	1,65 [-9,32; 12,62]
				0,822	
North America	10/31 (32,3)	6/13 (46,2)	0,70 [0,32; 1,52]	0,56 [0,15; 2,09]	-13,90 [-45,60; 17,81]
				0,496	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
BMI (p-value of the interaction test: 0,417)					
Underweight (<18.5 kg/m ²)	33/59 (55,9)	12/23 (52,2)	1,07 [0,68; 1,68]	1,16 [0,44; 3,06]	3,76 [-20,27; 27,78]
				0,808	
Normal (≥18.5 and <25 kg/m ²)	87/157 (55,4)	41/92 (44,6)	1,24 [0,95; 1,63]	1,55 [0,92; 2,59]	10,85 [-1,94; 23,64]
				0,115	
Overweight (≥25 and <30 kg/m ²)	40/68 (58,8)	19/28 (67,9)	0,87 [0,63; 1,20]	0,68 [0,27; 1,71]	-9,03 [-29,92; 11,85]
				0,492	
Obese and Extreme obese (≥30 kg/m ²)	22/47 (46,8)	11/21 (52,4)	0,89 [0,54; 1,49]	0,80 [0,29; 2,24]	-5,57 [-31,26; 20,11]
				0,794	
Tobacco use (p-value of the interaction test: 0,797)					
Current	46/76 (60,5)	17/32 (53,1)	1,14 [0,78; 1,65]	1,35 [0,59; 3,11]	7,40 [-13,09; 27,89]
				0,525	
Former	24/46 (52,2)	16/29 (55,2)	0,95 [0,62; 1,45]	0,89 [0,35; 2,25]	-3,00 [-26,15; 20,15]
				0,817	
Never	112/209 (53,6)	50/103 (48,5)	1,10 [0,87; 1,40]	1,22 [0,76; 1,96]	5,04 [-6,74; 16,83]
				0,470	
Prior biologic exposure (p-value of the interaction test: 0,620)					
Ever	20/36 (55,6)	7/12 (58,3)	0,95 [0,54; 1,67]	0,89 [0,24; 3,35]	-2,78 [-35,05; 29,50]
				1,000	
Never	162/295 (54,9)	76/152 (50,0)	1,10 [0,91; 1,33]	1,22 [0,82; 1,80]	4,92 [-4,85; 14,68]
				0,368	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline corticosteroid use (p-value of the interaction test: 0,075)					
Yes	64/113 (56,6)	23/56 (41,1)	1,38 [0,97; 1,96]	1,87 [0,98; 3,59]	15,57 [-0,23; 31,36]
			0,072		
No	118/218 (54,1)	60/108 (55,6)	0,97 [0,79; 1,20]	0,94 [0,59; 1,50]	-1,43 [-12,90; 10,04]
			0,814		
Baseline immunomodulator use (p-value of the interaction test: 0,845)					
Yes	67/102 (65,7)	32/53 (60,4)	1,09 [0,84; 1,41]	1,26 [0,63; 2,49]	5,31 [-10,76; 21,38]
			0,597		
No	115/229 (50,2)	51/111 (45,9)	1,09 [0,86; 1,39]	1,19 [0,75; 1,87]	4,27 [-7,04; 15,58]
			0,489		
Duration of CD (p-value of the interaction test: 0,909)					
<1 year	42/71 (59,2)	17/33 (51,5)	1,15 [0,78; 1,68]	1,36 [0,59; 3,13]	7,64 [-12,89; 28,17]
			0,526		
≥1 to <5 years	71/132 (53,8)	37/71 (52,1)	1,03 [0,79; 1,36]	1,07 [0,60; 1,91]	1,68 [-12,72; 16,08]
			0,883		
≥5 years	68/127 (53,5)	29/60 (48,3)	1,11 [0,81; 1,51]	1,23 [0,67; 2,28]	5,21 [-10,12; 20,54]
			0,534		
Baseline disease location (p-value of the interaction test: 0,853)					
Colonic	78/135 (57,8)	41/73 (56,2)	1,03 [0,80; 1,32]	1,07 [0,60; 1,90]	1,61 [-12,49; 15,72]
			0,884		
Ileal	21/41 (51,2)	12/24 (50,0)	1,02 [0,62; 1,69]	1,05 [0,38; 2,88]	1,22 [-23,96; 26,40]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Ileal-Colonic	83/155 (53,5)	30/65 (46,2)	1,16 [0,86; 1,57]	1,34 [0,75; 2,40]	7,39 [-7,05; 21,83]
0,375					
Baseline fecal calprotectin (p-value of the interaction test: 0,510)					
≤250	23/57 (40,4)	11/24 (45,8)	0,88 [0,51; 1,51]	0,80 [0,31; 2,09]	-5,48 [-29,14; 18,17]
0,806					
>250	119/203 (58,6)	56/103 (54,4)	1,08 [0,87; 1,33]	1,19 [0,74; 1,92]	4,25 [-7,51; 16,02]
0,541					
Baseline SES-CD total score (p-value of the interaction test: 0,386)					
<12	103/200 (51,5)	49/96 (51,0)	1,01 [0,80; 1,28]	1,02 [0,63; 1,66]	0,46 [-11,71; 12,62]
1,000					
≥12	79/131 (60,3)	34/66 (51,5)	1,17 [0,89; 1,54]	1,43 [0,79; 2,60]	8,79 [-5,89; 23,47]
0,286					
Baseline AP average (p-value of the interaction test: 0,377)					
<2	35/70 (50,0)	19/35 (54,3)	0,92 [0,63; 1,35]	0,84 [0,37; 1,90]	-4,29 [-24,52; 15,95]
0,836					
≥2	147/260 (56,5)	64/129 (49,6)	1,14 [0,93; 1,40]	1,32 [0,87; 2,02]	6,93 [-3,60; 17,45]
0,234					
Baseline SF average (p-value of the interaction test: 0,596)					
<7	149/265 (56,2)	67/125 (53,6)	1,05 [0,86; 1,27]	1,11 [0,73; 1,70]	2,63 [-7,96; 13,21]
0,663					
≥7	33/65 (50,8)	16/39 (41,0)	1,24 [0,79; 1,93]	1,48 [0,66; 3,31]	9,74 [-9,90; 29,39]
0,418					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline CDAI 1 (p-value of the interaction test: 0,694)					
<300	85/148 (57,4)	39/75 (52,0)	1,10 [0,85; 1,43]	1,25 [0,71; 2,18]	5,43 [-8,40; 19,26]
			0,477		
≥300	97/182 (53,3)	44/89 (49,4)	1,08 [0,84; 1,38]	1,17 [0,70; 1,94]	3,86 [-8,81; 16,52]
			0,605		
OECD Country (p-value of the interaction test: 0,826)					
Yes	113/209 (54,1)	47/94 (50,0)	1,08 [0,85; 1,37]	1,18 [0,72; 1,92]	4,07 [-8,09; 16,22]
			0,536		
No	69/122 (56,6)	36/70 (51,4)	1,10 [0,83; 1,45]	1,23 [0,68; 2,22]	5,13 [-9,52; 19,77]
			0,548		
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PRO: Patient Reported Outcome, defined as 2 of the patient-reported items of the CDAI (SF and AP); RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_prorem_sub_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Subgruppen für Corticosteroid-free from week 40 to week 52 and achieving clinical remission by PRO at week 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,567)					
<65 years	147/322 (45,7)	70/160 (43,8)	1,04 [0,84; 1,29]	1,08 [0,74; 1,58]	1,90 [-7,52; 11,32]
			0,699		
≥65 years	4/9 (44,4)	1/4 (25,0)	1,78 [0,28; 11,28]	2,40 [0,18; 32,88]	19,44 [-33,98; 72,87]
			1,000		
Age 2 (p-value of the interaction test: 0,531)					
<40 years	98/210 (46,7)	47/101 (46,5)	1,00 [0,78; 1,29]	1,01 [0,62; 1,62]	0,13 [-11,71; 11,97]
			1,000		
≥40 years	53/121 (43,8)	24/63 (38,1)	1,15 [0,79; 1,67]	1,27 [0,68; 2,36]	5,71 [-9,19; 20,60]
			0,529		
Sex (p-value of the interaction test: 0,898)					
Male	86/178 (48,3)	39/83 (47,0)	1,03 [0,78; 1,35]	1,05 [0,63; 1,78]	1,33 [-11,68; 14,33]
			0,894		
Female	65/153 (42,5)	32/81 (39,5)	1,08 [0,78; 1,49]	1,13 [0,65; 1,96]	2,98 [-10,24; 16,19]
			0,678		
Race (p-value of the interaction test: 0,557)					
White	123/268 (45,9)	62/137 (45,3)	1,01 [0,81; 1,27]	1,03 [0,68; 1,55]	0,64 [-9,61; 10,89]
			0,916		
Other	27/62 (43,5)	9/26 (34,6)	1,26 [0,69; 2,29]	1,46 [0,56; 3,77]	8,93 [-13,13; 30,99]
			0,484		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Geographic region 1 (p-value of the interaction test: 0,511)					
Europe	104/224 (46,4)	57/121 (47,1)	0,99 [0,78; 1,25]	0,97 [0,62; 1,52]	-0,68 [-11,71; 10,36]
				0,910	
North America	14/31 (45,2)	4/13 (30,8)	1,47 [0,59; 3,62]	1,85 [0,47; 7,32]	14,39 [-16,21; 44,99]
				0,507	
Other	33/76 (43,4)	10/30 (33,3)	1,30 [0,74; 2,30]	1,53 [0,63; 3,72]	10,09 [-10,13; 30,30]
				0,386	
Geographic region 2 (p-value of the interaction test: 0,646)					
Asia	23/58 (39,7)	6/23 (26,1)	1,52 [0,71; 3,24]	1,86 [0,64; 5,42]	13,57 [-8,35; 35,49]
				0,310	
Central America/South America	5/11 (45,5)	4/7 (57,1)	0,80 [0,32; 1,98]	0,63 [0,09; 4,22]	-11,69 [-58,70; 35,32]
				1,000	
Europe and ROW	109/231 (47,2)	57/121 (47,1)	1,00 [0,79; 1,26]	1,00 [0,65; 1,56]	0,08 [-10,90; 11,06]
				1,000	
North America	14/31 (45,2)	4/13 (30,8)	1,47 [0,59; 3,62]	1,85 [0,47; 7,32]	14,39 [-16,21; 44,99]
				0,507	
Weight (p-value of the interaction test: 0,292)					
<100 kg	143/309 (46,3)	65/153 (42,5)	1,09 [0,87; 1,36]	1,17 [0,79; 1,72]	3,79 [-5,81; 13,40]
				0,487	
≥100 kg	8/22 (36,4)	6/11 (54,5)	0,67 [0,31; 1,44]	0,48 [0,11; 2,07]	-18,18 [-53,82; 17,45]
				0,459	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
BMI (p-value of the interaction test: 0,489)					
Underweight (<18.5 kg/m ²)	24/59 (40,7)	8/23 (34,8)	1,17 [0,62; 2,22]	1,29 [0,47; 3,51]	5,90 [-17,26; 29,05]
				0,802	
Normal (≥18.5 and <25 kg/m ²)	73/157 (46,5)	36/92 (39,1)	1,19 [0,88; 1,61]	1,35 [0,80; 2,28]	7,37 [-5,30; 20,03]
				0,291	
Overweight (≥25 and <30 kg/m ²)	38/68 (55,9)	19/28 (67,9)	0,82 [0,59; 1,15]	0,60 [0,24; 1,52]	-11,97 [-32,92; 8,97]
				0,362	
Obese and Extreme obese (≥30 kg/m ²)	16/47 (34,0)	8/21 (38,1)	0,89 [0,45; 1,76]	0,84 [0,29; 2,44]	-4,05 [-28,85; 20,74]
				0,788	
Tobacco use (p-value of the interaction test: 0,426)					
Current	40/76 (52,6)	13/32 (40,6)	1,30 [0,81; 2,07]	1,62 [0,70; 3,75]	12,01 [-8,38; 32,39]
				0,296	
Former	22/46 (47,8)	12/29 (41,4)	1,16 [0,68; 1,96]	1,30 [0,51; 3,32]	6,45 [-16,57; 29,46]
				0,639	
Never	89/209 (42,6)	46/103 (44,7)	0,95 [0,73; 1,24]	0,92 [0,57; 1,48]	-2,08 [-13,79; 9,63]
				0,808	
Prior biologic exposure (p-value of the interaction test: 0,606)					
Ever	16/36 (44,4)	6/12 (50,0)	0,89 [0,45; 1,74]	0,80 [0,22; 2,96]	-5,56 [-38,17; 27,06]
				0,751	
Never	135/295 (45,8)	65/152 (42,8)	1,07 [0,86; 1,34]	1,13 [0,76; 1,68]	3,00 [-6,71; 12,70]
				0,616	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline corticosteroid use (p-value of the interaction test: 0,829)					
Yes	48/113 (42,5)	22/56 (39,3)	1,08 [0,73; 1,60]	1,14 [0,59; 2,19]	3,19 [-12,51; 18,90]
				0,742	
No	103/218 (47,2)	49/108 (45,4)	1,04 [0,81; 1,34]	1,08 [0,68; 1,71]	1,88 [-9,62; 13,37]
				0,814	
Baseline immunomodulator use (p-value of the interaction test: 0,683)					
Yes	53/102 (52,0)	25/53 (47,2)	1,10 [0,78; 1,55]	1,21 [0,62; 2,35]	4,79 [-11,78; 21,36]
				0,614	
No	98/229 (42,8)	46/111 (41,4)	1,03 [0,79; 1,35]	1,06 [0,67; 1,67]	1,35 [-9,83; 12,54]
				0,907	
Duration of CD (p-value of the interaction test: 0,949)					
<1 year	33/71 (46,5)	14/33 (42,4)	1,10 [0,69; 1,75]	1,18 [0,51; 2,71]	4,05 [-16,41; 24,52]
				0,833	
≥1 to <5 years	58/132 (43,9)	31/71 (43,7)	1,01 [0,73; 1,40]	1,01 [0,57; 1,81]	0,28 [-14,03; 14,59]
				1,000	
≥5 years	60/127 (47,2)	26/60 (43,3)	1,09 [0,77; 1,54]	1,17 [0,63; 2,17]	3,91 [-11,34; 19,16]
				0,640	
Baseline disease location (p-value of the interaction test: 0,176)					
Colonic	60/135 (44,4)	38/73 (52,1)	0,85 [0,64; 1,14]	0,74 [0,42; 1,30]	-7,61 [-21,81; 6,59]
				0,311	
Ileal	17/41 (41,5)	10/24 (41,7)	1,00 [0,55; 1,81]	0,99 [0,36; 2,76]	-0,20 [-25,03; 24,63]
				1,000	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Ileal-Colonic	74/155 (47,7)	23/65 (35,4)	1,35 [0,93; 1,95]	1,67 [0,92; 3,03]	12,36 [-1,68; 26,39]
0,103					
Baseline fecal calprotectin (p-value of the interaction test: 0,736)					
≤250	20/57 (35,1)	9/24 (37,5)	0,94 [0,50; 1,75]	0,90 [0,33; 2,42]	-2,41 [-25,40; 20,58]
1,000					
>250	97/203 (47,8)	46/103 (44,7)	1,07 [0,83; 1,39]	1,13 [0,70; 1,83]	3,12 [-8,68; 14,93]
0,629					
Baseline AP average (p-value of the interaction test: 0,693)					
<2	32/70 (45,7)	14/35 (40,0)	1,14 [0,71; 1,85]	1,26 [0,55; 2,88]	5,71 [-14,28; 25,70]
0,678					
≥2	119/260 (45,8)	57/129 (44,2)	1,04 [0,82; 1,31]	1,07 [0,70; 1,63]	1,58 [-8,91; 12,08]
0,829					
Baseline SF average (p-value of the interaction test: 0,498)					
<7	120/265 (45,3)	56/125 (44,8)	1,01 [0,80; 1,28]	1,02 [0,66; 1,56]	0,48 [-10,10; 11,06]
1,000					
≥7	31/65 (47,7)	15/39 (38,5)	1,24 [0,77; 1,99]	1,46 [0,65; 3,27]	9,23 [-10,28; 28,74]
0,418					
Baseline CDAI 1 (p-value of the interaction test: 0,392)					
<300	76/148 (51,4)	34/75 (45,3)	1,13 [0,84; 1,52]	1,27 [0,73; 2,22]	6,02 [-7,83; 19,87]
0,479					
≥300	75/182 (41,2)	37/89 (41,6)	0,99 [0,73; 1,34]	0,99 [0,59; 1,65]	-0,36 [-12,85; 12,12]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline CDAI 2 (p-value of the interaction test: 0,358)					
<150	3/5 (60,0)	2/6 (33,3)	1,80 [0,47; 6,87]	3,00 [0,25; 35,33]	26,67 [-30,49; 83,82]
				0,567	
≥150 and <220	14/27 (51,9)	7/18 (38,9)	1,33 [0,67; 2,64]	1,69 [0,50; 5,68]	12,96 [-16,40; 42,33]
				0,543	
≥220 and <450	129/275 (46,9)	55/125 (44,0)	1,07 [0,84; 1,35]	1,12 [0,74; 1,72]	2,91 [-7,60; 13,42]
				0,665	
≥450	5/23 (21,7)	7/15 (46,7)	0,47 [0,18; 1,20]	0,32 [0,08; 1,31]	-24,93 [-55,28; 5,43]
				0,157	
OECD Country (p-value of the interaction test: 0,846)					
Yes	102/209 (48,8)	43/94 (45,7)	1,07 [0,82; 1,38]	1,13 [0,69; 1,84]	3,06 [-9,08; 15,20]
				0,709	
No	49/122 (40,2)	28/70 (40,0)	1,00 [0,70; 1,44]	1,01 [0,55; 1,83]	0,16 [-14,24; 14,56]
				1,000	
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PRO: Patient Reported Outcome, defined as 2 of the patient-reported items of the CDAI (SF and AP); RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_csfirepro_sub_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba
20DEC2024 / 04:00

Anhang 4-G.3.6.1.2 Symptomatik**Darm- und systemische Symptome - IBDQ**

Subgruppen für Increase in IBDQ Bowel Symptoms by at least 9 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,918)					
<65 years	221/322 (68,6)	106/160 (66,3)	1,04 [0,91; 1,18]	1,11 [0,74; 1,67]	2,38 [-6,53; 11,29]
			0,606		
≥65 years	4/9 (44,4)	2/4 (50,0)	0,89 [0,26; 3,02]	0,80 [0,08; 8,47]	-5,56 [-64,33; 53,22]
			1,000		
Age 2 (p-value of the interaction test: 0,152)					
<40 years	151/210 (71,9)	65/101 (64,4)	1,12 [0,94; 1,32]	1,42 [0,85; 2,35]	7,55 [-3,60; 18,69]
			0,190		
≥40 years	74/121 (61,2)	43/63 (68,3)	0,90 [0,72; 1,12]	0,73 [0,38; 1,39]	-7,10 [-21,50; 7,31]
			0,420		
Sex (p-value of the interaction test: 0,068)					
Male	129/178 (72,5)	52/83 (62,7)	1,16 [0,96; 1,40]	1,57 [0,90; 2,73]	9,82 [-2,48; 22,12]
			0,115		
Female	96/153 (62,7)	56/81 (69,1)	0,91 [0,75; 1,10]	0,75 [0,42; 1,34]	-6,39 [-19,04; 6,25]
			0,388		
Race (p-value of the interaction test: 0,664)					
White	176/268 (65,7)	89/137 (65,0)	1,01 [0,87; 1,17]	1,03 [0,67; 1,59]	0,71 [-9,10; 10,51]
			0,912		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Other	49/62 (79,0)	19/26 (73,1)	1,08 [0,83; 1,41]	1,39 [0,48; 4,01]	5,96 [-13,88; 25,79]
0,583					
Geographic region 1 (p-value of the interaction test: 0,751)					
Europe	152/224 (67,9)	78/121 (64,5)	1,05 [0,90; 1,24]	1,16 [0,73; 1,85]	3,39 [-7,10; 13,89]
0,551					
North America	18/31 (58,1)	9/13 (69,2)	0,84 [0,52; 1,34]	0,62 [0,16; 2,44]	-11,17 [-41,68; 19,35]
0,735					
Other	55/76 (72,4)	21/30 (70,0)	1,03 [0,79; 1,36]	1,12 [0,44; 2,84]	2,37 [-16,87; 21,60]
0,814					
Geographic region 2 (p-value of the interaction test: 0,893)					
Asia	43/58 (74,1)	16/23 (69,6)	1,07 [0,78; 1,45]	1,25 [0,43; 3,64]	4,57 [-17,35; 26,50]
0,783					
Central America/South America	8/11 (72,7)	5/7 (71,4)	1,02 [0,56; 1,84]	1,07 [0,13; 8,79]	1,30 [-41,28; 43,87]
1,000					
Europe and ROW	156/231 (67,5)	78/121 (64,5)	1,05 [0,89; 1,23]	1,15 [0,72; 1,82]	3,07 [-7,38; 13,52]
0,635					
North America	18/31 (58,1)	9/13 (69,2)	0,84 [0,52; 1,34]	0,62 [0,16; 2,44]	-11,17 [-41,68; 19,35]
0,735					
Weight (p-value of the interaction test: 0,076)					
<100 kg	214/309 (69,3)	99/153 (64,7)	1,07 [0,93; 1,23]	1,23 [0,82; 1,85]	4,55 [-4,60; 13,70]
0,342					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
≥100 kg	11/22 (50,0)	9/11 (81,8)	0,61 [0,37; 1,01]	0,22 [0,04; 1,27]	-31,82 [-62,74; -0,90]
0,132					
BMI (p-value of the interaction test: 0,844)					
Underweight ($<18.5 \text{ kg/m}^2$)	41/59 (69,5)	15/23 (65,2)	1,07 [0,76; 1,50]	1,21 [0,44; 3,37]	4,27 [-18,46; 27,01]
0,793					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	103/157 (65,6)	57/92 (62,0)	1,06 [0,87; 1,29]	1,17 [0,69; 2,00]	3,65 [-8,75; 16,04]
0,586					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	52/68 (76,5)	23/28 (82,1)	0,93 [0,75; 1,16]	0,71 [0,23; 2,16]	-5,67 [-23,08; 11,73]
0,600					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	29/47 (61,7)	13/21 (61,9)	1,00 [0,67; 1,49]	0,99 [0,34; 2,86]	-0,20 [-25,19; 24,79]
1,000					
Tobacco use (p-value of the interaction test: 0,578)					
Current	50/76 (65,8)	18/32 (56,3)	1,17 [0,83; 1,65]	1,50 [0,64; 3,48]	9,54 [-10,69; 29,77]
0,387					
Former	29/46 (63,0)	19/29 (65,5)	0,96 [0,68; 1,36]	0,90 [0,34; 2,37]	-2,47 [-24,70; 19,75]
1,000					
Never	146/209 (69,9)	71/103 (68,9)	1,01 [0,87; 1,19]	1,04 [0,63; 1,74]	0,92 [-9,96; 11,81]
0,896					
Prior biologic exposure (p-value of the interaction test: 0,512)					
Ever	23/36 (63,9)	9/12 (75,0)	0,85 [0,57; 1,28]	0,59 [0,14; 2,57]	-11,11 [-40,20; 17,98]
0,725					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Never	202/295 (68,5)	99/152 (65,1)	1,05 [0,91; 1,21]	1,16 [0,77; 1,76]	3,34 [-5,90; 12,59]
0,523					
Baseline corticosteroid use (p-value of the interaction test: 0,945)					
Yes	77/113 (68,1)	37/56 (66,1)	1,03 [0,82; 1,29]	1,10 [0,56; 2,17]	2,07 [-13,02; 17,16]
0,862					
No	148/218 (67,9)	71/108 (65,7)	1,03 [0,88; 1,22]	1,10 [0,68; 1,80]	2,15 [-8,74; 13,04]
0,708					
Baseline immunomodulator use (p-value of the interaction test: 0,513)					
Yes	73/102 (71,6)	40/53 (75,5)	0,95 [0,78; 1,15]	0,82 [0,38; 1,75]	-3,90 [-18,42; 10,62]
0,704					
No	152/229 (66,4)	68/111 (61,3)	1,08 [0,91; 1,29]	1,25 [0,78; 2,00]	5,11 [-5,82; 16,05]
0,397					
Duration of CD (p-value of the interaction test: 0,585)					
<1 year	49/71 (69,0)	23/33 (69,7)	0,99 [0,75; 1,30]	0,97 [0,39; 2,37]	-0,68 [-19,70; 18,33]
1,000					
≥1 to <5 years	95/132 (72,0)	46/71 (64,8)	1,11 [0,91; 1,36]	1,40 [0,75; 2,59]	7,18 [-6,31; 20,68]
0,338					
≥5 years	80/127 (63,0)	39/60 (65,0)	0,97 [0,77; 1,22]	0,92 [0,48; 1,74]	-2,01 [-16,71; 12,69]
0,871					
Baseline disease location (p-value of the interaction test: 0,753)					
Colonic	94/135 (69,6)	53/73 (72,6)	0,96 [0,80; 1,15]	0,87 [0,46; 1,63]	-2,97 [-15,81; 9,87]
0,750					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Ileal	26/41 (63,4)	14/24 (58,3)	1,09 [0,72; 1,64]	1,24 [0,44; 3,47]	5,08 [-19,54; 29,71]
			0,793		
Ileal-Colonic	105/155 (67,7)	41/65 (63,1)	1,07 [0,87; 1,33]	1,23 [0,67; 2,25]	4,67 [-9,18; 18,51]
			0,534		
Baseline fecal calprotectin (p-value of the interaction test: 0,569)					
≤250	35/57 (61,4)	14/24 (58,3)	1,05 [0,71; 1,56]	1,14 [0,43; 3,00]	3,07 [-20,36; 26,50]
			0,808		
>250	145/203 (71,4)	74/103 (71,8)	0,99 [0,86; 1,15]	0,98 [0,58; 1,66]	-0,42 [-11,10; 10,26]
			1,000		
Baseline CRP (p-value of the interaction test: 0,536)					
≤10	144/217 (66,4)	71/108 (65,7)	1,01 [0,86; 1,19]	1,03 [0,63; 1,67]	0,62 [-10,32; 11,56]
			1,000		
>10	81/114 (71,1)	37/56 (66,1)	1,08 [0,86; 1,34]	1,26 [0,64; 2,50]	4,98 [-9,95; 19,92]
			0,596		
Baseline SES-CD total score (p-value of the interaction test: 0,473)					
<12	131/200 (65,5)	59/96 (61,5)	1,07 [0,88; 1,29]	1,19 [0,72; 1,97]	4,04 [-7,71; 15,80]
			0,519		
≥12	94/131 (71,8)	49/66 (74,2)	0,97 [0,81; 1,15]	0,88 [0,45; 1,72]	-2,49 [-15,55; 10,58]
			0,739		
Baseline SF average (p-value of the interaction test: 0,904)					
<7	179/265 (67,5)	81/125 (64,8)	1,04 [0,89; 1,22]	1,13 [0,72; 1,77]	2,75 [-7,35; 12,84]
			0,645		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
≥7	46/65 (70,8)	27/39 (69,2)	1,02 [0,79; 1,33]	1,08 [0,45; 2,56]	1,54 [-16,68; 19,76]
1,000					
Baseline CDAI 1 (p-value of the interaction test: 0,465)					
<300	91/148 (61,5)	48/75 (64,0)	0,96 [0,78; 1,19]	0,90 [0,50; 1,60]	-2,51 [-15,91; 10,88]
0,771					
≥300	134/182 (73,6)	60/89 (67,4)	1,09 [0,92; 1,29]	1,35 [0,78; 2,34]	6,21 [-5,44; 17,86]
0,317					
Baseline CDAI 2 (p-value of the interaction test: 0,051)					
<150	0/5 (0,0)	3/6 (50,0)	0,17 [0,01; 2,62]	0,09 [0,00; 2,35]	-50,00 [-90,01; -9,99]
0,182					
≥150 and <220	13/27 (48,1)	13/18 (72,2)	0,67 [0,41; 1,08]	0,36 [0,10; 1,28]	-24,07 [-52,06; 3,91]
0,134					
≥220 and <450	197/275 (71,6)	79/125 (63,2)	1,13 [0,97; 1,32]	1,47 [0,94; 2,30]	8,44 [-1,56; 18,43]
0,103					
≥450	15/23 (65,2)	13/15 (86,7)	0,75 [0,53; 1,08]	0,29 [0,05; 1,61]	-21,45 [-47,43; 4,53]
0,259					
OECD Country (p-value of the interaction test: 0,841)					
Yes	141/209 (67,5)	60/94 (63,8)	1,06 [0,88; 1,26]	1,18 [0,71; 1,96]	3,63 [-7,97; 15,24]
0,599					
No	84/122 (68,9)	48/70 (68,6)	1,00 [0,82; 1,22]	1,01 [0,54; 1,91]	0,28 [-13,35; 13,91]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_ibdqbsi9_sub_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba
20DEC2024 / 04:00

Subgruppen für Increase in IBDQ Systemic Symptoms by at least 4.5 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,168)					
<65 years	194/322 (60,2)	95/160 (59,4)	1,01 [0,87; 1,19]	1,04 [0,70; 1,53]	0,87 [-8,43; 10,17]
			0,921		
≥65 years	2/9 (22,2)	3/4 (75,0)	0,30 [0,08; 1,14]	0,10 [0,01; 1,50]	-52,78 [-100,00; -2,40]
			0,217		
Age 2 (p-value of the interaction test: 0,686)					
<40 years	130/210 (61,9)	61/101 (60,4)	1,02 [0,85; 1,24]	1,07 [0,66; 1,73]	1,51 [-10,07; 13,09]
			0,805		
≥40 years	66/121 (54,5)	37/63 (58,7)	0,93 [0,71; 1,21]	0,84 [0,46; 1,56]	-4,18 [-19,23; 10,87]
			0,640		
Sex (p-value of the interaction test: 0,734)					
Male	110/178 (61,8)	53/83 (63,9)	0,97 [0,79; 1,18]	0,92 [0,53; 1,57]	-2,06 [-14,62; 10,50]
			0,785		
Female	86/153 (56,2)	45/81 (55,6)	1,01 [0,80; 1,29]	1,03 [0,60; 1,77]	0,65 [-12,72; 14,03]
			1,000		
Race (p-value of the interaction test: 0,757)					
White	149/268 (55,6)	79/137 (57,7)	0,96 [0,81; 1,15]	0,92 [0,61; 1,39]	-2,07 [-12,26; 8,12]
			0,751		
Other	47/62 (75,8)	19/26 (73,1)	1,04 [0,79; 1,36]	1,15 [0,41; 3,28]	2,73 [-17,38; 22,84]
			0,792		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,529)					
Europe	131/224 (58,5)	71/121 (58,7)	1,00 [0,83; 1,20]	0,99 [0,63; 1,55]	-0,20 [-11,09; 10,70]
				1,000	
North America	16/31 (51,6)	5/13 (38,5)	1,34 [0,62; 2,89]	1,71 [0,46; 6,39]	13,15 [-18,61; 44,91]
				0,518	
Other	49/76 (64,5)	22/30 (73,3)	0,88 [0,67; 1,15]	0,66 [0,26; 1,68]	-8,86 [-28,00; 10,28]
				0,493	
Geographic region 2 (p-value of the interaction test: 0,736)					
Asia	42/58 (72,4)	17/23 (73,9)	0,98 [0,73; 1,31]	0,93 [0,31; 2,77]	-1,50 [-22,81; 19,82]
				1,000	
Central America/South America	5/11 (45,5)	5/7 (71,4)	0,64 [0,29; 1,41]	0,33 [0,04; 2,52]	-25,97 [-70,54; 18,59]
				0,367	
Europe and ROW	133/231 (57,6)	71/121 (58,7)	0,98 [0,81; 1,18]	0,96 [0,61; 1,49]	-1,10 [-11,95; 9,74]
				0,910	
North America	16/31 (51,6)	5/13 (38,5)	1,34 [0,62; 2,89]	1,71 [0,46; 6,39]	13,15 [-18,61; 44,91]
				0,518	
Weight (p-value of the interaction test: 0,133)					
<100 kg	190/309 (61,5)	92/153 (60,1)	1,02 [0,87; 1,20]	1,06 [0,71; 1,57]	1,36 [-8,11; 10,83]
				0,839	
≥100 kg	6/22 (27,3)	6/11 (54,5)	0,50 [0,21; 1,19]	0,31 [0,07; 1,42]	-27,27 [-62,09; 7,54]
				0,149	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
BMI (p-value of the interaction test: 0,856)					
Underweight ($<18.5 \text{ kg/m}^2$)	42/59 (71,2)	17/23 (73,9)	0,96 [0,72; 1,29]	0,87 [0,29; 2,59]	-2,73 [-24,07; 18,62]
				1,000	
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	89/157 (56,7)	53/92 (57,6)	0,98 [0,79; 1,23]	0,96 [0,57; 1,62]	-0,92 [-13,65; 11,81]
				0,895	
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	43/68 (63,2)	16/28 (57,1)	1,11 [0,77; 1,60]	1,29 [0,53; 3,16]	6,09 [-15,53; 27,71]
				0,647	
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	22/47 (46,8)	12/21 (57,1)	0,82 [0,51; 1,32]	0,66 [0,23; 1,86]	-10,33 [-35,86; 15,19]
				0,600	
Tobacco use (p-value of the interaction test: 0,709)					
Current	45/76 (59,2)	18/32 (56,3)	1,05 [0,74; 1,51]	1,13 [0,49; 2,60]	2,96 [-17,47; 23,39]
				0,832	
Former	26/46 (56,5)	16/29 (55,2)	1,02 [0,68; 1,55]	1,06 [0,41; 2,69]	1,35 [-21,73; 24,43]
				1,000	
Never	125/209 (59,8)	64/103 (62,1)	0,96 [0,80; 1,16]	0,91 [0,56; 1,47]	-2,33 [-13,81; 9,16]
				0,713	
Prior biologic exposure (p-value of the interaction test: 0,784)					
Ever	24/36 (66,7)	9/12 (75,0)	0,89 [0,60; 1,33]	0,67 [0,15; 2,93]	-8,33 [-37,27; 20,60]
				0,728	
Never	172/295 (58,3)	89/152 (58,6)	1,00 [0,84; 1,17]	0,99 [0,67; 1,47]	-0,25 [-9,89; 9,40]
				1,000	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline corticosteroid use (p-value of the interaction test: 0,616)					
Yes	66/113 (58,4)	35/56 (62,5)	0,93 [0,72; 1,21]	0,84 [0,44; 1,63]	-4,09 [-19,69; 11,51]
			0,622		
No	130/218 (59,6)	63/108 (58,3)	1,02 [0,84; 1,24]	1,06 [0,66; 1,69]	1,30 [-10,05; 12,65]
			0,905		
Baseline immunomodulator use (p-value of the interaction test: 0,259)					
Yes	63/102 (61,8)	38/53 (71,7)	0,86 [0,69; 1,08]	0,64 [0,31; 1,31]	-9,93 [-25,30; 5,43]
			0,286		
No	133/229 (58,1)	60/111 (54,1)	1,07 [0,88; 1,32]	1,18 [0,75; 1,86]	4,02 [-7,24; 15,28]
			0,486		
Duration of CD (p-value of the interaction test: 0,120)					
<1 year	34/71 (47,9)	22/33 (66,7)	0,72 [0,51; 1,01]	0,46 [0,19; 1,09]	-18,78 [-38,62; 1,06]
			0,092		
≥1 to <5 years	87/132 (65,9)	41/71 (57,7)	1,14 [0,90; 1,44]	1,41 [0,78; 2,56]	8,16 [-5,89; 22,21]
			0,287		
≥5 years	74/127 (58,3)	35/60 (58,3)	1,00 [0,77; 1,29]	1,00 [0,54; 1,86]	-0,07 [-15,20; 15,07]
			1,000		
Baseline disease location (p-value of the interaction test: 0,920)					
Colonic	88/135 (65,2)	50/73 (68,5)	0,95 [0,78; 1,16]	0,86 [0,47; 1,58]	-3,31 [-16,65; 10,04]
			0,648		
Ileal	21/41 (51,2)	13/24 (54,2)	0,95 [0,59; 1,52]	0,89 [0,32; 2,44]	-2,95 [-28,08; 22,18]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Ileal-Colonic	87/155 (56,1)	35/65 (53,8)	1,04 [0,80; 1,36]	1,10 [0,61; 1,96]	2,28 [-12,14; 16,70]
0,768					
Baseline fecal calprotectin (p-value of the interaction test: 0,816)					
≤250	31/57 (54,4)	15/24 (62,5)	0,87 [0,59; 1,29]	0,72 [0,27; 1,90]	-8,11 [-31,40; 15,17]
0,625					
>250	129/203 (63,5)	66/103 (64,1)	0,99 [0,83; 1,19]	0,98 [0,60; 1,60]	-0,53 [-11,92; 10,86]
1,000					
Baseline CRP (p-value of the interaction test: 0,333)					
≤10	117/217 (53,9)	62/108 (57,4)	0,94 [0,77; 1,15]	0,87 [0,54; 1,38]	-3,49 [-14,93; 7,95]
0,557					
>10	79/114 (69,3)	36/56 (64,3)	1,08 [0,86; 1,36]	1,25 [0,64; 2,47]	5,01 [-10,13; 20,15]
0,601					
Baseline SES-CD total score (p-value of the interaction test: 0,078)					
<12	115/200 (57,5)	50/96 (52,1)	1,10 [0,88; 1,38]	1,24 [0,76; 2,03]	5,42 [-6,70; 17,53]
0,385					
≥12	81/131 (61,8)	48/66 (72,7)	0,85 [0,70; 1,04]	0,61 [0,32; 1,16]	-10,90 [-24,48; 2,69]
0,154					
Baseline AP average (p-value of the interaction test: 0,105)					
<2	31/70 (44,3)	21/35 (60,0)	0,74 [0,51; 1,08]	0,53 [0,23; 1,21]	-15,71 [-35,68; 4,26]
0,151					
≥2	165/260 (63,5)	77/129 (59,7)	1,06 [0,90; 1,26]	1,17 [0,76; 1,81]	3,77 [-6,52; 14,06]
0,506					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline SF average (p-value of the interaction test: 0,582)					
<7	154/265 (58,1)	71/125 (56,8)	1,02 [0,85; 1,23]	1,06 [0,69; 1,62]	1,31 [-9,21; 11,83]
				0,827	
≥7	42/65 (64,6)	27/39 (69,2)	0,93 [0,71; 1,23]	0,81 [0,35; 1,90]	-4,62 [-23,19; 13,96]
				0,673	
Baseline CDAI 1 (p-value of the interaction test: 0,534)					
<300	75/148 (50,7)	37/75 (49,3)	1,03 [0,78; 1,36]	1,06 [0,61; 1,84]	1,34 [-12,55; 15,23]
				0,888	
≥300	121/182 (66,5)	61/89 (68,5)	0,97 [0,81; 1,15]	0,91 [0,53; 1,57]	-2,06 [-13,89; 9,78]
				0,784	
Baseline CDAI 2 (p-value of the interaction test: 0,310)					
<150	0/5 (0,0)	3/6 (50,0)	0,17 [0,01; 2,62]	0,09 [0,00; 2,35]	-50,00 [-90,01; -9,99]
				0,182	
≥150 and <220	13/27 (48,1)	9/18 (50,0)	0,96 [0,53; 1,76]	0,93 [0,28; 3,06]	-1,85 [-31,66; 27,96]
				1,000	
≥220 and <450	170/275 (61,8)	74/125 (59,2)	1,04 [0,88; 1,24]	1,12 [0,72; 1,72]	2,62 [-7,74; 12,97]
				0,659	
≥450	13/23 (56,5)	12/15 (80,0)	0,71 [0,46; 1,10]	0,33 [0,07; 1,47]	-23,48 [-52,12; 5,16]
				0,176	
OECD Country (p-value of the interaction test: 0,328)					
Yes	118/209 (56,5)	49/94 (52,1)	1,08 [0,86; 1,36]	1,19 [0,73; 1,94]	4,33 [-7,80; 16,46]
				0,533	

	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Subgruppe			p-Wert ^a		
No	78/122 (63,9)	49/70 (70,0)	0,91 [0,75; 1,12]	0,76 [0,40; 1,43]	-6,07 [-19,77; 7,64]
			0,431		
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_ibdqssi4_5_sub_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Stuhlfrequenz – CDAI-SF

Subgruppen für Reduction in Stool Frequency by at least 15 percent-points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,897)					
<65 years	247/322 (76,7)	120/160 (75,0)	1,02 [0,92; 1,14]	1,10 [0,71; 1,71]	1,71 [-6,44; 9,85]
			0,734		
≥65 years	6/9 (66,7)	3/4 (75,0)	0,89 [0,43; 1,85]	0,67 [0,05; 9,47]	-8,33 [-60,77; 44,10]
			1,000		
Age 2 (p-value of the interaction test: 0,334)					
<40 years	159/210 (75,7)	78/101 (77,2)	0,98 [0,86; 1,12]	0,92 [0,52; 1,61]	-1,51 [-11,54; 8,51]
			0,887		
≥40 years	94/121 (77,7)	45/63 (71,4)	1,09 [0,91; 1,31]	1,39 [0,70; 2,79]	6,26 [-7,14; 19,65]
			0,370		
Sex (p-value of the interaction test: 0,821)					
Male	139/178 (78,1)	65/83 (78,3)	1,00 [0,87; 1,14]	0,99 [0,52; 1,86]	-0,22 [-10,97; 10,53]
			1,000		
Female	114/153 (74,5)	58/81 (71,6)	1,04 [0,88; 1,23]	1,16 [0,63; 2,12]	2,90 [-9,10; 14,91]
			0,643		
Race (p-value of the interaction test: 0,231)					
White	200/268 (74,6)	104/137 (75,9)	0,98 [0,87; 1,11]	0,93 [0,58; 1,51]	-1,29 [-10,14; 7,57]
			0,809		
Other	52/62 (83,9)	19/26 (73,1)	1,15 [0,89; 1,48]	1,92 [0,64; 5,75]	10,79 [-8,56; 30,15]
			0,252		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,442)					
Europe	169/224 (75,4)	93/121 (76,9)	0,98 [0,87; 1,11]	0,93 [0,55; 1,56]	-1,41 [-10,81; 7,98]
				0,793	
North America	23/31 (74,2)	9/13 (69,2)	1,07 [0,71; 1,63]	1,28 [0,31; 5,32]	4,96 [-24,48; 34,40]
				0,727	
Other	61/76 (80,3)	21/30 (70,0)	1,15 [0,88; 1,49]	1,74 [0,66; 4,57]	10,26 [-8,42; 28,94]
				0,305	
Geographic region 2 (p-value of the interaction test: 0,614)					
Asia	47/58 (81,0)	16/23 (69,6)	1,16 [0,87; 1,57]	1,87 [0,62; 5,64]	11,47 [-9,87; 32,81]
				0,374	
Central America/South America	9/11 (81,8)	5/7 (71,4)	1,15 [0,66; 1,98]	1,80 [0,19; 16,98]	10,39 [-30,10; 50,88]
				1,000	
Europe and ROW	174/231 (75,3)	93/121 (76,9)	0,98 [0,87; 1,11]	0,92 [0,55; 1,54]	-1,53 [-10,88; 7,81]
				0,794	
North America	23/31 (74,2)	9/13 (69,2)	1,07 [0,71; 1,63]	1,28 [0,31; 5,32]	4,96 [-24,48; 34,40]
				0,727	
Weight (p-value of the interaction test: 0,972)					
<100 kg	235/309 (76,1)	114/153 (74,5)	1,02 [0,91; 1,14]	1,09 [0,69; 1,70]	1,54 [-6,84; 9,93]
				0,731	
≥100 kg	18/22 (81,8)	9/11 (81,8)	1,00 [0,71; 1,41]	1,00 [0,15; 6,53]	0,00 [-27,92; 27,92]
				1,000	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
BMI (p-value of the interaction test: 0,129)					
Underweight (<18.5 kg/m ²)	42/59 (71,2)	17/23 (73,9)	0,96 [0,72; 1,29]	0,87 [0,29; 2,59]	-2,73 [-24,07; 18,62]
				1,000	
Normal (≥18.5 and <25 kg/m ²)	123/157 (78,3)	65/92 (70,7)	1,11 [0,95; 1,30]	1,50 [0,83; 2,71]	7,69 [-3,63; 19,01]
				0,222	
Overweight (≥25 and <30 kg/m ²)	52/68 (76,5)	27/28 (96,4)	0,79 [0,68; 0,92]	0,12 [0,02; 0,96]	-19,96 [-32,16; -7,76]
				0,020	
Obese and Extreme obese (≥30 kg/m ²)	36/47 (76,6)	14/21 (66,7)	1,15 [0,82; 1,62]	1,64 [0,53; 5,07]	9,93 [-13,59; 33,45]
				0,392	
Tobacco use (p-value of the interaction test: 0,336)					
Current	59/76 (77,6)	21/32 (65,6)	1,18 [0,90; 1,56]	1,82 [0,73; 4,50]	12,01 [-6,93; 30,94]
				0,232	
Former	35/46 (76,1)	24/29 (82,8)	0,92 [0,73; 1,16]	0,66 [0,20; 2,15]	-6,67 [-25,14; 11,79]
				0,572	
Never	159/209 (76,1)	78/103 (75,7)	1,00 [0,88; 1,15]	1,02 [0,59; 1,77]	0,35 [-9,75; 10,45]
				1,000	
Prior biologic exposure (p-value of the interaction test: 0,225)					
Ever	32/36 (88,9)	9/12 (75,0)	1,19 [0,84; 1,68]	2,67 [0,50; 14,16]	13,89 [-12,67; 40,45]
				0,345	
Never	221/295 (74,9)	114/152 (75,0)	1,00 [0,89; 1,12]	1,00 [0,63; 1,56]	-0,08 [-8,56; 8,39]
				1,000	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline corticosteroid use (p-value of the interaction test: 0,256)					
Yes	82/113 (72,6)	44/56 (78,6)	0,92 [0,77; 1,10]	0,72 [0,34; 1,54]	-6,01 [-19,54; 7,53]
				0,456	
No	171/218 (78,4)	79/108 (73,1)	1,07 [0,94; 1,23]	1,34 [0,78; 2,28]	5,29 [-4,69; 15,28]
				0,330	
Baseline immunomodulator use (p-value of the interaction test: 0,464)					
Yes	87/102 (85,3)	43/53 (81,1)	1,05 [0,90; 1,22]	1,35 [0,56; 3,25]	4,16 [-8,42; 16,74]
				0,500	
No	166/229 (72,5)	80/111 (72,1)	1,01 [0,87; 1,16]	1,02 [0,62; 1,69]	0,42 [-9,74; 10,57]
				1,000	
Duration of CD (p-value of the interaction test: 0,422)					
<1 year	49/71 (69,0)	22/33 (66,7)	1,04 [0,78; 1,38]	1,11 [0,46; 2,69]	2,35 [-17,00; 21,70]
				0,824	
≥1 to <5 years	106/132 (80,3)	60/71 (84,5)	0,95 [0,83; 1,08]	0,75 [0,35; 1,62]	-4,20 [-15,01; 6,61]
				0,568	
≥5 years	97/127 (76,4)	41/60 (68,3)	1,12 [0,92; 1,36]	1,50 [0,76; 2,96]	8,04 [-5,85; 21,94]
				0,286	
Baseline disease location (p-value of the interaction test: 0,495)					
Colonic	107/135 (79,3)	58/73 (79,5)	1,00 [0,86; 1,15]	0,99 [0,49; 2,00]	-0,19 [-11,71; 11,33]
				1,000	
Ileal	31/41 (75,6)	15/24 (62,5)	1,21 [0,85; 1,73]	1,86 [0,62; 5,54]	13,11 [-10,30; 36,52]
				0,276	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Ileal-Colonic	115/155 (74,2)	50/65 (76,9)	0,96 [0,82; 1,13]	0,86 [0,44; 1,70]	-2,73 [-15,07; 9,61]
0,735					
Baseline fecal calprotectin (p-value of the interaction test: 0,424)					
≤250	45/57 (78,9)	17/24 (70,8)	1,11 [0,83; 1,49]	1,54 [0,52; 4,58]	8,11 [-12,93; 29,15]
0,566					
>250	162/203 (79,8)	81/103 (78,6)	1,01 [0,90; 1,15]	1,07 [0,60; 1,92]	1,16 [-8,49; 10,81]
0,881					
Baseline CRP (p-value of the interaction test: 0,205)					
≤10	163/217 (75,1)	83/108 (76,9)	0,98 [0,86; 1,11]	0,91 [0,53; 1,56]	-1,74 [-11,55; 8,08]
0,785					
>10	90/114 (78,9)	40/56 (71,4)	1,11 [0,91; 1,34]	1,50 [0,72; 3,13]	7,52 [-6,48; 21,52]
0,336					
Baseline SES-CD total score (p-value of the interaction test: 0,893)					
<12	150/200 (75,0)	71/96 (74,0)	1,01 [0,88; 1,17]	1,06 [0,61; 1,84]	1,04 [-9,59; 11,68]
0,887					
≥12	103/131 (78,6)	52/66 (78,8)	1,00 [0,86; 1,16]	0,99 [0,48; 2,04]	-0,16 [-12,27; 11,94]
1,000					
Baseline AP average (p-value of the interaction test: 0,433)					
<2	50/70 (71,4)	27/35 (77,1)	0,93 [0,73; 1,17]	0,74 [0,29; 1,90]	-5,71 [-23,19; 11,76]
0,642					
≥2	203/260 (78,1)	96/129 (74,4)	1,05 [0,93; 1,18]	1,22 [0,75; 2,00]	3,66 [-5,40; 12,71]
0,445					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline SF average (p-value of the interaction test: 0,948)					
<7	201/265 (75,8)	93/125 (74,4)	1,02 [0,90; 1,15]	1,08 [0,66; 1,76]	1,45 [-7,78; 10,67]
			0,801		
≥7	52/65 (80,0)	30/39 (76,9)	1,04 [0,84; 1,28]	1,20 [0,46; 3,14]	3,08 [-13,34; 19,49]
			0,805		
Baseline CDAI 1 (p-value of the interaction test: 0,543)					
<300	113/148 (76,4)	59/75 (78,7)	0,97 [0,84; 1,13]	0,88 [0,45; 1,71]	-2,32 [-13,84; 9,21]
			0,739		
≥300	140/182 (76,9)	64/89 (71,9)	1,07 [0,92; 1,25]	1,30 [0,73; 2,32]	5,01 [-6,15; 16,18]
			0,373		
Baseline CDAI 2 (p-value of the interaction test: 0,157)					
<150	3/5 (60,0)	4/6 (66,7)	0,90 [0,36; 2,24]	0,75 [0,06; 8,83]	-6,67 [-63,82; 50,49]
			1,000		
≥150 and <220	18/27 (66,7)	16/18 (88,9)	0,75 [0,55; 1,03]	0,25 [0,05; 1,33]	-22,22 [-45,18; 0,73]
			0,156		
≥220 and <450	215/275 (78,2)	89/125 (71,2)	1,10 [0,97; 1,25]	1,45 [0,90; 2,35]	6,98 [-2,34; 16,30]
			0,132		
≥450	17/23 (73,9)	14/15 (93,3)	0,79 [0,60; 1,05]	0,20 [0,02; 1,89]	-19,42 [-41,36; 2,52]
			0,209		
OECD Country (p-value of the interaction test: 0,895)					
Yes	159/209 (76,1)	69/94 (73,4)	1,04 [0,90; 1,20]	1,15 [0,66; 2,01]	2,67 [-7,97; 13,31]
			0,667		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
No	94/122 (77,0)	54/70 (77,1)	1,00 [0,85; 1,17]	0,99 [0,49; 2,00]	-0,09 [-12,44; 12,25]
			1,000		
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_sfi15p_sub_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba
20DEC2024 / 04:00

Imperativer Stuhldrang - Urgency NRS

Subgruppen für Urgency NRS Score ≤ 2 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,581)					
<65 years	129/322 (40,1)	59/160 (36,9)	1,09 [0,85; 1,38]	1,14 [0,77; 1,69]	3,19 [-6,01; 12,38]
			0,552		
≥65 years	3/9 (33,3)	2/4 (50,0)	0,67 [0,17; 2,56]	0,50 [0,05; 5,51]	-16,67 [-74,54; 41,21]
			1,000		
Age 2 (p-value of the interaction test: 0,649)					
<40 years	84/210 (40,0)	36/101 (35,6)	1,12 [0,82; 1,53]	1,20 [0,74; 1,97]	4,36 [-7,10; 15,81]
			0,534		
≥40 years	48/121 (39,7)	25/63 (39,7)	1,00 [0,69; 1,46]	1,00 [0,54; 1,86]	-0,01 [-14,91; 14,88]
			1,000		
Sex (p-value of the interaction test: 0,494)					
Male	78/178 (43,8)	32/83 (38,6)	1,14 [0,83; 1,56]	1,24 [0,73; 2,12]	5,27 [-7,49; 18,02]
			0,501		
Female	54/153 (35,3)	29/81 (35,8)	0,99 [0,69; 1,42]	0,98 [0,56; 1,72]	-0,51 [-13,41; 12,39]
			1,000		
Race (p-value of the interaction test: 0,389)					
White	101/268 (37,7)	51/137 (37,2)	1,01 [0,78; 1,32]	1,02 [0,67; 1,56]	0,46 [-9,50; 10,42]
			1,000		
Other	31/62 (50,0)	10/26 (38,5)	1,30 [0,75; 2,24]	1,60 [0,63; 4,07]	11,54 [-10,92; 34,00]
			0,357		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,577)					
Europe	86/224 (38,4)	47/121 (38,8)	0,99 [0,75; 1,31]	0,98 [0,62; 1,55]	-0,45 [-11,22; 10,32]
				1,000	
North America	12/31 (38,7)	4/13 (30,8)	1,26 [0,50; 3,18]	1,42 [0,36; 5,66]	7,94 [-22,45; 38,33]
				0,738	
Other	34/76 (44,7)	10/30 (33,3)	1,34 [0,76; 2,36]	1,62 [0,67; 3,92]	11,40 [-8,83; 31,64]
				0,382	
Geographic region 2 (p-value of the interaction test: 0,795)					
Asia	26/58 (44,8)	8/23 (34,8)	1,29 [0,69; 2,42]	1,52 [0,56; 4,15]	10,04 [-13,25; 33,34]
				0,462	
Central America/South America	5/11 (45,5)	2/7 (28,6)	1,59 [0,42; 6,07]	2,08 [0,28; 15,77]	16,88 [-27,68; 61,45]
				0,637	
Europe and ROW	89/231 (38,5)	47/121 (38,8)	0,99 [0,75; 1,31]	0,99 [0,63; 1,55]	-0,31 [-11,03; 10,40]
				1,000	
North America	12/31 (38,7)	4/13 (30,8)	1,26 [0,50; 3,18]	1,42 [0,36; 5,66]	7,94 [-22,45; 38,33]
				0,738	
BMI (p-value of the interaction test: 0,278)					
Underweight (<18.5 kg/m ²)	21/59 (35,6)	8/23 (34,8)	1,02 [0,53; 1,97]	1,04 [0,38; 2,85]	0,81 [-22,17; 23,79]
				1,000	
Normal (≥18.5 and <25 kg/m ²)	69/157 (43,9)	31/92 (33,7)	1,30 [0,93; 1,83]	1,54 [0,90; 2,63]	10,25 [-2,14; 22,65]
				0,141	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Overweight (≥25 and <30 kg/m²)	30/68 (44,1)	13/28 (46,4)	0,95 [0,59; 1,53]	0,91 [0,38; 2,20]	-2,31 [-24,23; 19,61]
			1,000		
Obese and Extreme obese (≥30 kg/m²)	12/47 (25,5)	9/21 (42,9)	0,60 [0,30; 1,19]	0,46 [0,15; 1,35]	-17,33 [-41,89; 7,24]
			0,168		
Tobacco use (p-value of the interaction test: 0,200)					
Current	38/76 (50,0)	10/32 (31,3)	1,60 [0,91; 2,80]	2,20 [0,92; 5,26]	18,75 [-0,85; 38,35]
			0,091		
Former	20/46 (43,5)	15/29 (51,7)	0,84 [0,52; 1,36]	0,72 [0,28; 1,82]	-8,25 [-31,40; 14,91]
			0,635		
Never	74/209 (35,4)	36/103 (35,0)	1,01 [0,73; 1,40]	1,02 [0,62; 1,67]	0,46 [-10,81; 11,72]
			1,000		
Prior biologic exposure (p-value of the interaction test: 0,917)					
Ever	11/36 (30,6)	3/12 (25,0)	1,22 [0,41; 3,66]	1,32 [0,30; 5,84]	5,56 [-23,20; 34,31]
			1,000		
Never	121/295 (41,0)	58/152 (38,2)	1,07 [0,84; 1,37]	1,13 [0,75; 1,68]	2,86 [-6,69; 12,41]
			0,611		
Baseline corticosteroid use (p-value of the interaction test: 0,757)					
Yes	41/113 (36,3)	18/56 (32,1)	1,13 [0,72; 1,77]	1,20 [0,61; 2,37]	4,14 [-10,97; 19,25]
			0,612		
No	91/218 (41,7)	43/108 (39,8)	1,05 [0,79; 1,39]	1,08 [0,68; 1,73]	1,93 [-9,39; 13,25]
			0,811		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline immunomodulator use (p-value of the interaction test: 0,210)					
Yes	48/102 (47,1)	19/53 (35,8)	1,31 [0,87; 1,99]	1,59 [0,80; 3,15]	11,21 [-4,93; 27,35]
				0,232	
No	84/229 (36,7)	42/111 (37,8)	0,97 [0,72; 1,30]	0,95 [0,60; 1,52]	-1,16 [-12,13; 9,81]
				0,905	
Duration of CD (p-value of the interaction test: 0,263)					
<1 year	34/71 (47,9)	10/33 (30,3)	1,58 [0,89; 2,80]	2,11 [0,88; 5,08]	17,58 [-1,93; 37,10]
				0,135	
≥1 to <5 years	50/132 (37,9)	27/71 (38,0)	1,00 [0,69; 1,44]	0,99 [0,55; 1,80]	-0,15 [-14,15; 13,85]
				1,000	
≥5 years	47/127 (37,0)	24/60 (40,0)	0,93 [0,63; 1,36]	0,88 [0,47; 1,65]	-2,99 [-17,96; 11,98]
				0,748	
Baseline disease location (p-value of the interaction test: 0,245)					
Colonic	50/135 (37,0)	32/73 (43,8)	0,84 [0,60; 1,19]	0,75 [0,42; 1,35]	-6,80 [-20,80; 7,20]
				0,374	
Ileal	19/41 (46,3)	9/24 (37,5)	1,24 [0,67; 2,28]	1,44 [0,51; 4,03]	8,84 [-15,82; 33,50]
				0,606	
Ileal-Colonic	63/155 (40,6)	20/65 (30,8)	1,32 [0,88; 1,99]	1,54 [0,83; 2,85]	9,88 [-3,75; 23,50]
				0,175	
Baseline fecal calprotectin (p-value of the interaction test: 0,676)					
≤250	16/57 (28,1)	8/24 (33,3)	0,84 [0,42; 1,70]	0,78 [0,28; 2,18]	-5,26 [-27,44; 16,91]
				0,790	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
>250	80/203 (39,4)	40/103 (38,8)	1,01 [0,75; 1,36]	1,02 [0,63; 1,67]	0,57 [-10,99; 12,14]
1,000					
Baseline SES-CD total score (p-value of the interaction test: 0,559)					
<12	77/200 (38,5)	37/96 (38,5)	1,00 [0,73; 1,36]	1,00 [0,61; 1,65]	-0,04 [-11,88; 11,80]
1,000					
≥12	55/131 (42,0)	24/66 (36,4)	1,15 [0,79; 1,68]	1,27 [0,69; 2,33]	5,62 [-8,74; 19,98]
0,538					
Baseline AP average (p-value of the interaction test: 0,161)					
<2	19/70 (27,1)	13/35 (37,1)	0,73 [0,41; 1,30]	0,63 [0,27; 1,50]	-10,00 [-29,10; 9,10]
0,369					
≥2	113/260 (43,5)	48/129 (37,2)	1,17 [0,90; 1,52]	1,30 [0,84; 2,00]	6,25 [-4,04; 16,54]
0,274					
Baseline SF average (p-value of the interaction test: 0,189)					
<7	106/265 (40,0)	51/125 (40,8)	0,98 [0,76; 1,27]	0,97 [0,63; 1,49]	-0,80 [-11,24; 9,64]
0,912					
≥7	26/65 (40,0)	10/39 (25,6)	1,56 [0,85; 2,88]	1,93 [0,81; 4,63]	14,36 [-3,80; 32,51]
0,201					
Baseline CDAI 1 (p-value of the interaction test: 0,848)					
<300	57/148 (38,5)	28/75 (37,3)	1,03 [0,72; 1,47]	1,05 [0,59; 1,87]	1,18 [-12,28; 14,64]
0,885					
≥300	75/182 (41,2)	33/89 (37,1)	1,11 [0,81; 1,53]	1,19 [0,71; 2,00]	4,13 [-8,19; 16,45]
0,597					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline CDAI 2 (p-value of the interaction test: 0,326)					
<150	1/5 (20,0)	3/6 (50,0)	0,40 [0,06; 2,75]	0,25 [0,02; 3,77]	-30,00 [-83,20; 23,20]
				0,545	
≥150 and <220	9/27 (33,3)	9/18 (50,0)	0,67 [0,33; 1,35]	0,50 [0,15; 1,70]	-16,67 [-45,82; 12,48]
				0,355	
≥220 and <450	118/275 (42,9)	45/125 (36,0)	1,19 [0,91; 1,56]	1,34 [0,86; 2,07]	6,91 [-3,34; 17,16]
				0,227	
≥450	4/23 (17,4)	4/15 (26,7)	0,65 [0,19; 2,22]	0,58 [0,12; 2,79]	-9,28 [-36,49; 17,94]
				0,687	
OECD Country (p-value of the interaction test: 0,605)					
Yes	84/209 (40,2)	33/94 (35,1)	1,14 [0,83; 1,58]	1,24 [0,75; 2,06]	5,09 [-6,63; 16,80]
				0,445	
No	48/122 (39,3)	28/70 (40,0)	0,98 [0,69; 1,41]	0,97 [0,53; 1,77]	-0,66 [-15,04; 13,73]
				1,000	
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NRS: Numeric Rating Scale; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_urgle2_sub_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba
20DEC2024 / 04:00

Subgruppen für Reduction in Urgency NRS Score by at least 3 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,854)					
<65 years	167/322 (51,9)	74/160 (46,3)	1,12 [0,92; 1,37]	1,25 [0,86; 1,83]	5,61 [-3,85; 15,07]
			0,287		
≥65 years	7/9 (77,8)	3/4 (75,0)	1,04 [0,53; 2,02]	1,17 [0,07; 18,35]	2,78 [-47,60; 53,16]
			1,000		
Age 2 (p-value of the interaction test: 0,906)					
<40 years	110/210 (52,4)	46/101 (45,5)	1,15 [0,90; 1,48]	1,32 [0,82; 2,12]	6,84 [-4,99; 18,67]
			0,277		
≥40 years	64/121 (52,9)	31/63 (49,2)	1,07 [0,79; 1,45]	1,16 [0,63; 2,13]	3,69 [-11,53; 18,90]
			0,645		
Sex (p-value of the interaction test: 0,507)					
Male	95/178 (53,4)	42/83 (50,6)	1,05 [0,82; 1,36]	1,12 [0,66; 1,88]	2,77 [-10,25; 15,78]
			0,692		
Female	79/153 (51,6)	35/81 (43,2)	1,19 [0,89; 1,60]	1,40 [0,82; 2,41]	8,42 [-4,96; 21,81]
			0,271		
Race (p-value of the interaction test: 0,847)					
White	142/268 (53,0)	65/137 (47,4)	1,12 [0,91; 1,38]	1,25 [0,83; 1,89]	5,54 [-4,74; 15,82]
			0,296		
Other	32/62 (51,6)	12/26 (46,2)	1,12 [0,69; 1,81]	1,24 [0,50; 3,12]	5,46 [-17,39; 28,30]
			0,816		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,681)					
Europe	119/224 (53,1)	59/121 (48,8)	1,09 [0,87; 1,36]	1,19 [0,76; 1,85]	4,36 [-6,68; 15,41]
				0,498	
North America	18/31 (58,1)	5/13 (38,5)	1,51 [0,71; 3,20]	2,22 [0,59; 8,34]	19,60 [-12,04; 51,24]
				0,325	
Other	37/76 (48,7)	13/30 (43,3)	1,12 [0,70; 1,80]	1,24 [0,53; 2,90]	5,35 [-15,64; 26,34]
				0,670	
Geographic region 2 (p-value of the interaction test: 0,844)					
Asia	27/58 (46,6)	9/23 (39,1)	1,19 [0,67; 2,12]	1,35 [0,51; 3,62]	7,42 [-16,30; 31,14]
				0,624	
Central America/South America	7/11 (63,6)	4/7 (57,1)	1,11 [0,51; 2,43]	1,31 [0,19; 9,10]	6,49 [-39,90; 52,88]
				1,000	
Europe and ROW	122/231 (52,8)	59/121 (48,8)	1,08 [0,87; 1,35]	1,18 [0,76; 1,83]	4,05 [-6,94; 15,04]
				0,501	
North America	18/31 (58,1)	5/13 (38,5)	1,51 [0,71; 3,20]	2,22 [0,59; 8,34]	19,60 [-12,04; 51,24]
				0,325	
Weight (p-value of the interaction test: 0,926)					
<100 kg	163/309 (52,8)	72/153 (47,1)	1,12 [0,92; 1,37]	1,26 [0,85; 1,85]	5,69 [-3,98; 15,36]
				0,277	
≥100 kg	11/22 (50,0)	5/11 (45,5)	1,10 [0,51; 2,38]	1,20 [0,28; 5,12]	4,55 [-31,54; 40,63]
				1,000	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
BMI (p-value of the interaction test: 0,606)					
Underweight ($<18.5 \text{ kg/m}^2$)	28/59 (47,5)	7/23 (30,4)	1,56 [0,79; 3,06]	2,06 [0,74; 5,75]	17,02 [-5,69; 39,74]
				0,216	
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	85/157 (54,1)	47/92 (51,1)	1,06 [0,83; 1,36]	1,13 [0,68; 1,89]	3,05 [-9,80; 15,90]
				0,694	
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	37/68 (54,4)	14/28 (50,0)	1,09 [0,71; 1,67]	1,19 [0,49; 2,88]	4,41 [-17,57; 26,39]
				0,823	
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	24/47 (51,1)	9/21 (42,9)	1,19 [0,68; 2,10]	1,39 [0,49; 3,92]	8,21 [-17,33; 33,75]
				0,605	
Tobacco use (p-value of the interaction test: 0,098)					
Current	43/76 (56,6)	12/32 (37,5)	1,51 [0,93; 2,46]	2,17 [0,93; 5,07]	19,08 [-1,06; 39,22]
				0,092	
Former	20/46 (43,5)	17/29 (58,6)	0,74 [0,47; 1,16]	0,54 [0,21; 1,39]	-15,14 [-38,09; 7,80]
				0,240	
Never	111/209 (53,1)	48/103 (46,6)	1,14 [0,89; 1,45]	1,30 [0,81; 2,08]	6,51 [-5,26; 18,28]
				0,335	
Prior biologic exposure (p-value of the interaction test: 0,061)					
Ever	22/36 (61,1)	3/12 (25,0)	2,44 [0,89; 6,74]	4,71 [1,09; 20,47]	36,11 [6,89; 65,33]
				0,046	
Never	152/295 (51,5)	74/152 (48,7)	1,06 [0,87; 1,29]	1,12 [0,76; 1,66]	2,84 [-6,94; 12,62]
				0,618	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline corticosteroid use (p-value of the interaction test: 0,826)					
Yes	61/113 (54,0)	28/56 (50,0)	1,08 [0,79; 1,48]	1,17 [0,62; 2,23]	3,98 [-12,02; 19,98]
				0,744	
No	113/218 (51,8)	49/108 (45,4)	1,14 [0,90; 1,46]	1,30 [0,82; 2,06]	6,46 [-5,03; 17,96]
				0,291	
Baseline immunomodulator use (p-value of the interaction test: 0,221)					
Yes	57/102 (55,9)	23/53 (43,4)	1,29 [0,91; 1,83]	1,65 [0,85; 3,23]	12,49 [-3,97; 28,94]
				0,176	
No	117/229 (51,1)	54/111 (48,6)	1,05 [0,83; 1,32]	1,10 [0,70; 1,74]	2,44 [-8,89; 13,77]
				0,729	
Duration of CD (p-value of the interaction test: 0,669)					
<1 year	33/71 (46,5)	16/33 (48,5)	0,96 [0,62; 1,48]	0,92 [0,40; 2,11]	-2,01 [-22,63; 18,62]
				1,000	
≥1 to <5 years	71/132 (53,8)	35/71 (49,3)	1,09 [0,82; 1,45]	1,20 [0,67; 2,13]	4,49 [-9,92; 18,90]
				0,559	
≥5 years	69/127 (54,3)	26/60 (43,3)	1,25 [0,90; 1,74]	1,56 [0,84; 2,89]	11,00 [-4,24; 26,24]
				0,210	
Baseline disease location (p-value of the interaction test: 0,440)					
Colonic	72/135 (53,3)	40/73 (54,8)	0,97 [0,75; 1,26]	0,94 [0,53; 1,67]	-1,46 [-15,64; 12,72]
				0,885	
Ileal	24/41 (58,5)	10/24 (41,7)	1,40 [0,82; 2,41]	1,98 [0,71; 5,49]	16,87 [-7,96; 41,70]
				0,210	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Ileal-Colonic	78/155 (50,3)	27/65 (41,5)	1,21 [0,87; 1,68]	1,43 [0,79; 2,56]	8,78 [-5,55; 23,12]
0,241					
Baseline fecal calprotectin (p-value of the interaction test: 0,408)					
≤250	27/57 (47,4)	13/24 (54,2)	0,87 [0,55; 1,38]	0,76 [0,29; 1,98]	-6,80 [-30,58; 16,98]
0,632					
>250	113/203 (55,7)	49/103 (47,6)	1,17 [0,92; 1,48]	1,38 [0,86; 2,23]	8,09 [-3,73; 19,91]
0,185					
Baseline CRP (p-value of the interaction test: 0,789)					
≤10	118/217 (54,4)	53/108 (49,1)	1,11 [0,88; 1,39]	1,24 [0,78; 1,96]	5,30 [-6,22; 16,83]
0,410					
>10	56/114 (49,1)	24/56 (42,9)	1,15 [0,80; 1,64]	1,29 [0,68; 2,45]	6,27 [-9,62; 22,15]
0,514					
Baseline SES-CD total score (p-value of the interaction test: 0,859)					
<12	97/200 (48,5)	41/96 (42,7)	1,14 [0,87; 1,49]	1,26 [0,77; 2,06]	5,79 [-6,29; 17,87]
0,385					
≥12	77/131 (58,8)	36/66 (54,5)	1,08 [0,83; 1,40]	1,19 [0,65; 2,16]	4,23 [-10,44; 18,91]
0,647					
Baseline AP average (p-value of the interaction test: 0,084)					
<2	21/70 (30,0)	14/35 (40,0)	0,75 [0,44; 1,29]	0,64 [0,28; 1,50]	-10,00 [-29,46; 9,46]
0,381					
≥2	153/260 (58,8)	63/129 (48,8)	1,20 [0,98; 1,48]	1,50 [0,98; 2,29]	10,01 [-0,49; 20,51]
0,066					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline SF average (p-value of the interaction test: 0,074)					
<7	133/265 (50,2)	61/125 (48,8)	1,03 [0,83; 1,28]	1,06 [0,69; 1,62]	1,39 [-9,24; 12,02]
			0,829		
≥7	41/65 (63,1)	16/39 (41,0)	1,54 [1,01; 2,34]	2,46 [1,09; 5,54]	22,05 [2,66; 41,44]
			0,041		
Baseline CDAI 1 (p-value of the interaction test: 0,373)					
<300	61/148 (41,2)	31/75 (41,3)	1,00 [0,72; 1,39]	1,00 [0,57; 1,75]	-0,12 [-13,80; 13,56]
			1,000		
≥300	113/182 (62,1)	46/89 (51,7)	1,20 [0,95; 1,51]	1,53 [0,92; 2,56]	10,40 [-2,15; 22,95]
			0,116		
Baseline CDAI 2 (p-value of the interaction test: 0,356)					
<150	1/5 (20,0)	1/6 (16,7)	1,20 [0,10; 14,69]	1,25 [0,06; 26,87]	3,33 [-42,69; 49,36]
			1,000		
≥150 and <220	7/27 (25,9)	8/18 (44,4)	0,58 [0,26; 1,33]	0,44 [0,12; 1,55]	-18,52 [-46,81; 9,77]
			0,218		
≥220 and <450	153/275 (55,6)	58/125 (46,4)	1,20 [0,97; 1,49]	1,45 [0,95; 2,21]	9,24 [-1,29; 19,77]
			0,105		
≥450	13/23 (56,5)	10/15 (66,7)	0,85 [0,51; 1,41]	0,65 [0,17; 2,52]	-10,14 [-41,44; 21,15]
			0,736		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NRS: Numeric Rating Scale; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_urg3_sub_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Abdominelle Schmerzen – CDAI-AP

Subgruppen für Clinical Remission by PRO (AP=0) in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Age 1 (p-value of the interaction test: 0,349)					
<65 years	76/322 (23,6)	30/160 (18,8)	1,26 [0,86; 1,84]	1,34 [0,83; 2,15]	4,85 [-2,77; 12,47]
				0,244	
≥65 years	2/9 (22,2)	2/4 (50,0)	0,44 [0,09; 2,13]	0,29 [0,02; 3,52]	-27,78 [-83,80; 28,25]
				0,530	
Age 2 (p-value of the interaction test: 0,820)					
<40 years	47/210 (22,4)	19/101 (18,8)	1,19 [0,74; 1,92]	1,24 [0,69; 2,26]	3,57 [-5,91; 13,05]
				0,554	
≥40 years	31/121 (25,6)	13/63 (20,6)	1,24 [0,70; 2,20]	1,32 [0,64; 2,76]	4,98 [-7,68; 17,65]
				0,585	
Sex (p-value of the interaction test: 0,176)					
Male	51/178 (28,7)	16/83 (19,3)	1,49 [0,90; 2,44]	1,68 [0,89; 3,17]	9,37 [-1,40; 20,15]
				0,128	
Female	27/153 (17,6)	16/81 (19,8)	0,89 [0,51; 1,56]	0,87 [0,44; 1,73]	-2,11 [-12,67; 8,46]
				0,724	
Race (p-value of the interaction test: 0,578)					
White	56/268 (20,9)	26/137 (19,0)	1,10 [0,73; 1,67]	1,13 [0,67; 1,89]	1,92 [-6,26; 10,09]
				0,696	
Other	21/62 (33,9)	6/26 (23,1)	1,47 [0,67; 3,21]	1,71 [0,60; 4,89]	10,79 [-9,23; 30,82]
				0,448	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,747)					
Europe	48/224 (21,4)	22/121 (18,2)	1,18 [0,75; 1,86]	1,23 [0,70; 2,15]	3,25 [-5,48; 11,97]
				0,575	
North America	8/31 (25,8)	4/13 (30,8)	0,84 [0,31; 2,30]	0,78 [0,19; 3,26]	-4,96 [-34,40; 24,48]
				0,727	
Other	22/76 (28,9)	6/30 (20,0)	1,45 [0,65; 3,21]	1,63 [0,59; 4,53]	8,95 [-8,63; 26,52]
				0,465	
Geographic region 2 (p-value of the interaction test: 0,779)					
Asia	17/58 (29,3)	4/23 (17,4)	1,69 [0,63; 4,47]	1,97 [0,58; 6,65]	11,92 [-7,50; 31,34]
				0,400	
Central America/South America	2/11 (18,2)	2/7 (28,6)	0,64 [0,11; 3,54]	0,56 [0,06; 5,24]	-10,39 [-50,88; 30,10]
				1,000	
Europe and ROW	51/231 (22,1)	22/121 (18,2)	1,21 [0,78; 1,90]	1,28 [0,73; 2,23]	3,90 [-4,81; 12,60]
				0,410	
North America	8/31 (25,8)	4/13 (30,8)	0,84 [0,31; 2,30]	0,78 [0,19; 3,26]	-4,96 [-34,40; 24,48]
				0,727	
Weight (p-value of the interaction test: 0,368)					
<100 kg	74/309 (23,9)	29/153 (19,0)	1,26 [0,86; 1,85]	1,35 [0,83; 2,18]	4,99 [-2,83; 12,82]
				0,237	
≥100 kg	4/22 (18,2)	3/11 (27,3)	0,67 [0,18; 2,47]	0,59 [0,11; 3,29]	-9,09 [-39,95; 21,77]
				0,661	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
BMI (p-value of the interaction test: 0,460)					
Underweight (<18.5 kg/m ²)	12/59 (20,3)	4/23 (17,4)	1,17 [0,42; 3,26]	1,21 [0,35; 4,24]	2,95 [-15,64; 21,53]
				1,000	
Normal (≥18.5 and <25 kg/m ²)	39/157 (24,8)	20/92 (21,7)	1,14 [0,71; 1,83]	1,19 [0,64; 2,20]	3,10 [-7,70; 13,91]
				0,645	
Overweight (≥25 and <30 kg/m ²)	19/68 (27,9)	3/28 (10,7)	2,61 [0,84; 8,12]	3,23 [0,87; 11,97]	17,23 [1,57; 32,88]
				0,107	
Obese and Extreme obese (≥30 kg/m ²)	8/47 (17,0)	5/21 (23,8)	0,71 [0,27; 1,93]	0,66 [0,19; 2,31]	-6,79 [-27,94; 14,36]
				0,520	
Tobacco use (p-value of the interaction test: 0,929)					
Current	22/76 (28,9)	7/32 (21,9)	1,32 [0,63; 2,78]	1,46 [0,55; 3,85]	7,07 [-10,51; 24,65]
				0,488	
Former	11/46 (23,9)	6/29 (20,7)	1,16 [0,48; 2,79]	1,20 [0,39; 3,71]	3,22 [-15,99; 22,44]
				0,786	
Never	45/209 (21,5)	19/103 (18,4)	1,17 [0,72; 1,89]	1,21 [0,67; 2,20]	3,08 [-6,25; 12,42]
				0,555	
Prior biologic exposure (p-value of the interaction test: 0,066)					
Ever	5/36 (13,9)	4/12 (33,3)	0,42 [0,13; 1,30]	0,32 [0,07; 1,49]	-19,44 [-48,41; 9,52]
				0,199	
Never	73/295 (24,7)	28/152 (18,4)	1,34 [0,91; 1,98]	1,46 [0,89; 2,37]	6,32 [-1,56; 14,21]
				0,152	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline corticosteroid use (p-value of the interaction test: 0,929)					
Yes	17/113 (15,0)	7/56 (12,5)	1,20 [0,53; 2,73]	1,24 [0,48; 3,19]	2,54 [-8,34; 13,43]
				0,816	
No	61/218 (28,0)	25/108 (23,1)	1,21 [0,81; 1,81]	1,29 [0,75; 2,20]	4,83 [-5,11; 14,77]
				0,423	
Baseline immunomodulator use (p-value of the interaction test: 0,297)					
Yes	32/102 (31,4)	11/53 (20,8)	1,51 [0,83; 2,75]	1,75 [0,80; 3,83]	10,62 [-3,53; 24,77]
				0,188	
No	46/229 (20,1)	21/111 (18,9)	1,06 [0,67; 1,69]	1,08 [0,61; 1,91]	1,17 [-7,78; 10,11]
				0,885	
Duration of CD (p-value of the interaction test: 0,743)					
<1 year	14/71 (19,7)	4/33 (12,1)	1,63 [0,58; 4,56]	1,78 [0,54; 5,90]	7,60 [-6,88; 22,08]
				0,414	
≥1 to <5 years	28/132 (21,2)	12/71 (16,9)	1,26 [0,68; 2,31]	1,32 [0,63; 2,80]	4,31 [-6,85; 15,47]
				0,579	
≥5 years	35/127 (27,6)	16/60 (26,7)	1,03 [0,62; 1,71]	1,05 [0,52; 2,09]	0,89 [-12,73; 14,52]
				1,000	
Baseline disease location (p-value of the interaction test: 0,243)					
Colonic	34/135 (25,2)	16/73 (21,9)	1,15 [0,68; 1,94]	1,20 [0,61; 2,36]	3,27 [-8,72; 15,25]
				0,734	
Ileal	4/41 (9,8)	5/24 (20,8)	0,47 [0,14; 1,58]	0,41 [0,10; 1,71]	-11,08 [-29,69; 7,54]
				0,272	

	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Subgruppe			p-Wert ^a		
Ileal-Colonic	40/155 (25,8)	11/65 (16,9)	1,52 [0,84; 2,78]	1,71 [0,81; 3,58]	8,88 [-2,54; 20,31]
0,166					
Baseline CRP (p-value of the interaction test: 0,068)					
≤10	51/217 (23,5)	26/108 (24,1)	0,98 [0,65; 1,47]	0,97 [0,56; 1,66]	-0,57 [-10,41; 9,27]
1,000					
>10	27/114 (23,7)	6/56 (10,7)	2,21 [0,97; 5,04]	2,59 [1,00; 6,69]	12,97 [1,72; 24,22]
0,062					
Baseline SES-CD total score (p-value of the interaction test: 0,383)					
<12	41/200 (20,5)	19/96 (19,8)	1,04 [0,64; 1,68]	1,05 [0,57; 1,92]	0,71 [-9,03; 10,45]
1,000					
≥12	37/131 (28,2)	13/66 (19,7)	1,43 [0,82; 2,51]	1,60 [0,78; 3,28]	8,55 [-3,76; 20,86]
0,227					
Baseline AP average (p-value of the interaction test: 0,678)					
<2	19/70 (27,1)	9/35 (25,7)	1,06 [0,53; 2,09]	1,08 [0,43; 2,71]	1,43 [-16,41; 19,27]
1,000					
≥2	59/260 (22,7)	23/129 (17,8)	1,27 [0,83; 1,96]	1,35 [0,79; 2,31]	4,86 [-3,48; 13,20]
0,293					
Baseline SF average (p-value of the interaction test: 0,420)					
<7	59/265 (22,3)	25/125 (20,0)	1,11 [0,73; 1,69]	1,15 [0,68; 1,94]	2,26 [-6,35; 10,88]
0,693					
≥7	19/65 (29,2)	7/39 (17,9)	1,63 [0,75; 3,52]	1,89 [0,71; 5,02]	11,28 [-5,07; 27,63]
0,246					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Baseline CDAI 1 (p-value of the interaction test: 0,273)					
<300	38/148 (25,7)	13/75 (17,3)	1,48 [0,84; 2,61]	1,65 [0,82; 3,33]	8,34 [-2,74; 19,43]
				0,180	
≥300	40/182 (22,0)	19/89 (21,3)	1,03 [0,63; 1,67]	1,04 [0,56; 1,92]	0,63 [-9,79; 11,05]
				1,000	
Baseline CDAI 2 (p-value of the interaction test: 0,513)					
<150	2/5 (40,0)	0/6 (0,0)	5,83 [0,34; 99,23]	9,29 [0,34; >100]	40,00 [-2,94; 82,94]
				0,182	
≥150 and <220	7/27 (25,9)	5/18 (27,8)	0,93 [0,35; 2,49]	0,91 [0,24; 3,49]	-1,85 [-28,34; 24,63]
				1,000	
≥220 and <450	68/275 (24,7)	25/125 (20,0)	1,24 [0,82; 1,86]	1,31 [0,78; 2,20]	4,73 [-3,94; 13,40]
				0,371	
≥450	1/23 (4,3)	2/15 (13,3)	0,33 [0,03; 3,29]	0,30 [0,02; 3,59]	-8,99 [-28,10; 10,13]
				0,550	
OECD Country (p-value of the interaction test: 0,435)					
Yes	54/209 (25,8)	18/94 (19,1)	1,35 [0,84; 2,17]	1,47 [0,81; 2,68]	6,69 [-3,24; 16,61]
				0,244	
No	24/122 (19,7)	14/70 (20,0)	0,98 [0,55; 1,77]	0,98 [0,47; 2,05]	-0,33 [-12,06; 11,40]
				1,000	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PRO: Patient Reported Outcome, defined as 2 of the patient-reported items of the CDAI (SF and AP); RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_prorap3_sub_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba
20DEC2024 / 04:00

Subgruppen für Reduction in Abdominal pain by at least 0.45 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,451)					
<65 years	224/322 (69,6)	116/160 (72,5)	0,96 [0,85; 1,08]	0,87 [0,57; 1,32]	-2,93 [-11,49; 5,62]
			0,526		
≥65 years	4/9 (44,4)	3/4 (75,0)	0,59 [0,24; 1,49]	0,27 [0,02; 3,65]	-30,56 [-83,98; 22,87]
			0,559		
Age 2 (p-value of the interaction test: 0,717)					
<40 years	148/210 (70,5)	76/101 (75,2)	0,94 [0,81; 1,08]	0,79 [0,46; 1,35]	-4,77 [-15,21; 5,66]
			0,420		
≥40 years	80/121 (66,1)	43/63 (68,3)	0,97 [0,78; 1,20]	0,91 [0,47; 1,74]	-2,14 [-16,39; 12,12]
			0,869		
Sex (p-value of the interaction test: 0,472)					
Male	129/178 (72,5)	66/83 (79,5)	0,91 [0,79; 1,05]	0,68 [0,36; 1,27]	-7,05 [-17,93; 3,84]
			0,284		
Female	99/153 (64,7)	53/81 (65,4)	0,99 [0,81; 1,20]	0,97 [0,55; 1,70]	-0,73 [-13,56; 12,10]
			1,000		
Race (p-value of the interaction test: 0,303)					
White	181/268 (67,5)	101/137 (73,7)	0,92 [0,80; 1,04]	0,74 [0,47; 1,17]	-6,19 [-15,45; 3,07]
			0,211		
Other	46/62 (74,2)	18/26 (69,2)	1,07 [0,80; 1,44]	1,28 [0,47; 3,50]	4,96 [-15,85; 25,78]
			0,793		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,464)					
Europe	152/224 (67,9)	90/121 (74,4)	0,91 [0,79; 1,05]	0,73 [0,44; 1,19]	-6,52 [-16,42; 3,37]
				0,220	
North America	24/31 (77,4)	10/13 (76,9)	1,01 [0,71; 1,43]	1,03 [0,22; 4,80]	0,50 [-26,73; 27,72]
				1,000	
Other	52/76 (68,4)	19/30 (63,3)	1,08 [0,79; 1,48]	1,25 [0,52; 3,04]	5,09 [-15,08; 25,25]
				0,651	
Geographic region 2 (p-value of the interaction test: 0,395)					
Asia	40/58 (69,0)	15/23 (65,2)	1,06 [0,75; 1,49]	1,19 [0,43; 3,30]	3,75 [-19,07; 26,57]
				0,795	
Central America/South America	9/11 (81,8)	4/7 (57,1)	1,43 [0,71; 2,88]	3,38 [0,40; 28,74]	24,68 [-18,49; 67,84]
				0,326	
Europe and ROW	155/231 (67,1)	90/121 (74,4)	0,90 [0,79; 1,04]	0,70 [0,43; 1,15]	-7,28 [-17,14; 2,58]
				0,180	
North America	24/31 (77,4)	10/13 (76,9)	1,01 [0,71; 1,43]	1,03 [0,22; 4,80]	0,50 [-26,73; 27,72]
				1,000	
Weight (p-value of the interaction test: 0,797)					
<100 kg	212/309 (68,6)	111/153 (72,5)	0,95 [0,84; 1,07]	0,83 [0,54; 1,27]	-3,94 [-12,70; 4,82]
				0,451	
≥100 kg	16/22 (72,7)	8/11 (72,7)	1,00 [0,64; 1,56]	1,00 [0,20; 5,08]	0,00 [-32,23; 32,23]
				1,000	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
BMI (p-value of the interaction test: 0,388)					
Underweight (<18.5 kg/m ²)	35/59 (59,3)	18/23 (78,3)	0,76 [0,56; 1,02]	0,41 [0,13; 1,24]	-18,94 [-39,95; 2,07]
				0,129	
Normal (≥18.5 and <25 kg/m ²)	112/157 (71,3)	63/92 (68,5)	1,04 [0,88; 1,24]	1,15 [0,65; 2,00]	2,86 [-8,98; 14,70]
				0,668	
Overweight (≥25 and <30 kg/m ²)	48/68 (70,6)	24/28 (85,7)	0,82 [0,66; 1,02]	0,40 [0,12; 1,30]	-15,13 [-32,02; 1,76]
				0,194	
Obese and Extreme obese (≥30 kg/m ²)	33/47 (70,2)	14/21 (66,7)	1,05 [0,74; 1,50]	1,18 [0,39; 3,55]	3,55 [-20,48; 27,58]
				0,783	
Tobacco use (p-value of the interaction test: 0,249)					
Current	53/76 (69,7)	22/32 (68,8)	1,01 [0,77; 1,34]	1,05 [0,43; 2,56]	0,99 [-18,11; 20,08]
				1,000	
Former	28/46 (60,9)	24/29 (82,8)	0,74 [0,55; 0,98]	0,32 [0,10; 1,00]	-21,89 [-41,58; -2,19]
				0,071	
Never	147/209 (70,3)	73/103 (70,9)	0,99 [0,85; 1,16]	0,97 [0,58; 1,64]	-0,54 [-11,28; 10,20]
				1,000	
Prior biologic exposure (p-value of the interaction test: 0,171)					
Ever	28/36 (77,8)	8/12 (66,7)	1,17 [0,75; 1,81]	1,75 [0,42; 7,35]	11,11 [-18,82; 41,04]
				0,462	
Never	200/295 (67,8)	111/152 (73,0)	0,93 [0,82; 1,05]	0,78 [0,50; 1,20]	-5,23 [-14,07; 3,61]
				0,279	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline corticosteroid use (p-value of the interaction test: 0,280)					
Yes	77/113 (68,1)	37/56 (66,1)	1,03 [0,82; 1,29]	1,10 [0,56; 2,17]	2,07 [-13,02; 17,16]
				0,862	
No	151/218 (69,3)	82/108 (75,9)	0,91 [0,79; 1,05]	0,71 [0,42; 1,21]	-6,66 [-16,79; 3,47]
				0,242	
Baseline immunomodulator use (p-value of the interaction test: 0,956)					
Yes	71/102 (69,6)	40/53 (75,5)	0,92 [0,76; 1,13]	0,74 [0,35; 1,58]	-5,86 [-20,49; 8,76]
				0,573	
No	157/229 (68,6)	79/111 (71,2)	0,96 [0,83; 1,12]	0,88 [0,54; 1,45]	-2,61 [-12,96; 7,74]
				0,707	
Duration of CD (p-value of the interaction test: 0,941)					
<1 year	49/71 (69,0)	24/33 (72,7)	0,95 [0,73; 1,23]	0,84 [0,33; 2,09]	-3,71 [-22,33; 14,90]
				0,819	
≥1 to <5 years	98/132 (74,2)	54/71 (76,1)	0,98 [0,83; 1,15]	0,91 [0,46; 1,77]	-1,81 [-14,23; 10,60]
				0,866	
≥5 years	80/127 (63,0)	41/60 (68,3)	0,92 [0,74; 1,15]	0,79 [0,41; 1,51]	-5,34 [-19,80; 9,12]
				0,515	
Baseline disease location (p-value of the interaction test: 0,912)					
Colonic	94/135 (69,6)	53/73 (72,6)	0,96 [0,80; 1,15]	0,87 [0,46; 1,63]	-2,97 [-15,81; 9,87]
				0,750	
Ileal	27/41 (65,9)	17/24 (70,8)	0,93 [0,66; 1,30]	0,79 [0,27; 2,37]	-4,98 [-28,25; 18,29]
				0,787	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Ileal-Colonic	107/155 (69,0)	49/65 (75,4)	0,92 [0,77; 1,09]	0,73 [0,38; 1,41]	-6,35 [-19,11; 6,40]
0,417					
Baseline fecal calprotectin (p-value of the interaction test: 0,648)					
≤250	41/57 (71,9)	19/24 (79,2)	0,91 [0,70; 1,18]	0,67 [0,22; 2,11]	-7,24 [-27,24; 12,76]
0,587					
>250	140/203 (69,0)	80/103 (77,7)	0,89 [0,77; 1,02]	0,64 [0,37; 1,11]	-8,70 [-18,96; 1,55]
0,139					
Baseline CRP (p-value of the interaction test: 0,154)					
≤10	150/217 (69,1)	83/108 (76,9)	0,90 [0,78; 1,03]	0,67 [0,40; 1,15]	-7,73 [-17,78; 2,33]
0,153					
>10	78/114 (68,4)	36/56 (64,3)	1,06 [0,84; 1,34]	1,20 [0,61; 2,36]	4,14 [-11,04; 19,31]
0,606					
Baseline SES-CD total score (p-value of the interaction test: 0,429)					
<12	135/200 (67,5)	72/96 (75,0)	0,90 [0,77; 1,05]	0,69 [0,40; 1,20]	-7,50 [-18,32; 3,32]
0,223					
≥12	93/131 (71,0)	47/66 (71,2)	1,00 [0,83; 1,20]	0,99 [0,51; 1,90]	-0,22 [-13,63; 13,19]
1,000					
Baseline AP average (p-value of the interaction test: 0,326)					
<2	28/70 (40,0)	19/35 (54,3)	0,74 [0,49; 1,12]	0,56 [0,25; 1,27]	-14,29 [-34,39; 5,82]
0,212					
≥2	200/260 (76,9)	100/129 (77,5)	0,99 [0,89; 1,11]	0,97 [0,58; 1,60]	-0,60 [-9,43; 8,24]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline SF average (p-value of the interaction test: 0,690)					
<7	180/265 (67,9)	88/125 (70,4)	0,96 [0,84; 1,11]	0,89 [0,56; 1,41]	-2,48 [-12,25; 7,30]
			0,642		
≥7	48/65 (73,8)	31/39 (79,5)	0,93 [0,75; 1,15]	0,73 [0,28; 1,89]	-5,64 [-22,22; 10,93]
			0,637		
Baseline CDAI 1 (p-value of the interaction test: 0,101)					
<300	90/148 (60,8)	55/75 (73,3)	0,83 [0,69; 1,00]	0,56 [0,31; 1,04]	-12,52 [-25,25; 0,21]
			0,075		
≥300	138/182 (75,8)	64/89 (71,9)	1,05 [0,90; 1,23]	1,23 [0,69; 2,17]	3,91 [-7,31; 15,13]
			0,553		
Baseline CDAI 2 (p-value of the interaction test: 0,190)					
<150	1/5 (20,0)	3/6 (50,0)	0,40 [0,06; 2,75]	0,25 [0,02; 3,77]	-30,00 [-83,20; 23,20]
			0,545		
≥150 and <220	11/27 (40,7)	13/18 (72,2)	0,56 [0,33; 0,97]	0,26 [0,07; 0,96]	-31,48 [-59,26; -3,70]
			0,066		
≥220 and <450	198/275 (72,0)	89/125 (71,2)	1,01 [0,88; 1,16]	1,04 [0,65; 1,66]	0,80 [-8,75; 10,35]
			0,905		
≥450	18/23 (78,3)	14/15 (93,3)	0,84 [0,65; 1,08]	0,26 [0,03; 2,46]	-15,07 [-36,13; 5,99]
			0,371		
OECD Country (p-value of the interaction test: 0,653)					
Yes	146/209 (69,9)	67/94 (71,3)	0,98 [0,84; 1,15]	0,93 [0,55; 1,60]	-1,42 [-12,48; 9,64]
			0,892		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
No	82/122 (67,2)	52/70 (74,3)	0,90 [0,75; 1,09]	0,71 [0,37; 1,37]	-7,07 [-20,27; 6,13]
			0,331		
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_api0_45_sub_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba
20DEC2024 / 04:00

Fatigue – FACIT Fatigue

Subgruppen für Increase in FACIT-Fatigue Score by at least 8 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,170)					
<65 years	137/322 (42,5)	70/160 (43,8)	0,97 [0,78; 1,21]	0,95 [0,65; 1,40]	-1,20 [-10,60; 8,19]
			0,845		
≥65 years	2/9 (22,2)	3/4 (75,0)	0,30 [0,08; 1,14]	0,10 [0,01; 1,50]	-52,78 [-100,00; -2,40]
			0,217		
Age 2 (p-value of the interaction test: 0,241)					
<40 years	96/210 (45,7)	44/101 (43,6)	1,05 [0,80; 1,37]	1,09 [0,68; 1,76]	2,15 [-9,64; 13,94]
			0,808		
≥40 years	43/121 (35,5)	29/63 (46,0)	0,77 [0,54; 1,11]	0,65 [0,35; 1,20]	-10,49 [-25,47; 4,48]
			0,203		
Sex (p-value of the interaction test: 0,769)					
Male	77/178 (43,3)	39/83 (47,0)	0,92 [0,69; 1,22]	0,86 [0,51; 1,45]	-3,73 [-16,70; 9,24]
			0,595		
Female	62/153 (40,5)	34/81 (42,0)	0,97 [0,70; 1,33]	0,94 [0,55; 1,63]	-1,45 [-14,72; 11,81]
			0,889		
Race (p-value of the interaction test: 0,321)					
White	113/268 (42,2)	59/137 (43,1)	0,98 [0,77; 1,24]	0,96 [0,64; 1,46]	-0,90 [-11,09; 9,28]
			0,915		
Other	26/62 (41,9)	14/26 (53,8)	0,78 [0,49; 1,23]	0,62 [0,25; 1,56]	-11,91 [-34,67; 10,85]
			0,353		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,656)					
Europe	100/224 (44,6)	55/121 (45,5)	0,98 [0,77; 1,25]	0,97 [0,62; 1,51]	-0,81 [-11,82; 10,19]
				0,910	
North America	9/31 (29,0)	3/13 (23,1)	1,26 [0,40; 3,91]	1,36 [0,30; 6,14]	5,96 [-21,97; 33,88]
				1,000	
Other	30/76 (39,5)	15/30 (50,0)	0,79 [0,50; 1,24]	0,65 [0,28; 1,53]	-10,53 [-31,52; 10,47]
				0,385	
Geographic region 2 (p-value of the interaction test: 0,873)					
Asia	24/58 (41,4)	11/23 (47,8)	0,87 [0,51; 1,46]	0,77 [0,29; 2,03]	-6,45 [-30,48; 17,58]
				0,627	
Central America/South America	4/11 (36,4)	4/7 (57,1)	0,64 [0,23; 1,75]	0,43 [0,06; 2,97]	-20,78 [-67,17; 25,61]
				0,630	
Europe and ROW	102/231 (44,2)	55/121 (45,5)	0,97 [0,76; 1,24]	0,95 [0,61; 1,48]	-1,30 [-12,24; 9,64]
				0,822	
North America	9/31 (29,0)	3/13 (23,1)	1,26 [0,40; 3,91]	1,36 [0,30; 6,14]	5,96 [-21,97; 33,88]
				1,000	
Weight (p-value of the interaction test: 0,550)					
<100 kg	135/309 (43,7)	72/153 (47,1)	0,93 [0,75; 1,15]	0,87 [0,59; 1,29]	-3,37 [-13,02; 6,28]
				0,551	
≥100 kg	4/22 (18,2)	1/11 (9,1)	2,00 [0,25; 15,82]	2,22 [0,22; 22,70]	9,09 [-14,33; 32,51]
				0,643	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
BMI (p-value of the interaction test: 0,602)					
Underweight ($<18.5 \text{ kg/m}^2$)	29/59 (49,2)	13/23 (56,5)	0,87 [0,56; 1,35]	0,74 [0,28; 1,96]	-7,37 [-31,31; 16,57]
				0,627	
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	65/157 (41,4)	41/92 (44,6)	0,93 [0,69; 1,25]	0,88 [0,52; 1,48]	-3,16 [-15,91; 9,58]
				0,691	
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	28/68 (41,2)	14/28 (50,0)	0,82 [0,52; 1,31]	0,70 [0,29; 1,69]	-8,82 [-30,73; 13,08]
				0,500	
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	17/47 (36,2)	5/21 (23,8)	1,52 [0,65; 3,57]	1,81 [0,56; 5,83]	12,36 [-10,45; 35,18]
				0,405	
Tobacco use (p-value of the interaction test: 0,994)					
Current	31/76 (40,8)	15/32 (46,9)	0,87 [0,55; 1,38]	0,78 [0,34; 1,79]	-6,09 [-26,60; 14,43]
				0,671	
Former	14/46 (30,4)	10/29 (34,5)	0,88 [0,45; 1,72]	0,83 [0,31; 2,24]	-4,05 [-25,87; 17,77]
				0,801	
Never	94/209 (45,0)	48/103 (46,6)	0,97 [0,75; 1,25]	0,94 [0,58; 1,50]	-1,63 [-13,39; 10,13]
				0,810	
Prior biologic exposure (p-value of the interaction test: 0,435)					
Ever	17/36 (47,2)	8/12 (66,7)	0,71 [0,42; 1,20]	0,45 [0,11; 1,76]	-19,44 [-50,71; 11,82]
				0,324	
Never	122/295 (41,4)	65/152 (42,8)	0,97 [0,77; 1,22]	0,94 [0,64; 1,40]	-1,41 [-11,07; 8,26]
				0,840	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline corticosteroid use (p-value of the interaction test: 0,729)					
Yes	51/113 (45,1)	28/56 (50,0)	0,90 [0,65; 1,26]	0,82 [0,43; 1,56]	-4,87 [-20,86; 11,12]
				0,624	
No	88/218 (40,4)	45/108 (41,7)	0,97 [0,74; 1,28]	0,95 [0,59; 1,51]	-1,30 [-12,65; 10,05]
				0,905	
Baseline immunomodulator use (p-value of the interaction test: 0,110)					
Yes	40/102 (39,2)	29/53 (54,7)	0,72 [0,51; 1,01]	0,53 [0,27; 1,04]	-15,50 [-31,91; 0,91]
				0,088	
No	99/229 (43,2)	44/111 (39,6)	1,09 [0,83; 1,43]	1,16 [0,73; 1,84]	3,59 [-7,54; 14,73]
				0,559	
Duration of CD (p-value of the interaction test: 0,221)					
<1 year	27/71 (38,0)	18/33 (54,5)	0,70 [0,45; 1,07]	0,51 [0,22; 1,18]	-16,52 [-36,92; 3,88]
				0,139	
≥1 to <5 years	60/132 (45,5)	35/71 (49,3)	0,92 [0,68; 1,25]	0,86 [0,48; 1,53]	-3,84 [-18,24; 10,56]
				0,659	
≥5 years	52/127 (40,9)	20/60 (33,3)	1,23 [0,81; 1,86]	1,39 [0,73; 2,64]	7,61 [-7,07; 22,29]
				0,339	
Baseline disease location (p-value of the interaction test: 0,272)					
Colonic	57/135 (42,2)	38/73 (52,1)	0,81 [0,60; 1,09]	0,67 [0,38; 1,19]	-9,83 [-24,00; 4,34]
				0,191	
Ileal	16/41 (39,0)	12/24 (50,0)	0,78 [0,45; 1,36]	0,64 [0,23; 1,77]	-10,98 [-35,94; 13,99]
				0,443	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Ileal-Colonic	66/155 (42,6)	23/65 (35,4)	1,20 [0,83; 1,75]	1,35 [0,74; 2,47]	7,20 [-6,79; 21,19]
0,368					
Baseline fecal calprotectin (p-value of the interaction test: 0,100)					
≤250	29/57 (50,9)	9/24 (37,5)	1,36 [0,76; 2,41]	1,73 [0,65; 4,58]	13,38 [-9,94; 36,69]
0,333					
>250	90/203 (44,3)	51/103 (49,5)	0,90 [0,70; 1,15]	0,81 [0,50; 1,31]	-5,18 [-17,01; 6,65]
0,399					
Baseline CRP (p-value of the interaction test: 0,867)					
≤10	84/217 (38,7)	45/108 (41,7)	0,93 [0,70; 1,23]	0,88 [0,55; 1,41]	-2,96 [-14,29; 8,38]
0,631					
>10	55/114 (48,2)	28/56 (50,0)	0,96 [0,70; 1,33]	0,93 [0,49; 1,77]	-1,75 [-17,74; 14,23]
0,871					
Baseline SES-CD total score (p-value of the interaction test: 0,370)					
<12	80/200 (40,0)	38/96 (39,6)	1,01 [0,75; 1,36]	1,02 [0,62; 1,67]	0,42 [-11,49; 12,32]
1,000					
≥12	59/131 (45,0)	35/66 (53,0)	0,85 [0,63; 1,14]	0,73 [0,40; 1,31]	-7,99 [-22,74; 6,76]
0,295					
Baseline AP average (p-value of the interaction test: 0,139)					
<2	14/70 (20,0)	12/35 (34,3)	0,58 [0,30; 1,12]	0,48 [0,19; 1,19]	-14,29 [-32,59; 4,02]
0,150					
≥2	125/260 (48,1)	61/129 (47,3)	1,02 [0,81; 1,27]	1,03 [0,68; 1,58]	0,79 [-9,75; 11,33]
0,914					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Baseline SF average (p-value of the interaction test: 0,952)					
<7	107/265 (40,4)	53/125 (42,4)	0,95 [0,74; 1,22]	0,92 [0,60; 1,42]	-2,02 [-12,51; 8,46]
			0,741		
≥7	32/65 (49,2)	20/39 (51,3)	0,96 [0,65; 1,42]	0,92 [0,42; 2,04]	-2,05 [-21,90; 17,79]
			1,000		
Baseline CDAI 1 (p-value of the interaction test: 0,576)					
<300	43/148 (29,1)	22/75 (29,3)	0,99 [0,64; 1,53]	0,99 [0,54; 1,82]	-0,28 [-12,92; 12,36]
			1,000		
≥300	96/182 (52,7)	51/89 (57,3)	0,92 [0,73; 1,15]	0,83 [0,50; 1,39]	-4,56 [-17,13; 8,02]
			0,518		
Baseline CDAI 2 (p-value of the interaction test: 0,825)					
<150	0/5 (0,0)	1/6 (16,7)	0,39 [0,02; 7,88]	0,33 [0,01; 10,11]	-16,67 [-46,49; 13,15]
			1,000		
≥150 and <220	4/27 (14,8)	2/18 (11,1)	1,33 [0,27; 6,53]	1,39 [0,23; 8,53]	3,70 [-16,05; 23,46]
			1,000		
≥220 and <450	122/275 (44,4)	59/125 (47,2)	0,94 [0,75; 1,18]	0,89 [0,58; 1,36]	-2,84 [-13,38; 7,70]
			0,665		
≥450	13/23 (56,5)	11/15 (73,3)	0,77 [0,48; 1,23]	0,47 [0,12; 1,94]	-16,81 [-47,00; 13,38]
			0,329		
OECD Country (p-value of the interaction test: 0,816)					
Yes	81/209 (38,8)	37/94 (39,4)	0,98 [0,73; 1,33]	0,97 [0,59; 1,61]	-0,61 [-12,49; 11,28]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
No	58/122 (47,5)	36/70 (51,4)	0,92 [0,69; 1,24]	0,86 [0,48; 1,54]	-3,89 [-18,57; 10,80]
0,654					
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; FACIT: Functional Assessment of Chronic Illness Therapy-Fatigue; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_faciti8_sub_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba
20DEC2024 / 04:00

Subgruppen für Increase in FACIT-Fatigue Score by at least 9 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,169)					
<65 years	129/322 (40,1)	63/160 (39,4)	1,02 [0,81; 1,29]	1,03 [0,70; 1,52]	0,69 [-8,58; 9,96]
			0,921		
≥65 years	2/9 (22,2)	3/4 (75,0)	0,30 [0,08; 1,14]	0,10 [0,01; 1,50]	-52,78 [-100,00; -2,40]
			0,217		
Age 2 (p-value of the interaction test: 0,345)					
<40 years	90/210 (42,9)	40/101 (39,6)	1,08 [0,81; 1,44]	1,14 [0,71; 1,85]	3,25 [-8,40; 14,91]
			0,625		
≥40 years	41/121 (33,9)	26/63 (41,3)	0,82 [0,56; 1,21]	0,73 [0,39; 1,37]	-7,39 [-22,18; 7,41]
			0,337		
Sex (p-value of the interaction test: 0,775)					
Male	74/178 (41,6)	36/83 (43,4)	0,96 [0,71; 1,30]	0,93 [0,55; 1,57]	-1,80 [-14,69; 11,09]
			0,789		
Female	57/153 (37,3)	30/81 (37,0)	1,01 [0,71; 1,43]	1,01 [0,58; 1,76]	0,22 [-12,79; 13,23]
			1,000		
Race (p-value of the interaction test: 0,404)					
White	105/268 (39,2)	53/137 (38,7)	1,01 [0,78; 1,31]	1,02 [0,67; 1,56]	0,49 [-9,54; 10,53]
			1,000		
Other	26/62 (41,9)	13/26 (50,0)	0,84 [0,52; 1,36]	0,72 [0,29; 1,81]	-8,06 [-30,87; 14,74]
			0,639		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,749)					
Europe	92/224 (41,1)	49/121 (40,5)	1,01 [0,78; 1,32]	1,02 [0,65; 1,61]	0,58 [-10,29; 11,44]
				1,000	
North America	9/31 (29,0)	3/13 (23,1)	1,26 [0,40; 3,91]	1,36 [0,30; 6,14]	5,96 [-21,97; 33,88]
				1,000	
Other	30/76 (39,5)	14/30 (46,7)	0,85 [0,53; 1,36]	0,75 [0,32; 1,75]	-7,19 [-28,16; 13,77]
				0,519	
Geographic region 2 (p-value of the interaction test: 0,901)					
Asia	24/58 (41,4)	10/23 (43,5)	0,95 [0,54; 1,66]	0,92 [0,35; 2,44]	-2,10 [-26,00; 21,80]
				1,000	
Central America/South America	4/11 (36,4)	4/7 (57,1)	0,64 [0,23; 1,75]	0,43 [0,06; 2,97]	-20,78 [-67,17; 25,61]
				0,630	
Europe and ROW	94/231 (40,7)	49/121 (40,5)	1,00 [0,77; 1,31]	1,01 [0,64; 1,58]	0,20 [-10,60; 11,00]
				1,000	
North America	9/31 (29,0)	3/13 (23,1)	1,26 [0,40; 3,91]	1,36 [0,30; 6,14]	5,96 [-21,97; 33,88]
				1,000	
Weight (p-value of the interaction test: 0,594)					
<100 kg	127/309 (41,1)	65/153 (42,5)	0,97 [0,77; 1,21]	0,94 [0,64; 1,40]	-1,38 [-10,95; 8,18]
				0,841	
≥100 kg	4/22 (18,2)	1/11 (9,1)	2,00 [0,25; 15,82]	2,22 [0,22; 22,70]	9,09 [-14,33; 32,51]
				0,643	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
BMI (p-value of the interaction test: 0,720)					
Underweight ($<18.5 \text{ kg/m}^2$)	28/59 (47,5)	11/23 (47,8)	0,99 [0,60; 1,64]	0,99 [0,38; 2,59]	-0,37 [-24,43; 23,70]
			1,000		
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	61/157 (38,9)	38/92 (41,3)	0,94 [0,69; 1,29]	0,90 [0,53; 1,53]	-2,45 [-15,07; 10,17]
			0,789		
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	26/68 (38,2)	12/28 (42,9)	0,89 [0,53; 1,51]	0,83 [0,34; 2,02]	-4,62 [-26,29; 17,04]
			0,819		
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	16/47 (34,0)	5/21 (23,8)	1,43 [0,60; 3,39]	1,65 [0,51; 5,33]	10,23 [-12,47; 32,93]
			0,571		
Tobacco use (p-value of the interaction test: 0,740)					
Current	29/76 (38,2)	11/32 (34,4)	1,11 [0,64; 1,94]	1,18 [0,50; 2,79]	3,78 [-15,97; 23,53]
			0,828		
Former	14/46 (30,4)	9/29 (31,0)	0,98 [0,49; 1,97]	0,97 [0,36; 2,66]	-0,60 [-22,05; 20,86]
			1,000		
Never	88/209 (42,1)	46/103 (44,7)	0,94 [0,72; 1,23]	0,90 [0,56; 1,45]	-2,55 [-14,26; 9,15]
			0,716		
Prior biologic exposure (p-value of the interaction test: 0,266)					
Ever	16/36 (44,4)	8/12 (66,7)	0,67 [0,39; 1,15]	0,40 [0,10; 1,57]	-22,22 [-53,44; 9,00]
			0,318		
Never	115/295 (39,0)	58/152 (38,2)	1,02 [0,80; 1,31]	1,04 [0,69; 1,55]	0,83 [-8,69; 10,34]
			0,918		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline corticosteroid use (p-value of the interaction test: 0,623)					
Yes	48/113 (42,5)	26/56 (46,4)	0,91 [0,64; 1,30]	0,85 [0,45; 1,62]	-3,95 [-19,88; 11,98]
				0,742	
No	83/218 (38,1)	40/108 (37,0)	1,03 [0,76; 1,39]	1,05 [0,65; 1,68]	1,04 [-10,12; 12,19]
				0,904	
Baseline immunomodulator use (p-value of the interaction test: 0,100)					
Yes	38/102 (37,3)	27/53 (50,9)	0,73 [0,51; 1,05]	0,57 [0,29; 1,12]	-13,69 [-30,09; 2,72]
				0,123	
No	93/229 (40,6)	39/111 (35,1)	1,16 [0,86; 1,56]	1,26 [0,79; 2,02]	5,48 [-5,45; 16,40]
				0,345	
Duration of CD (p-value of the interaction test: 0,206)					
<1 year	24/71 (33,8)	16/33 (48,5)	0,70 [0,43; 1,13]	0,54 [0,23; 1,26]	-14,68 [-34,98; 5,61]
				0,195	
≥1 to <5 years	57/132 (43,2)	32/71 (45,1)	0,96 [0,69; 1,32]	0,93 [0,52; 1,66]	-1,89 [-16,22; 12,44]
				0,882	
≥5 years	50/127 (39,4)	18/60 (30,0)	1,31 [0,84; 2,04]	1,52 [0,79; 2,92]	9,37 [-5,01; 23,75]
				0,255	
Baseline disease location (p-value of the interaction test: 0,109)					
Colonic	53/135 (39,3)	37/73 (50,7)	0,77 [0,57; 1,05]	0,63 [0,35; 1,12]	-11,43 [-25,55; 2,69]
				0,142	
Ileal	15/41 (36,6)	10/24 (41,7)	0,88 [0,47; 1,63]	0,81 [0,29; 2,26]	-5,08 [-29,71; 19,54]
				0,793	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Ileal-Colonic	63/155 (40,6)	19/65 (29,2)	1,39 [0,91; 2,12]	1,66 [0,89; 3,09]	11,41 [-2,08; 24,91]
0,128					
Baseline fecal calprotectin (p-value of the interaction test: 0,155)					
≤250	28/57 (49,1)	9/24 (37,5)	1,31 [0,73; 2,34]	1,61 [0,61; 4,27]	11,62 [-11,69; 34,94]
0,464					
>250	84/203 (41,4)	47/103 (45,6)	0,91 [0,69; 1,18]	0,84 [0,52; 1,36]	-4,25 [-16,02; 7,51]
0,541					
Baseline CRP (p-value of the interaction test: 0,826)					
≤10	79/217 (36,4)	39/108 (36,1)	1,01 [0,74; 1,37]	1,01 [0,63; 1,64]	0,29 [-10,80; 11,39]
1,000					
>10	52/114 (45,6)	27/56 (48,2)	0,95 [0,68; 1,33]	0,90 [0,47; 1,71]	-2,60 [-18,56; 13,36]
0,870					
Baseline SES-CD total score (p-value of the interaction test: 0,172)					
<12	75/200 (37,5)	32/96 (33,3)	1,13 [0,80; 1,57]	1,20 [0,72; 2,00]	4,17 [-7,41; 15,74]
0,520					
≥12	56/131 (42,7)	34/66 (51,5)	0,83 [0,61; 1,13]	0,70 [0,39; 1,27]	-8,77 [-23,50; 5,97]
0,289					
Baseline AP average (p-value of the interaction test: 0,230)					
<2	13/70 (18,6)	10/35 (28,6)	0,65 [0,32; 1,33]	0,57 [0,22; 1,47]	-10,00 [-27,52; 7,52]
0,317					
≥2	118/260 (45,4)	56/129 (43,4)	1,05 [0,82; 1,33]	1,08 [0,71; 1,66]	1,97 [-8,50; 12,45]
0,746					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline SF average (p-value of the interaction test: 0,840)					
<7	102/265 (38,5)	49/125 (39,2)	0,98 [0,75; 1,28]	0,97 [0,63; 1,50]	-0,71 [-11,08; 9,66]
				0,912	
≥7	29/65 (44,6)	17/39 (43,6)	1,02 [0,65; 1,60]	1,04 [0,47; 2,32]	1,03 [-18,68; 20,73]
				1,000	
Baseline CDAI 1 (p-value of the interaction test: 0,297)					
<300	43/148 (29,1)	19/75 (25,3)	1,15 [0,72; 1,82]	1,21 [0,64; 2,27]	3,72 [-8,54; 15,98]
				0,636	
≥300	88/182 (48,4)	47/89 (52,8)	0,92 [0,72; 1,17]	0,84 [0,50; 1,39]	-4,46 [-17,12; 8,20]
				0,519	
Baseline CDAI 2 (p-value of the interaction test: 0,763)					
<150	0/5 (0,0)	1/6 (16,7)	0,39 [0,02; 7,88]	0,33 [0,01; 10,11]	-16,67 [-46,49; 13,15]
				1,000	
≥150 and <220	4/27 (14,8)	2/18 (11,1)	1,33 [0,27; 6,53]	1,39 [0,23; 8,53]	3,70 [-16,05; 23,46]
				1,000	
≥220 and <450	116/275 (42,2)	53/125 (42,4)	0,99 [0,78; 1,27]	0,99 [0,65; 1,52]	-0,22 [-10,66; 10,23]
				1,000	
≥450	11/23 (47,8)	10/15 (66,7)	0,72 [0,41; 1,25]	0,46 [0,12; 1,77]	-18,84 [-50,24; 12,56]
				0,326	
OECD Country (p-value of the interaction test: 0,358)					
Yes	77/209 (36,8)	31/94 (33,0)	1,12 [0,80; 1,57]	1,19 [0,71; 1,98]	3,86 [-7,67; 15,40]
				0,604	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
No	54/122 (44,3)	35/70 (50,0)	0,89 [0,65; 1,20]	0,79 [0,44; 1,43]	-5,74 [-20,40; 8,92]
0,456					
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; FACIT: Functional Assessment of Chronic Illness Therapy-Fatigue; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_faciti9_sub_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba
20DEC2024 / 04:00

Depressionen – QIDS-SR16

Subgruppen für Reduction in QIDS-SR16 Total Score by at least 4.05 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Age 1 (p-value of the interaction test: 0,884)					
<65 years	67/322 (20,8)	38/160 (23,8)	0,88 [0,62; 1,24]	0,84 [0,54; 1,33]	-2,94 [-10,89; 5,00]
				0,483	
≥65 years	3/9 (33,3)	1/4 (25,0)	1,33 [0,19; 9,21]	1,50 [0,11; 21,31]	8,33 [-44,10; 60,77]
				1,000	
Age 2 (p-value of the interaction test: 0,476)					
<40 years	48/210 (22,9)	24/101 (23,8)	0,96 [0,63; 1,48]	0,95 [0,54; 1,66]	-0,91 [-10,96; 9,15]
				0,886	
≥40 years	22/121 (18,2)	15/63 (23,8)	0,76 [0,43; 1,37]	0,71 [0,34; 1,49]	-5,63 [-18,19; 6,94]
				0,439	
Sex (p-value of the interaction test: 0,081)					
Male	32/178 (18,0)	23/83 (27,7)	0,65 [0,41; 1,04]	0,57 [0,31; 1,06]	-9,73 [-20,89; 1,43]
				0,076	
Female	38/153 (24,8)	16/81 (19,8)	1,26 [0,75; 2,11]	1,34 [0,69; 2,59]	5,08 [-5,96; 16,13]
				0,418	
Race (p-value of the interaction test: 0,155)					
White	59/268 (22,0)	30/137 (21,9)	1,01 [0,68; 1,48]	1,01 [0,61; 1,66]	0,12 [-8,40; 8,64]
				1,000	
Other	11/62 (17,7)	9/26 (34,6)	0,51 [0,24; 1,09]	0,41 [0,14; 1,15]	-16,87 [-37,48; 3,74]
				0,100	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,504)					
Europe	49/224 (21,9)	29/121 (24,0)	0,91 [0,61; 1,36]	0,89 [0,53; 1,50]	-2,09 [-11,43; 7,24]
				0,687	
North America	6/31 (19,4)	1/13 (7,7)	2,52 [0,34; 18,88]	2,88 [0,31; 26,68]	11,66 [-8,42; 31,74]
				0,654	
Other	15/76 (19,7)	9/30 (30,0)	0,66 [0,32; 1,34]	0,57 [0,22; 1,50]	-10,26 [-28,94; 8,42]
				0,305	
Geographic region 2 (p-value of the interaction test: 0,609)					
Asia	10/58 (17,2)	7/23 (30,4)	0,57 [0,25; 1,31]	0,48 [0,16; 1,46]	-13,19 [-34,36; 7,98]
				0,230	
Central America/South America	4/11 (36,4)	2/7 (28,6)	1,27 [0,31; 5,20]	1,43 [0,18; 11,09]	7,79 [-36,12; 51,70]
				1,000	
Europe and ROW	50/231 (21,6)	29/121 (24,0)	0,90 [0,60; 1,35]	0,88 [0,52; 1,48]	-2,32 [-11,60; 6,95]
				0,687	
North America	6/31 (19,4)	1/13 (7,7)	2,52 [0,34; 18,88]	2,88 [0,31; 26,68]	11,66 [-8,42; 31,74]
				0,654	
Weight (p-value of the interaction test: 0,636)					
<100 kg	69/309 (22,3)	38/153 (24,8)	0,90 [0,64; 1,27]	0,87 [0,55; 1,37]	-2,51 [-10,78; 5,77]
				0,559	
≥100 kg	1/22 (4,5)	1/11 (9,1)	0,50 [0,03; 7,26]	0,48 [0,03; 8,42]	-4,55 [-23,63; 14,54]
				1,000	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
BMI (p-value of the interaction test: 0,521)					
Underweight ($<18.5 \text{ kg/m}^2$)	15/59 (25,4)	5/23 (21,7)	1,17 [0,48; 2,85]	1,23 [0,39; 3,88]	3,68 [-16,50; 23,87]
				1,000	
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	34/157 (21,7)	21/92 (22,8)	0,95 [0,59; 1,53]	0,93 [0,50; 1,73]	-1,17 [-11,90; 9,56]
				0,875	
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	13/68 (19,1)	10/28 (35,7)	0,54 [0,27; 1,07]	0,43 [0,16; 1,14]	-16,60 [-36,66; 3,46]
				0,114	
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	8/47 (17,0)	3/21 (14,3)	1,19 [0,35; 4,05]	1,23 [0,29; 5,19]	2,74 [-15,69; 21,16]
				1,000	
Tobacco use (p-value of the interaction test: 0,389)					
Current	17/76 (22,4)	8/32 (25,0)	0,89 [0,43; 1,86]	0,86 [0,33; 2,27]	-2,63 [-20,32; 15,06]
				0,805	
Former	7/46 (15,2)	9/29 (31,0)	0,49 [0,21; 1,17]	0,40 [0,13; 1,23]	-15,82 [-35,60; 3,96]
				0,148	
Never	46/209 (22,0)	22/103 (21,4)	1,03 [0,66; 1,62]	1,04 [0,59; 1,84]	0,65 [-9,06; 10,36]
				1,000	
Prior biologic exposure (p-value of the interaction test: 0,392)					
Ever	9/36 (25,0)	2/12 (16,7)	1,50 [0,38; 6,00]	1,67 [0,31; 9,08]	8,33 [-17,06; 33,72]
				0,705	
Never	61/295 (20,7)	37/152 (24,3)	0,85 [0,59; 1,22]	0,81 [0,51; 1,29]	-3,66 [-11,90; 4,58]
				0,399	

	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Subgruppe			p-Wert ^a		
Baseline corticosteroid use (p-value of the interaction test: 0,339)					
Yes	23/113 (20,4)	16/56 (28,6)	0,71 [0,41; 1,24]	0,64 [0,31; 1,34]	-8,22 [-22,19; 5,75]
			0,249		
No	47/218 (21,6)	23/108 (21,3)	1,01 [0,65; 1,58]	1,02 [0,58; 1,78]	0,26 [-9,19; 9,72]
			1,000		
Baseline immunomodulator use (p-value of the interaction test: 0,687)					
Yes	16/102 (15,7)	11/53 (20,8)	0,76 [0,38; 1,51]	0,71 [0,30; 1,66]	-5,07 [-18,07; 7,93]
			0,504		
No	54/229 (23,6)	28/111 (25,2)	0,93 [0,63; 1,39]	0,91 [0,54; 1,55]	-1,64 [-11,42; 8,13]
			0,787		
Duration of CD (p-value of the interaction test: 0,561)					
<1 year	13/71 (18,3)	10/33 (30,3)	0,60 [0,30; 1,23]	0,52 [0,20; 1,34]	-11,99 [-30,07; 6,08]
			0,207		
≥1 to <5 years	33/132 (25,0)	18/71 (25,4)	0,99 [0,60; 1,62]	0,98 [0,51; 1,91]	-0,35 [-12,88; 12,18]
			1,000		
≥5 years	24/127 (18,9)	11/60 (18,3)	1,03 [0,54; 1,96]	1,04 [0,47; 2,29]	0,56 [-11,36; 12,49]
			1,000		
Baseline disease location (p-value of the interaction test: 0,541)					
Colonic	25/135 (18,5)	19/73 (26,0)	0,71 [0,42; 1,20]	0,65 [0,33; 1,27]	-7,51 [-19,52; 4,50]
			0,217		
Ileal	13/41 (31,7)	7/24 (29,2)	1,09 [0,50; 2,34]	1,13 [0,38; 3,38]	2,54 [-20,56; 25,64]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Ileal-Colonic	32/155 (20,6)	13/65 (20,0)	1,03 [0,58; 1,84]	1,04 [0,51; 2,14]	0,65 [-10,98; 12,27]
1,000					
Baseline fecal calprotectin (p-value of the interaction test: 0,659)					
≤250	17/57 (29,8)	7/24 (29,2)	1,02 [0,49; 2,14]	1,03 [0,36; 2,94]	0,66 [-21,06; 22,38]
1,000					
>250	42/203 (20,7)	25/103 (24,3)	0,85 [0,55; 1,32]	0,81 [0,46; 1,43]	-3,58 [-13,56; 6,40]
0,469					
Baseline CRP (p-value of the interaction test: 0,756)					
≤10	42/217 (19,4)	25/108 (23,1)	0,84 [0,54; 1,30]	0,80 [0,46; 1,39]	-3,79 [-13,33; 5,74]
0,467					
>10	28/114 (24,6)	14/56 (25,0)	0,98 [0,56; 1,71]	0,98 [0,47; 2,05]	-0,44 [-14,26; 13,38]
1,000					
Baseline SES-CD total score (p-value of the interaction test: 0,687)					
<12	45/200 (22,5)	26/96 (27,1)	0,83 [0,55; 1,26]	0,78 [0,45; 1,37]	-4,58 [-15,19; 6,02]
0,387					
≥12	25/131 (19,1)	13/66 (19,7)	0,97 [0,53; 1,77]	0,96 [0,46; 2,03]	-0,61 [-12,33; 11,11]
1,000					
Baseline AP average (p-value of the interaction test: 0,934)					
<2	11/70 (15,7)	6/35 (17,1)	0,92 [0,37; 2,27]	0,90 [0,30; 2,68]	-1,43 [-16,55; 13,69]
1,000					
≥2	59/260 (22,7)	33/129 (25,6)	0,89 [0,61; 1,28]	0,85 [0,52; 1,39]	-2,89 [-11,98; 6,20]
0,529					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline SF average (p-value of the interaction test: 0,555)					
<7	58/265 (21,9)	29/125 (23,2)	0,94 [0,64; 1,40]	0,93 [0,56; 1,54]	-1,31 [-10,23; 7,61]
			0,795		
≥7	12/65 (18,5)	10/39 (25,6)	0,72 [0,34; 1,51]	0,66 [0,25; 1,70]	-7,18 [-23,82; 9,46]
			0,459		
Baseline CDAI 1 (p-value of the interaction test: 0,604)					
<300	26/148 (17,6)	13/75 (17,3)	1,01 [0,55; 1,86]	1,02 [0,49; 2,11]	0,23 [-10,30; 10,77]
			1,000		
≥300	44/182 (24,2)	26/89 (29,2)	0,83 [0,55; 1,25]	0,77 [0,44; 1,36]	-5,04 [-16,35; 6,27]
			0,379		
Baseline CDAI 2 (p-value of the interaction test: 0,354)					
<150	0/5 (0,0)	1/6 (16,7)	0,39 [0,02; 7,88]	0,33 [0,01; 10,11]	-16,67 [-46,49; 13,15]
			1,000		
≥150 and <220	3/27 (11,1)	0/18 (0,0)	4,75 [0,26; 86,79]	5,29 [0,26; >100]	11,11 [-0,74; 22,97]
			0,264		
≥220 and <450	63/275 (22,9)	32/125 (25,6)	0,89 [0,62; 1,29]	0,86 [0,53; 1,41]	-2,69 [-11,81; 6,43]
			0,612		
≥450	4/23 (17,4)	6/15 (40,0)	0,43 [0,15; 1,29]	0,32 [0,07; 1,41]	-22,61 [-51,84; 6,62]
			0,150		
OECD Country (p-value of the interaction test: 0,578)					
Yes	37/209 (17,7)	20/94 (21,3)	0,83 [0,51; 1,35]	0,80 [0,43; 1,46]	-3,57 [-13,33; 6,19]
			0,525		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
No	33/122 (27,0)	19/70 (27,1)	1,00 [0,62; 1,61]	1,00 [0,51; 1,93]	-0,09 [-13,16; 12,97]
1,000					
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; QIDS-SR16: Quick Inventory of Depressive Symptomatology - Self Report (16 items); RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_qidsi4_05_sub_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba
20DEC2024 / 04:00

Extraintestinale Manifestationen (EIM)

Subgruppen für Resolution of extra-intestinal manifestations in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population, Participants with EIMs at baseline)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Age 2 (p-value of the interaction test: 0,443)					
<40 years	23/37 (62,2)	18/24 (75,0)	0,83 [0,59; 1,17]	0,55 [0,18; 1,71]	-12,84 [-36,17; 10,49]
			0,405		
≥40 years	17/35 (48,6)	7/16 (43,8)	1,11 [0,58; 2,13]	1,21 [0,37; 3,99]	4,82 [-24,59; 34,23]
			0,772		
Sex (p-value of the interaction test: 0,184)					
Male	20/27 (74,1)	9/14 (64,3)	1,15 [0,73; 1,81]	1,59 [0,39; 6,38]	9,79 [-20,27; 39,84]
			0,719		
Female	20/45 (44,4)	16/26 (61,5)	0,72 [0,46; 1,13]	0,50 [0,19; 1,34]	-17,09 [-40,77; 6,58]
			0,220		
Tobacco use (p-value of the interaction test: 0,979)					
Current	4/12 (33,3)	5/10 (50,0)	0,67 [0,24; 1,83]	0,50 [0,09; 2,81]	-16,67 [-57,55; 24,22]
			0,666		
Former	5/9 (55,6)	4/6 (66,7)	0,83 [0,37; 1,88]	0,63 [0,07; 5,35]	-11,11 [-60,88; 38,65]
			1,000		
Never	31/51 (60,8)	16/24 (66,7)	0,91 [0,64; 1,31]	0,78 [0,28; 2,14]	-5,88 [-29,02; 17,25]
			0,799		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Prior biologic exposure (p-value of the interaction test: 0,304)					
Ever	6/7 (85,7)	2/3 (66,7)	1,29 [0,55; 3,02]	3,00 [0,12; 73,64]	19,05 [-40,26; 78,36]
				1,000	
Never	34/65 (52,3)	23/37 (62,2)	0,84 [0,60; 1,18]	0,67 [0,29; 1,52]	-9,85 [-29,64; 9,94]
				0,408	
Baseline corticosteroid use (p-value of the interaction test: 0,305)					
Yes	19/29 (65,5)	13/15 (86,7)	0,76 [0,54; 1,05]	0,29 [0,05; 1,56]	-21,15 [-45,55; 3,25]
				0,171	
No	21/43 (48,8)	12/25 (48,0)	1,02 [0,61; 1,69]	1,03 [0,39; 2,77]	0,84 [-23,80; 25,47]
				1,000	
Baseline immunomodulator use (p-value of the interaction test: 0,474)					
Yes	14/21 (66,7)	8/12 (66,7)	1,00 [0,61; 1,65]	1,00 [0,22; 4,50]	0,00 [-33,43; 33,43]
				1,000	
No	26/51 (51,0)	17/28 (60,7)	0,84 [0,56; 1,25]	0,67 [0,26; 1,72]	-9,73 [-32,44; 12,97]
				0,482	
Duration of CD (p-value of the interaction test: 0,285)					
<1 year	5/11 (45,5)	8/9 (88,9)	0,51 [0,26; 1,02]	0,10 [0,01; 1,14]	-43,43 [-79,31; -7,55]
				0,070	
≥1 to <5 years	16/29 (55,2)	9/15 (60,0)	0,92 [0,54; 1,56]	0,82 [0,23; 2,91]	-4,83 [-35,52; 25,87]
				1,000	
≥5 years	19/32 (59,4)	8/16 (50,0)	1,19 [0,67; 2,09]	1,46 [0,44; 4,89]	9,38 [-20,45; 39,20]
				0,555	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Baseline disease location (p-value of the interaction test: 0,344)					
Colonic	16/27 (59,3)	16/22 (72,7)	0,81 [0,54; 1,22]	0,55 [0,16; 1,83]	-13,47 [-39,73; 12,80]
				0,378	
Ileal	6/9 (66,7)	2/6 (33,3)	2,00 [0,59; 6,79]	4,00 [0,45; 35,79]	33,33 [-15,36; 82,03]
				0,315	
Ileal-Colonic	18/36 (50,0)	7/10 (70,0)	0,71 [0,42; 1,20]	0,43 [0,10; 1,92]	-20,00 [-52,76; 12,76]
				0,306	
Baseline fecal calprotectin (p-value of the interaction test: 0,981)					
≤250	5/15 (33,3)	1/3 (33,3)	1,00 [0,17; 5,77]	1,00 [0,07; 13,87]	0,00 [-58,43; 58,43]
				1,000	
>250	29/45 (64,4)	15/24 (62,5)	1,03 [0,71; 1,51]	1,09 [0,39; 3,04]	1,94 [-21,95; 25,83]
				1,000	
Baseline CRP (p-value of the interaction test: 0,883)					
≤10	26/52 (50,0)	16/28 (57,1)	0,88 [0,57; 1,33]	0,75 [0,30; 1,89]	-7,14 [-29,96; 15,68]
				0,641	
>10	14/20 (70,0)	9/12 (75,0)	0,93 [0,60; 1,44]	0,78 [0,15; 3,93]	-5,00 [-36,68; 26,68]
				1,000	
Baseline SES-CD total score (p-value of the interaction test: 0,536)					
<12	27/48 (56,3)	12/20 (60,0)	0,94 [0,61; 1,45]	0,86 [0,30; 2,48]	-3,75 [-29,40; 21,90]
				1,000	
≥12	13/24 (54,2)	13/18 (72,2)	0,75 [0,47; 1,20]	0,45 [0,12; 1,68]	-18,06 [-46,79; 10,68]
				0,338	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline AP average (p-value of the interaction test: 0,733)					
<2	7/15 (46,7)	6/12 (50,0)	0,93 [0,43; 2,04]	0,88 [0,19; 4,00]	-3,33 [-41,25; 34,58]
				1,000	
≥2	33/57 (57,9)	19/28 (67,9)	0,85 [0,61; 1,20]	0,65 [0,25; 1,69]	-9,96 [-31,49; 11,57]
				0,479	
Baseline SF average (p-value of the interaction test: 0,789)					
<7	30/58 (51,7)	19/32 (59,4)	0,87 [0,60; 1,27]	0,73 [0,31; 1,76]	-7,65 [-28,98; 13,68]
				0,515	
≥7	10/14 (71,4)	6/8 (75,0)	0,95 [0,57; 1,60]	0,83 [0,12; 6,01]	-3,57 [-41,79; 34,64]
				1,000	
Baseline CDAI 1 (p-value of the interaction test: 0,174)					
<300	15/30 (50,0)	7/16 (43,8)	1,14 [0,59; 2,21]	1,29 [0,38; 4,35]	6,25 [-23,93; 36,43]
				0,763	
≥300	25/42 (59,5)	18/24 (75,0)	0,79 [0,56; 1,11]	0,49 [0,16; 1,49]	-15,48 [-38,29; 7,34]
				0,285	
OECD Country (p-value of the interaction test: 0,877)					
Yes	26/48 (54,2)	16/27 (59,3)	0,91 [0,61; 1,37]	0,81 [0,31; 2,11]	-5,09 [-28,38; 18,19]
				0,809	
No	14/24 (58,3)	9/13 (69,2)	0,84 [0,51; 1,38]	0,62 [0,15; 2,60]	-10,90 [-42,81; 21,02]
				0,724	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; EIMs: Extra-Intestinal Manifestations; ITT: Intention-to-treat Population; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_eimsresov_sub_eim_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Subgruppen für Resolution of extra-intestinal manifestations: Arthritis/Arthralgia in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population, Participants with EIMs at baseline)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 2 (p-value of the interaction test: 0,344)					
<40 years	20/33 (60,6)	15/20 (75,0)	0,81 [0,56; 1,17]	0,51 [0,15; 1,75]	-14,39 [-39,65; 10,87]
			0,375		
≥40 years	17/35 (48,6)	6/15 (40,0)	1,21 [0,60; 2,46]	1,42 [0,42; 4,83]	8,57 [-21,24; 38,38]
			0,758		
Sex (p-value of the interaction test: 0,208)					
Male	20/26 (76,9)	8/12 (66,7)	1,15 [0,73; 1,81]	1,67 [0,37; 7,53]	10,26 [-20,95; 41,46]
			0,694		
Female	17/42 (40,5)	13/23 (56,5)	0,72 [0,43; 1,20]	0,52 [0,19; 1,46]	-16,05 [-41,16; 9,07]
			0,299		
BMI (p-value of the interaction test: 0,063)					
Underweight ($<18.5 \text{ kg/m}^2$)	4/7 (57,1)	7/7 (100)	0,60 [0,32; 1,13]	0,09 [0,00; 2,07]	-42,86 [-79,52; -6,20]
			0,192		
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	16/30 (53,3)	6/15 (40,0)	1,33 [0,66; 2,70]	1,71 [0,49; 6,03]	13,33 [-17,22; 43,88]
			0,530		
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	6/15 (40,0)	7/8 (87,5)	0,46 [0,23; 0,90]	0,10 [0,01; 0,98]	-47,50 [-81,26; -13,74]
			0,074		
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	11/16 (68,8)	1/5 (20,0)	3,44 [0,58; 20,46]	8,80 [0,77; >100]	48,75 [6,98; 90,52]
			0,119		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Tobacco use (p-value of the interaction test: 0,711)					
Current	3/11 (27,3)	4/8 (50,0)	0,55 [0,17; 1,79]	0,38 [0,06; 2,55]	-22,73 [-66,24; 20,78]
				0,377	
Former	5/9 (55,6)	2/4 (50,0)	1,11 [0,36; 3,48]	1,25 [0,12; 13,24]	5,56 [-53,22; 64,33]
				1,000	
Never	29/48 (60,4)	15/23 (65,2)	0,93 [0,64; 1,35]	0,81 [0,29; 2,29]	-4,80 [-28,68; 19,08]
				0,797	
Prior biologic exposure (p-value of the interaction test: 0,335)					
Ever	6/7 (85,7)	2/3 (66,7)	1,29 [0,55; 3,02]	3,00 [0,12; 73,64]	19,05 [-40,26; 78,36]
				1,000	
Never	31/61 (50,8)	19/32 (59,4)	0,86 [0,59; 1,25]	0,71 [0,30; 1,68]	-8,56 [-29,70; 12,59]
				0,514	
Baseline corticosteroid use (p-value of the interaction test: 0,345)					
Yes	17/26 (65,4)	11/13 (84,6)	0,77 [0,54; 1,11]	0,34 [0,06; 1,90]	-19,23 [-46,05; 7,58]
				0,276	
No	20/42 (47,6)	10/22 (45,5)	1,05 [0,60; 1,83]	1,09 [0,39; 3,07]	2,16 [-23,55; 27,88]
				1,000	
Baseline immunomodulator use (p-value of the interaction test: 0,407)					
Yes	14/21 (66,7)	7/11 (63,6)	1,05 [0,61; 1,80]	1,14 [0,25; 5,26]	3,03 [-31,82; 37,88]
				1,000	
No	23/47 (48,9)	14/24 (58,3)	0,84 [0,54; 1,31]	0,68 [0,25; 1,85]	-9,40 [-33,75; 14,96]
				0,616	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Duration of CD (p-value of the interaction test: 0,308)					
<1 year	4/9 (44,4)	6/7 (85,7)	0,52 [0,24; 1,14]	0,13 [0,01; 1,61]	-41,27 [-82,81; 0,27]
				0,145	
≥1 to <5 years	14/27 (51,9)	8/13 (61,5)	0,84 [0,48; 1,48]	0,67 [0,17; 2,59]	-9,69 [-42,16; 22,79]
				0,737	
≥5 years	19/32 (59,4)	7/15 (46,7)	1,27 [0,69; 2,35]	1,67 [0,49; 5,75]	12,71 [-17,74; 43,15]
				0,533	
Baseline disease location (p-value of the interaction test: 0,191)					
Colonic	14/25 (56,0)	14/19 (73,7)	0,76 [0,49; 1,18]	0,45 [0,13; 1,65]	-17,68 [-45,44; 10,08]
				0,344	
Ileal	5/7 (71,4)	1/5 (20,0)	3,57 [0,58; 21,92]	10,00 [0,65; >100]	51,43 [2,96; 99,90]
				0,242	
Ileal-Colonic	18/36 (50,0)	6/9 (66,7)	0,75 [0,43; 1,32]	0,50 [0,11; 2,31]	-16,67 [-51,53; 18,19]
				0,469	
Baseline fecal calprotectin (p-value of the interaction test: 0,933)					
≤250	5/15 (33,3)	1/3 (33,3)	1,00 [0,17; 5,77]	1,00 [0,07; 13,87]	0,00 [-58,43; 58,43]
				1,000	
>250	27/42 (64,3)	14/22 (63,6)	1,01 [0,69; 1,49]	1,03 [0,35; 3,01]	0,65 [-24,13; 25,43]
				1,000	
Baseline CRP (p-value of the interaction test: 0,783)					
≤10	23/49 (46,9)	14/26 (53,8)	0,87 [0,55; 1,39]	0,76 [0,29; 1,97]	-6,91 [-30,62; 16,81]
				0,632	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
>10	14/19 (73,7)	7/9 (77,8)	0,95 [0,61; 1,47]	0,80 [0,12; 5,21]	-4,09 [-37,71; 29,52]
1,000					
Baseline SES-CD total score (p-value of the interaction test: 0,443)					
<12	25/45 (55,6)	10/18 (55,6)	1,00 [0,61; 1,63]	1,00 [0,33; 3,00]	0,00 [-27,16; 27,16]
1,000					
≥12	12/23 (52,2)	11/15 (73,3)	0,71 [0,43; 1,17]	0,40 [0,10; 1,62]	-21,16 [-51,45; 9,13]
0,310					
Baseline AP average (p-value of the interaction test: 0,597)					
<2	7/15 (46,7)	5/11 (45,5)	1,03 [0,44; 2,39]	1,05 [0,22; 5,00]	1,21 [-37,56; 39,98]
1,000					
≥2	30/53 (56,6)	16/24 (66,7)	0,85 [0,59; 1,23]	0,65 [0,24; 1,79]	-10,06 [-33,17; 13,04]
0,460					
Baseline SF average (p-value of the interaction test: 0,664)					
<7	28/55 (50,9)	15/27 (55,6)	0,92 [0,60; 1,40]	0,83 [0,33; 2,09]	-4,65 [-27,58; 18,29]
0,815					
≥7	9/13 (69,2)	6/8 (75,0)	0,92 [0,54; 1,58]	0,75 [0,10; 5,47]	-5,77 [-44,88; 33,34]
1,000					
Baseline CDAI 1 (p-value of the interaction test: 0,274)					
<300	14/29 (48,3)	6/14 (42,9)	1,13 [0,55; 2,30]	1,24 [0,34; 4,50]	5,42 [-26,25; 37,08]
1,000					
≥300	23/39 (59,0)	15/21 (71,4)	0,83 [0,57; 1,20]	0,58 [0,18; 1,80]	-12,45 [-37,19; 12,28]
0,408					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
				p-Wert ^a	
OECD Country (p-value of the interaction test: 0,633)					
Yes	25/47 (53,2)	13/24 (54,2)	0,98 [0,62; 1,55]	0,96 [0,36; 2,58]	-0,98 [-25,49; 23,54]
			1,000		
No	12/21 (57,1)	8/11 (72,7)	0,79 [0,47; 1,32]	0,50 [0,10; 2,44]	-15,58 [-49,36; 18,19]
			0,465		
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; EIMs: Extra-Intestinal Manifestations; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_eimsresa_sub_eim_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

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Anhang 4-G.3.6.1.3 Gesundheitszustand**Gesundheitszustand – EQ-5D VAS**

Subgruppen für Increase in EQ-5D VAS Score by at least 15 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,574)					
<65 years	169/322 (52,5)	87/160 (54,4)	0,97 [0,81; 1,15]	0,93 [0,63; 1,36]	-1,89 [-11,34; 7,56]
			0,700		
≥65 years	2/9 (22,2)	2/4 (50,0)	0,44 [0,09; 2,13]	0,29 [0,02; 3,52]	-27,78 [-83,80; 28,25]
			0,530		
Age 2 (p-value of the interaction test: 0,265)					
<40 years	117/210 (55,7)	54/101 (53,5)	1,04 [0,84; 1,30]	1,09 [0,68; 1,76]	2,25 [-9,57; 14,07]
			0,717		
≥40 years	54/121 (44,6)	35/63 (55,6)	0,80 [0,60; 1,08]	0,64 [0,35; 1,19]	-10,93 [-26,06; 4,21]
			0,166		
Sex (p-value of the interaction test: 0,462)					
Male	92/178 (51,7)	42/83 (50,6)	1,02 [0,79; 1,32]	1,04 [0,62; 1,76]	1,08 [-11,94; 14,11]
			0,895		
Female	79/153 (51,6)	47/81 (58,0)	0,89 [0,70; 1,13]	0,77 [0,45; 1,33]	-6,39 [-19,74; 6,96]
			0,409		
Race (p-value of the interaction test: 0,705)					
White	136/268 (50,7)	73/137 (53,3)	0,95 [0,78; 1,16]	0,90 [0,60; 1,36]	-2,54 [-12,82; 7,74]
			0,675		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Other	35/62 (56,5)	16/26 (61,5)	0,92 [0,63; 1,33]	0,81 [0,32; 2,07]	-5,09 [-27,49; 17,32]
0,813					
Geographic region 1 (p-value of the interaction test: 0,521)					
Europe	121/224 (54,0)	64/121 (52,9)	1,02 [0,83; 1,26]	1,05 [0,67; 1,63]	1,13 [-9,91; 12,16]
0,910					
North America	13/31 (41,9)	7/13 (53,8)	0,78 [0,41; 1,49]	0,62 [0,17; 2,28]	-11,91 [-44,10; 20,28]
0,522					
Other	37/76 (48,7)	18/30 (60,0)	0,81 [0,56; 1,18]	0,63 [0,27; 1,49]	-11,32 [-32,14; 9,51]
0,389					
Geographic region 2 (p-value of the interaction test: 0,284)					
Asia	33/58 (56,9)	12/23 (52,2)	1,09 [0,69; 1,71]	1,21 [0,46; 3,19]	4,72 [-19,34; 28,79]
0,805					
Central America/South America	3/11 (27,3)	6/7 (85,7)	0,32 [0,12; 0,87]	0,06 [0,01; 0,76]	-58,44 [-95,38; -21,50]
0,050					
Europe and ROW	122/231 (52,8)	64/121 (52,9)	1,00 [0,81; 1,23]	1,00 [0,64; 1,55]	-0,08 [-11,06; 10,90]
1,000					
North America	13/31 (41,9)	7/13 (53,8)	0,78 [0,41; 1,49]	0,62 [0,17; 2,28]	-11,91 [-44,10; 20,28]
0,522					
Weight (p-value of the interaction test: 0,699)					
<100 kg	162/309 (52,4)	85/153 (55,6)	0,94 [0,79; 1,13]	0,88 [0,60; 1,30]	-3,13 [-12,77; 6,52]
0,553					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
≥100 kg	9/22 (40,9)	4/11 (36,4)	1,13 [0,44; 2,85]	1,21 [0,27; 5,40]	4,55 [-30,53; 39,62]
1,000					
BMI (p-value of the interaction test: 0,533)					
Underweight ($<18.5 \text{ kg/m}^2$)	32/59 (54,2)	12/23 (52,2)	1,04 [0,66; 1,64]	1,09 [0,41; 2,85]	2,06 [-21,99; 26,11]
1,000					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	74/157 (47,1)	51/92 (55,4)	0,85 [0,66; 1,09]	0,72 [0,43; 1,20]	-8,30 [-21,11; 4,51]
0,238					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	39/68 (57,4)	16/28 (57,1)	1,00 [0,69; 1,47]	1,01 [0,41; 2,45]	0,21 [-21,57; 21,99]
1,000					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	26/47 (55,3)	10/21 (47,6)	1,16 [0,69; 1,95]	1,36 [0,49; 3,82]	7,70 [-17,96; 33,36]
0,606					
Tobacco use (p-value of the interaction test: 0,946)					
Current	40/76 (52,6)	19/32 (59,4)	0,89 [0,62; 1,27]	0,76 [0,33; 1,76]	-6,74 [-27,13; 13,64]
0,535					
Former	25/46 (54,3)	16/29 (55,2)	0,99 [0,65; 1,50]	0,97 [0,38; 2,46]	-0,82 [-23,95; 22,30]
1,000					
Never	106/209 (50,7)	54/103 (52,4)	0,97 [0,77; 1,21]	0,93 [0,58; 1,50]	-1,71 [-13,50; 10,08]
0,810					
Prior biologic exposure (p-value of the interaction test: 0,863)					
Ever	16/36 (44,4)	6/12 (50,0)	0,89 [0,45; 1,74]	0,80 [0,22; 2,96]	-5,56 [-38,17; 27,06]
0,751					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Never	155/295 (52,5)	83/152 (54,6)	0,96 [0,80; 1,15]	0,92 [0,62; 1,36]	-2,06 [-11,82; 7,69]
0,690					
Baseline corticosteroid use (p-value of the interaction test: 0,875)					
Yes	62/113 (54,9)	33/56 (58,9)	0,93 [0,71; 1,23]	0,85 [0,44; 1,62]	-4,06 [-19,88; 11,76]
0,626					
No	109/218 (50,0)	56/108 (51,9)	0,96 [0,77; 1,21]	0,93 [0,59; 1,47]	-1,85 [-13,38; 9,67]
0,814					
Baseline immunomodulator use (p-value of the interaction test: 0,371)					
Yes	51/102 (50,0)	32/53 (60,4)	0,83 [0,62; 1,11]	0,66 [0,33; 1,29]	-10,38 [-26,73; 5,98]
0,239					
No	120/229 (52,4)	57/111 (51,4)	1,02 [0,82; 1,27]	1,04 [0,66; 1,64]	1,05 [-10,28; 12,38]
0,908					
Duration of CD (p-value of the interaction test: 0,237)					
<1 year	33/71 (46,5)	18/33 (54,5)	0,85 [0,57; 1,27]	0,72 [0,32; 1,66]	-8,07 [-28,64; 12,51]
0,529					
≥1 to <5 years	81/132 (61,4)	39/71 (54,9)	1,12 [0,87; 1,44]	1,30 [0,73; 2,34]	6,43 [-7,81; 20,68]
0,454					
≥5 years	56/127 (44,1)	32/60 (53,3)	0,83 [0,61; 1,12]	0,69 [0,37; 1,28]	-9,24 [-24,53; 6,06]
0,273					
Baseline disease location (p-value of the interaction test: 0,509)					
Colonic	78/135 (57,8)	47/73 (64,4)	0,90 [0,72; 1,12]	0,76 [0,42; 1,36]	-6,61 [-20,39; 7,18]
0,377					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Ileal	18/41 (43,9)	8/24 (33,3)	1,32 [0,68; 2,56]	1,57 [0,55; 4,47]	10,57 [-13,65; 34,79]
			0,443		
Ileal-Colonic	75/155 (48,4)	34/65 (52,3)	0,93 [0,70; 1,23]	0,85 [0,48; 1,53]	-3,92 [-18,39; 10,55]
			0,658		
Baseline fecal calprotectin (p-value of the interaction test: 0,907)					
≤250	25/57 (43,9)	12/24 (50,0)	0,88 [0,53; 1,44]	0,78 [0,30; 2,03]	-6,14 [-29,93; 17,65]
			0,634		
>250	112/203 (55,2)	61/103 (59,2)	0,93 [0,76; 1,14]	0,85 [0,52; 1,37]	-4,05 [-15,75; 7,65]
			0,543		
Baseline SES-CD total score (p-value of the interaction test: 0,557)					
<12	94/200 (47,0)	46/96 (47,9)	0,98 [0,76; 1,27]	0,96 [0,59; 1,57]	-0,92 [-13,07; 11,24]
			0,902		
≥12	77/131 (58,8)	43/66 (65,2)	0,90 [0,72; 1,13]	0,76 [0,41; 1,41]	-6,37 [-20,63; 7,88]
			0,441		
Baseline AP average (p-value of the interaction test: 0,345)					
<2	26/70 (37,1)	17/35 (48,6)	0,76 [0,48; 1,21]	0,63 [0,28; 1,42]	-11,43 [-31,49; 8,63]
			0,297		
≥2	145/260 (55,8)	72/129 (55,8)	1,00 [0,83; 1,21]	1,00 [0,65; 1,53]	-0,04 [-10,53; 10,44]
			1,000		
Baseline SF average (p-value of the interaction test: 0,574)					
<7	136/265 (51,3)	69/125 (55,2)	0,93 [0,76; 1,13]	0,86 [0,56; 1,31]	-3,88 [-14,47; 6,71]
			0,515		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
≥ 7	35/65 (53,8)	20/39 (51,3)	1,05 [0,72; 1,54]	1,11 [0,50; 2,45]	2,56 [-17,26; 22,39]
0,841					
Baseline CDAI 1 (p-value of the interaction test: 0,785)					
<300	69/148 (46,6)	37/75 (49,3)	0,95 [0,71; 1,26]	0,90 [0,51; 1,56]	-2,71 [-16,59; 11,17]
0,777					
≥ 300	102/182 (56,0)	52/89 (58,4)	0,96 [0,77; 1,19]	0,91 [0,54; 1,52]	-2,38 [-14,91; 10,14]
0,794					
Baseline CDAI 2 (p-value of the interaction test: 0,685)					
<150	0/5 (0,0)	2/6 (33,3)	0,23 [0,01; 3,97]	0,16 [0,01; 4,36]	-33,33 [-71,05; 4,39]
0,455					
≥ 150 and <220	11/27 (40,7)	7/18 (38,9)	1,05 [0,50; 2,19]	1,08 [0,32; 3,66]	1,85 [-27,31; 31,02]
1,000					
≥ 220 and <450	147/275 (53,5)	69/125 (55,2)	0,97 [0,80; 1,17]	0,93 [0,61; 1,43]	-1,75 [-12,27; 8,78]
0,829					
≥ 450	13/23 (56,5)	11/15 (73,3)	0,77 [0,48; 1,23]	0,47 [0,12; 1,94]	-16,81 [-47,00; 13,38]
0,329					
OECD Country (p-value of the interaction test: 0,775)					
Yes	99/209 (47,4)	47/94 (50,0)	0,95 [0,74; 1,21]	0,90 [0,55; 1,46]	-2,63 [-14,80; 9,53]
0,710					
No	72/122 (59,0)	42/70 (60,0)	0,98 [0,77; 1,25]	0,96 [0,53; 1,75]	-0,98 [-15,40; 13,43]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
				p-Wert ^a	
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; EQ-5D: Fragebogen der EuroQoI-Gruppe zur Lebensqualität auf 5 Dimensionen; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; VAS: Visuelle Analogskala. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_vasi15_sub_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba
20DEC2024 / 04:00

Gesundheitszustand – PGRS

Subgruppen für Reduction in PGRS score by at least 1 point in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,383)					
<65 years	223/322 (69,3)	97/160 (60,6)	1,14 [0,99; 1,32]	1,46 [0,98; 2,17]	8,63 [-0,47; 17,72]
			0,066		
≥65 years	5/9 (55,6)	3/4 (75,0)	0,74 [0,33; 1,67]	0,42 [0,03; 5,71]	-19,44 [-72,87; 33,98]
			1,000		
Age 2 (p-value of the interaction test: 0,580)					
<40 years	149/210 (71,0)	62/101 (61,4)	1,16 [0,97; 1,38]	1,54 [0,93; 2,53]	9,57 [-1,74; 20,87]
			0,094		
≥40 years	79/121 (65,3)	38/63 (60,3)	1,08 [0,85; 1,37]	1,24 [0,66; 2,32]	4,97 [-9,79; 19,73]
			0,522		
Sex (p-value of the interaction test: 0,878)					
Male	131/178 (73,6)	55/83 (66,3)	1,11 [0,93; 1,33]	1,42 [0,81; 2,49]	7,33 [-4,73; 19,39]
			0,242		
Female	97/153 (63,4)	45/81 (55,6)	1,14 [0,91; 1,43]	1,39 [0,80; 2,40]	7,84 [-5,40; 21,09]
			0,262		
Race (p-value of the interaction test: 0,245)					
White	180/268 (67,2)	85/137 (62,0)	1,08 [0,93; 1,26]	1,25 [0,81; 1,92]	5,12 [-4,76; 15,00]
			0,322		
Other	47/62 (75,8)	15/26 (57,7)	1,31 [0,92; 1,88]	2,30 [0,87; 6,07]	18,11 [-3,66; 39,89]
			0,124		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,326)					
Europe	152/224 (67,9)	77/121 (63,6)	1,07 [0,91; 1,25]	1,21 [0,76; 1,92]	4,22 [-6,31; 14,75]
				0,474	
North America	22/31 (71,0)	8/13 (61,5)	1,15 [0,71; 1,87]	1,53 [0,39; 5,95]	9,43 [-21,47; 40,33]
				0,724	
Other	54/76 (71,1)	15/30 (50,0)	1,42 [0,97; 2,09]	2,45 [1,03; 5,86]	21,05 [0,46; 41,65]
				0,046	
Geographic region 2 (p-value of the interaction test: 0,382)					
Asia	41/58 (70,7)	12/23 (52,2)	1,35 [0,89; 2,07]	2,21 [0,82; 5,98]	18,52 [-5,02; 42,05]
				0,128	
Central America/South America	9/11 (81,8)	3/7 (42,9)	1,91 [0,78; 4,69]	6,00 [0,70; 51,10]	38,96 [-4,21; 82,13]
				0,141	
Europe and ROW	156/231 (67,5)	77/121 (63,6)	1,06 [0,90; 1,25]	1,19 [0,75; 1,89]	3,90 [-6,59; 14,38]
				0,478	
North America	22/31 (71,0)	8/13 (61,5)	1,15 [0,71; 1,87]	1,53 [0,39; 5,95]	9,43 [-21,47; 40,33]
				0,724	
Weight (p-value of the interaction test: 0,490)					
<100 kg	213/309 (68,9)	92/153 (60,1)	1,15 [0,99; 1,33]	1,47 [0,98; 2,20]	8,80 [-0,52; 18,12]
				0,076	
≥100 kg	15/22 (68,2)	8/11 (72,7)	0,94 [0,59; 1,49]	0,80 [0,16; 3,99]	-4,55 [-37,28; 28,19]
				1,000	
BMI (p-value of the interaction test: 0,194)					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Underweight (<18.5 kg/m ²)	36/59 (61,0)	16/23 (69,6)	0,88 [0,63; 1,23]	0,68 [0,24; 1,92]	-8,55 [-31,10; 14,00]
			0,611		
Normal (≥18.5 and <25 kg/m ²)	110/157 (70,1)	49/92 (53,3)	1,32 [1,06; 1,63]	2,05 [1,20; 3,50]	16,80 [4,34; 29,26]
			0,009		
Overweight (≥25 and <30 kg/m ²)	47/68 (69,1)	22/28 (78,6)	0,88 [0,68; 1,13]	0,61 [0,22; 1,73]	-9,45 [-28,20; 9,30]
			0,456		
Obese and Extreme obese (≥30 kg/m ²)	35/47 (74,5)	13/21 (61,9)	1,20 [0,83; 1,75]	1,79 [0,60; 5,38]	12,56 [-11,66; 36,79]
			0,389		
Tobacco use (p-value of the interaction test: 0,278)					
Current	53/76 (69,7)	17/32 (53,1)	1,31 [0,92; 1,88]	2,03 [0,87; 4,75]	16,61 [-3,53; 36,75]
			0,124		
Former	28/46 (60,9)	20/29 (69,0)	0,88 [0,63; 1,24]	0,70 [0,26; 1,87]	-8,10 [-30,06; 13,87]
			0,622		
Never	147/209 (70,3)	63/103 (61,2)	1,15 [0,96; 1,37]	1,51 [0,92; 2,47]	9,17 [-2,10; 20,44]
			0,124		
Prior biologic exposure (p-value of the interaction test: 0,878)					
Ever	26/36 (72,2)	8/12 (66,7)	1,08 [0,69; 1,70]	1,30 [0,32; 5,30]	5,56 [-24,87; 35,98]
			0,726		
Never	202/295 (68,5)	92/152 (60,5)	1,13 [0,97; 1,31]	1,42 [0,94; 2,13]	7,95 [-1,46; 17,36]
			0,114		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline corticosteroid use (p-value of the interaction test: 0,591)					
Yes	79/113 (69,9)	33/56 (58,9)	1,19 [0,92; 1,52]	1,62 [0,83; 3,16]	10,98 [-4,43; 26,40]
				0,170	
No	149/218 (68,3)	67/108 (62,0)	1,10 [0,93; 1,31]	1,32 [0,82; 2,14]	6,31 [-4,73; 17,35]
				0,265	
Baseline immunomodulator use (p-value of the interaction test: 0,527)					
Yes	74/102 (72,5)	33/53 (62,3)	1,17 [0,92; 1,48]	1,60 [0,79; 3,24]	10,28 [-5,38; 25,95]
				0,204	
No	154/229 (67,2)	67/111 (60,4)	1,11 [0,93; 1,33]	1,35 [0,84; 2,16]	6,89 [-4,05; 17,83]
				0,227	
Duration of CD (p-value of the interaction test: 0,255)					
<1 year	47/71 (66,2)	22/33 (66,7)	0,99 [0,74; 1,33]	0,98 [0,41; 2,35]	-0,47 [-19,96; 19,02]
				1,000	
≥1 to <5 years	95/132 (72,0)	39/71 (54,9)	1,31 [1,03; 1,66]	2,11 [1,15; 3,85]	17,04 [3,16; 30,92]
				0,020	
≥5 years	85/127 (66,9)	39/60 (65,0)	1,03 [0,82; 1,29]	1,09 [0,57; 2,08]	1,93 [-12,65; 16,51]
				0,869	
Baseline disease location (p-value of the interaction test: 0,542)					
Colonic	94/135 (69,6)	45/73 (61,6)	1,13 [0,91; 1,40]	1,43 [0,78; 2,59]	7,99 [-5,60; 21,57]
				0,281	
Ileal	31/41 (75,6)	14/24 (58,3)	1,30 [0,89; 1,90]	2,21 [0,75; 6,52]	17,28 [-6,43; 40,98]
				0,172	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Ileal-Colonic	103/155 (66,5)	41/65 (63,1)	1,05 [0,85; 1,31]	1,16 [0,63; 2,12]	3,37 [-10,51; 17,26]
0,644					
Baseline fecal calprotectin (p-value of the interaction test: 0,514)					
≤250	41/57 (71,9)	15/24 (62,5)	1,15 [0,81; 1,63]	1,54 [0,56; 4,21]	9,43 [-13,18; 32,04]
0,437					
>250	141/203 (69,5)	67/103 (65,0)	1,07 [0,90; 1,26]	1,22 [0,74; 2,02]	4,41 [-6,77; 15,59]
0,440					
Baseline SES-CD total score (p-value of the interaction test: 0,344)					
<12	136/200 (68,0)	62/96 (64,6)	1,05 [0,88; 1,26]	1,17 [0,70; 1,95]	3,42 [-8,13; 14,96]
0,599					
≥12	92/131 (70,2)	38/66 (57,6)	1,22 [0,96; 1,54]	1,74 [0,94; 3,22]	12,65 [-1,61; 26,92]
0,082					
Baseline AP average (p-value of the interaction test: 0,890)					
<2	35/70 (50,0)	14/35 (40,0)	1,25 [0,78; 2,00]	1,50 [0,66; 3,41]	10,00 [-10,02; 30,02]
0,408					
≥2	193/260 (74,2)	86/129 (66,7)	1,11 [0,97; 1,28]	1,44 [0,91; 2,28]	7,56 [-2,15; 17,28]
0,122					
Baseline SF average (p-value of the interaction test: 0,328)					
<7	179/265 (67,5)	77/125 (61,6)	1,10 [0,93; 1,29]	1,30 [0,83; 2,02]	5,95 [-4,27; 16,17]
0,255					
≥7	49/65 (75,4)	23/39 (59,0)	1,28 [0,95; 1,72]	2,13 [0,91; 4,99]	16,41 [-2,24; 35,06]
0,085					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline CDAI 1 (p-value of the interaction test: 0,185)					
<300	91/148 (61,5)	45/75 (60,0)	1,02 [0,82; 1,28]	1,06 [0,60; 1,88]	1,49 [-12,09; 15,07]
			0,885		
≥300	137/182 (75,3)	55/89 (61,8)	1,22 [1,01; 1,46]	1,88 [1,09; 3,24]	13,48 [1,59; 25,36]
			0,024		
Baseline CDAI 2 (p-value of the interaction test: 0,573)					
<150	1/5 (20,0)	2/6 (33,3)	0,60 [0,07; 4,83]	0,50 [0,03; 7,99]	-13,33 [-64,83; 38,16]
			1,000		
≥150 and <220	14/27 (51,9)	10/18 (55,6)	0,93 [0,54; 1,62]	0,86 [0,26; 2,85]	-3,70 [-33,40; 26,00]
			1,000		
≥220 and <450	196/275 (71,3)	76/125 (60,8)	1,17 [1,00; 1,37]	1,60 [1,03; 2,49]	10,47 [0,38; 20,56]
			0,049		
≥450	17/23 (73,9)	12/15 (80,0)	0,92 [0,65; 1,31]	0,71 [0,15; 3,41]	-6,09 [-33,14; 20,96]
			1,000		
OECD Country (p-value of the interaction test: 0,240)					
Yes	147/209 (70,3)	54/94 (57,4)	1,22 [1,01; 1,49]	1,76 [1,06; 2,91]	12,89 [1,13; 24,65]
			0,035		
No	81/122 (66,4)	46/70 (65,7)	1,01 [0,82; 1,25]	1,03 [0,55; 1,92]	0,68 [-13,25; 14,60]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PGRS: Patient Global Rating of Severity; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_pgarsi1_sub_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

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Gesundheitszustand – PGIC

Subgruppen für Reaching a value of 1 or 2 or 3 of PGIC Score in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,785)					
<65 years	257/322 (79,8)	134/160 (83,8)	0,95 [0,87; 1,04]	0,77 [0,47; 1,27]	-3,94 [-11,14; 3,27]
			0,325		
≥65 years	5/9 (55,6)	3/4 (75,0)	0,74 [0,33; 1,67]	0,42 [0,03; 5,71]	-19,44 [-72,87; 33,98]
			1,000		
Age 2 (p-value of the interaction test: 0,167)					
<40 years	172/210 (81,9)	83/101 (82,2)	1,00 [0,89; 1,11]	0,98 [0,53; 1,82]	-0,27 [-9,37; 8,83]
			1,000		
≥40 years	90/121 (74,4)	54/63 (85,7)	0,87 [0,75; 1,00]	0,48 [0,21; 1,09]	-11,33 [-22,96; 0,29]
			0,091		
Sex (p-value of the interaction test: 0,621)					
Male	150/178 (84,3)	75/83 (90,4)	0,93 [0,85; 1,03]	0,57 [0,25; 1,31]	-6,09 [-14,39; 2,21]
			0,247		
Female	112/153 (73,2)	62/81 (76,5)	0,96 [0,82; 1,12]	0,84 [0,45; 1,57]	-3,34 [-14,93; 8,25]
			0,639		
Geographic region 1 (p-value of the interaction test: 0,803)					
Europe	175/224 (78,1)	100/121 (82,6)	0,95 [0,85; 1,05]	0,75 [0,43; 1,32]	-4,52 [-13,17; 4,13]
			0,400		
North America	22/31 (71,0)	11/13 (84,6)	0,84 [0,61; 1,16]	0,44 [0,08; 2,42]	-13,65 [-38,95; 11,65]
			0,461		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Other	65/76 (85,5)	26/30 (86,7)	0,99 [0,83; 1,17]	0,91 [0,27; 3,11]	-1,14 [-15,65; 13,37]
1,000					
Geographic region 2 (p-value of the interaction test: 0,571)					
Asia	51/58 (87,9)	19/23 (82,6)	1,06 [0,86; 1,31]	1,53 [0,40; 5,84]	5,32 [-12,29; 22,94]
0,498					
Central America/South America	9/11 (81,8)	7/7 (100)	0,84 [0,60; 1,19]	0,25 [0,01; 6,11]	-18,18 [-40,97; 4,61]
0,497					
Europe and ROW	180/231 (77,9)	100/121 (82,6)	0,94 [0,85; 1,05]	0,74 [0,42; 1,30]	-4,72 [-13,33; 3,89]
0,332					
North America	22/31 (71,0)	11/13 (84,6)	0,84 [0,61; 1,16]	0,44 [0,08; 2,42]	-13,65 [-38,95; 11,65]
0,461					
Weight (p-value of the interaction test: 0,836)					
<100 kg	244/309 (79,0)	127/153 (83,0)	0,95 [0,87; 1,04]	0,77 [0,46; 1,27]	-4,04 [-11,53; 3,45]
0,323					
≥100 kg	18/22 (81,8)	10/11 (90,9)	0,90 [0,69; 1,18]	0,45 [0,04; 4,60]	-9,09 [-32,51; 14,33]
0,643					
BMI (p-value of the interaction test: 0,211)					
Underweight (<18.5 kg/m ²)	45/59 (76,3)	19/23 (82,6)	0,92 [0,73; 1,17]	0,68 [0,20; 2,32]	-6,34 [-25,25; 12,58]
0,767					
Normal (≥18.5 and <25 kg/m ²)	123/157 (78,3)	74/92 (80,4)	0,97 [0,86; 1,11]	0,88 [0,46; 1,67]	-2,09 [-12,45; 8,26]
0,749					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Overweight (≥25 and <30 kg/m²)	54/68 (79,4)	28/28 (100)	0,80 [0,71; 0,92]	0,07 [0,00; 1,15]	-20,59 [-30,20; -10,98]
			0,009		
Obese and Extreme obese (≥30 kg/m²)	40/47 (85,1)	16/21 (76,2)	1,12 [0,85; 1,46]	1,79 [0,49; 6,46]	8,92 [-11,95; 29,78]
			0,493		
Tobacco use (p-value of the interaction test: 0,549)					
Current	62/76 (81,6)	26/32 (81,3)	1,00 [0,82; 1,22]	1,02 [0,35; 2,95]	0,33 [-15,76; 16,42]
			1,000		
Former	33/46 (71,7)	25/29 (86,2)	0,83 [0,66; 1,05]	0,41 [0,12; 1,40]	-14,47 [-32,55; 3,61]
			0,169		
Never	167/209 (79,9)	86/103 (83,5)	0,96 [0,86; 1,07]	0,79 [0,42; 1,46]	-3,59 [-12,59; 5,40]
			0,539		
Prior biologic exposure (p-value of the interaction test: 0,780)					
Ever	29/36 (80,6)	11/12 (91,7)	0,88 [0,70; 1,11]	0,38 [0,04; 3,42]	-11,11 [-31,40; 9,18]
			0,659		
Never	233/295 (79,0)	126/152 (82,9)	0,95 [0,87; 1,05]	0,78 [0,47; 1,29]	-3,91 [-11,49; 3,67]
			0,380		
Baseline corticosteroid use (p-value of the interaction test: 0,825)					
Yes	90/113 (79,6)	47/56 (83,9)	0,95 [0,82; 1,10]	0,75 [0,32; 1,75]	-4,28 [-16,43; 7,87]
			0,540		
No	172/218 (78,9)	90/108 (83,3)	0,95 [0,85; 1,06]	0,75 [0,41; 1,36]	-4,43 [-13,31; 4,44]
			0,377		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline immunomodulator use (p-value of the interaction test: 0,505)					
Yes	84/102 (82,4)	48/53 (90,6)	0,91 [0,80; 1,03]	0,49 [0,17; 1,39]	-8,21 [-19,01; 2,59]
			0,235		
No	178/229 (77,7)	89/111 (80,2)	0,97 [0,86; 1,09]	0,86 [0,49; 1,51]	-2,45 [-11,62; 6,72]
			0,674		
Duration of CD (p-value of the interaction test: 0,933)					
<1 year	53/71 (74,6)	27/33 (81,8)	0,91 [0,74; 1,13]	0,65 [0,23; 1,84]	-7,17 [-23,77; 9,43]
			0,465		
≥1 to <5 years	109/132 (82,6)	60/71 (84,5)	0,98 [0,86; 1,11]	0,87 [0,40; 1,90]	-1,93 [-12,55; 8,69]
			0,845		
≥5 years	99/127 (78,0)	50/60 (83,3)	0,94 [0,81; 1,08]	0,71 [0,32; 1,57]	-5,38 [-17,25; 6,49]
			0,442		
Baseline disease location (p-value of the interaction test: 0,597)					
Colonic	107/135 (79,3)	63/73 (86,3)	0,92 [0,81; 1,04]	0,61 [0,28; 1,33]	-7,04 [-17,48; 3,40]
			0,261		
Ileal	32/41 (78,0)	18/24 (75,0)	1,04 [0,78; 1,38]	1,19 [0,36; 3,87]	3,05 [-18,41; 24,51]
			0,770		
Ileal-Colonic	123/155 (79,4)	56/65 (86,2)	0,92 [0,81; 1,05]	0,62 [0,28; 1,38]	-6,80 [-17,34; 3,74]
			0,262		
Baseline fecal calprotectin (p-value of the interaction test: 0,704)					
≤250	42/57 (73,7)	20/24 (83,3)	0,88 [0,70; 1,12]	0,56 [0,16; 1,91]	-9,65 [-28,44; 9,14]
			0,405		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
>250	167/203 (82,3)	86/103 (83,5)	0,99 [0,89; 1,10]	0,92 [0,49; 1,73]	-1,23 [-10,12; 7,66]
0,874					
Baseline CRP (p-value of the interaction test: 0,096)					
≤10	169/217 (77,9)	93/108 (86,1)	0,90 [0,82; 1,00]	0,57 [0,30; 1,07]	-8,23 [-16,78; 0,32]
0,101					
>10	93/114 (81,6)	44/56 (78,6)	1,04 [0,88; 1,22]	1,21 [0,55; 2,67]	3,01 [-9,88; 15,90]
0,682					
Baseline SES-CD total score (p-value of the interaction test: 0,622)					
<12	157/200 (78,5)	82/96 (85,4)	0,92 [0,82; 1,03]	0,62 [0,32; 1,21]	-6,92 [-15,99; 2,15]
0,207					
≥12	105/131 (80,2)	55/66 (83,3)	0,96 [0,84; 1,10]	0,81 [0,37; 1,76]	-3,18 [-14,47; 8,11]
0,700					
Baseline AP average (p-value of the interaction test: 0,159)					
<2	53/70 (75,7)	32/35 (91,4)	0,83 [0,70; 0,98]	0,29 [0,08; 1,08]	-15,71 [-29,39; -2,04]
0,066					
≥2	209/260 (80,4)	105/129 (81,4)	0,99 [0,89; 1,09]	0,94 [0,55; 1,61]	-1,01 [-9,28; 7,26]
0,892					
Baseline SF average (p-value of the interaction test: 0,415)					
<7	211/265 (79,6)	103/125 (82,4)	0,97 [0,87; 1,07]	0,83 [0,48; 1,44]	-2,78 [-11,03; 5,47]
0,585					
≥7	51/65 (78,5)	34/39 (87,2)	0,90 [0,76; 1,07]	0,54 [0,18; 1,62]	-8,72 [-23,21; 5,77]
0,306					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline CDAI 1 (p-value of the interaction test: 0,398)					
<300	118/148 (79,7)	66/75 (88,0)	0,91 [0,81; 1,02]	0,54 [0,24; 1,20]	-8,27 [-18,07; 1,53]
			0,139		
≥300	144/182 (79,1)	71/89 (79,8)	0,99 [0,87; 1,13]	0,96 [0,51; 1,80]	-0,65 [-10,88; 9,57]
			1,000		
OECD Country (p-value of the interaction test: 0,932)					
Yes	163/209 (78,0)	77/94 (81,9)	0,95 [0,85; 1,07]	0,78 [0,42; 1,45]	-3,92 [-13,52; 5,67]
			0,541		
No	99/122 (81,1)	60/70 (85,7)	0,95 [0,83; 1,08]	0,72 [0,32; 1,61]	-4,57 [-15,31; 6,17]
			0,552		
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PGIC: Patient Global Impression of Change; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_pgici_sub_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Gesundheitszustand – WPAI-CD (Aktivitätsbeeinträchtigung)

Subgruppen für Reduction in percentage of impairment in activities by at least 15 percent-points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population, Participants with baseline employment status of Yes)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 2 (p-value of the interaction test: 0,859)					
<40 years	78/127 (61,4)	32/58 (55,2)	1,11 [0,85; 1,46]	1,29 [0,69; 2,43]	6,24 [-9,10; 21,59]
			0,425		
≥40 years	45/75 (60,0)	19/33 (57,6)	1,04 [0,74; 1,47]	1,11 [0,48; 2,54]	2,42 [-17,76; 22,61]
			0,834		
Sex (p-value of the interaction test: 0,528)					
Male	73/117 (62,4)	29/53 (54,7)	1,14 [0,86; 1,51]	1,37 [0,71; 2,65]	7,68 [-8,34; 23,70]
			0,399		
Female	50/85 (58,8)	22/38 (57,9)	1,02 [0,73; 1,41]	1,04 [0,48; 2,26]	0,93 [-17,94; 19,79]
			1,000		
Race (p-value of the interaction test: 0,871)					
White	106/174 (60,9)	44/80 (55,0)	1,11 [0,88; 1,40]	1,28 [0,75; 2,18]	5,92 [-7,17; 19,01]
			0,411		
Other	17/27 (63,0)	7/11 (63,6)	0,99 [0,58; 1,68]	0,97 [0,23; 4,17]	-0,67 [-34,44; 33,09]
			1,000		
Geographic region 1 (p-value of the interaction test: 0,549)					
Europe	94/149 (63,1)	36/68 (52,9)	1,19 [0,92; 1,54]	1,52 [0,85; 2,72]	10,15 [-4,02; 24,32]
			0,180		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
North America	9/17 (52,9)	5/7 (71,4)	0,74 [0,39; 1,42]	0,45 [0,07; 3,00]	-18,49 [-59,51; 22,54]
			0,653		
Other	20/36 (55,6)	10/16 (62,5)	0,89 [0,55; 1,44]	0,75 [0,22; 2,51]	-6,94 [-35,69; 21,80]
			0,765		
Geographic region 2 (p-value of the interaction test: 0,730)					
Asia	15/24 (62,5)	7/11 (63,6)	0,98 [0,57; 1,69]	0,95 [0,22; 4,19]	-1,14 [-35,53; 33,26]
			1,000		
Central America/South America	2/6 (33,3)	3/5 (60,0)	0,56 [0,15; 2,12]	0,33 [0,03; 3,93]	-26,67 [-83,82; 30,49]
			0,567		
Europe and ROW	97/155 (62,6)	36/68 (52,9)	1,18 [0,92; 1,53]	1,49 [0,84; 2,65]	9,64 [-4,46; 23,74]
			0,185		
North America	9/17 (52,9)	5/7 (71,4)	0,74 [0,39; 1,42]	0,45 [0,07; 3,00]	-18,49 [-59,51; 22,54]
			0,653		
Weight (p-value of the interaction test: 0,633)					
<100 kg	113/187 (60,4)	47/83 (56,6)	1,07 [0,86; 1,33]	1,17 [0,69; 1,97]	3,80 [-8,96; 16,56]
			0,593		
≥100 kg	10/15 (66,7)	4/8 (50,0)	1,33 [0,61; 2,91]	2,00 [0,35; 11,54]	16,67 [-25,40; 58,73]
			0,657		
BMI (p-value of the interaction test: 0,284)					
Underweight (<18.5 kg/m²)	11/23 (47,8)	8/10 (80,0)	0,60 [0,35; 1,01]	0,23 [0,04; 1,32]	-32,17 [-64,29; -0,06]
			0,131		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Normal (≥18.5 and <25 kg/m ²)	63/108 (58,3)	27/51 (52,9)	1,10 [0,81; 1,49]	1,24 [0,64; 2,43]	5,39 [-11,16; 21,95]
			0,608		
Overweight (≥25 and <30 kg/m ²)	30/42 (71,4)	11/19 (57,9)	1,23 [0,80; 1,89]	1,82 [0,59; 5,63]	13,53 [-12,53; 39,60]
			0,380		
Obese and Extreme obese (≥30 kg/m ²)	19/29 (65,5)	5/11 (45,5)	1,44 [0,72; 2,90]	2,28 [0,56; 9,36]	20,06 [-14,07; 54,20]
			0,295		
Tobacco use (p-value of the interaction test: 0,089)					
Current	39/58 (67,2)	8/19 (42,1)	1,60 [0,91; 2,79]	2,82 [0,97; 8,17]	25,14 [-0,14; 50,41]
			0,062		
Former	19/28 (67,9)	12/15 (80,0)	0,85 [0,59; 1,21]	0,53 [0,12; 2,35]	-12,14 [-38,77; 14,48]
			0,492		
Never	65/116 (56,0)	31/57 (54,4)	1,03 [0,77; 1,37]	1,07 [0,57; 2,02]	1,65 [-14,12; 17,42]
			0,872		
Prior biologic exposure (p-value of the interaction test: 0,732)					
Ever	16/24 (66,7)	2/4 (50,0)	1,33 [0,48; 3,70]	2,00 [0,24; 16,93]	16,67 [-35,84; 69,17]
			0,601		
Never	107/178 (60,1)	49/87 (56,3)	1,07 [0,86; 1,33]	1,17 [0,70; 1,96]	3,79 [-8,87; 16,45]
			0,596		
Baseline corticosteroid use (p-value of the interaction test: 0,831)					
Yes	41/65 (63,1)	17/29 (58,6)	1,08 [0,75; 1,54]	1,21 [0,49; 2,95]	4,46 [-16,97; 25,88]
			0,819		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
No	82/137 (59,9)	34/62 (54,8)	1,09 [0,84; 1,42]	1,23 [0,67; 2,25]	5,02 [-9,84; 19,88]
0,537					
Baseline immunomodulator use (p-value of the interaction test: 0,898)					
Yes	36/60 (60,0)	16/27 (59,3)	1,01 [0,70; 1,47]	1,03 [0,41; 2,60]	0,74 [-21,56; 23,04]
1,000					
No	87/142 (61,3)	35/64 (54,7)	1,12 [0,87; 1,45]	1,31 [0,72; 2,38]	6,58 [-8,01; 21,17]
0,444					
Duration of CD (p-value of the interaction test: 0,767)					
<1 year	22/36 (61,1)	11/17 (64,7)	0,94 [0,61; 1,46]	0,86 [0,26; 2,84]	-3,59 [-31,34; 24,15]
1,000					
≥1 to <5 years	48/79 (60,8)	22/38 (57,9)	1,05 [0,76; 1,45]	1,13 [0,51; 2,47]	2,86 [-16,17; 21,90]
0,841					
≥5 years	52/86 (60,5)	18/36 (50,0)	1,21 [0,84; 1,75]	1,53 [0,70; 3,35]	10,47 [-8,86; 29,79]
0,320					
Baseline disease location (p-value of the interaction test: 0,383)					
Colonic	52/80 (65,0)	23/42 (54,8)	1,19 [0,86; 1,63]	1,53 [0,72; 3,29]	10,24 [-8,09; 28,56]
0,329					
Ileal	11/21 (52,4)	6/12 (50,0)	1,05 [0,52; 2,10]	1,10 [0,27; 4,55]	2,38 [-33,07; 37,83]
1,000					
Ileal-Colonic	60/101 (59,4)	22/35 (62,9)	0,95 [0,70; 1,28]	0,86 [0,39; 1,91]	-3,45 [-22,11; 15,20]
0,842					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline fecal calprotectin (p-value of the interaction test: 0,714)					
≤250	22/35 (62,9)	6/11 (54,5)	1,15 [0,63; 2,09]	1,41 [0,36; 5,55]	8,31 [-25,19; 41,81]
				0,728	
>250	75/122 (61,5)	34/60 (56,7)	1,08 [0,83; 1,41]	1,22 [0,65; 2,29]	4,81 [-10,42; 20,03]
				0,630	
Baseline CRP (p-value of the interaction test: 0,806)					
≤10	81/137 (59,1)	35/66 (53,0)	1,11 [0,85; 1,46]	1,28 [0,71; 2,31]	6,09 [-8,49; 20,68]
				0,451	
>10	42/65 (64,6)	16/25 (64,0)	1,01 [0,72; 1,43]	1,03 [0,39; 2,69]	0,62 [-21,50; 22,73]
				1,000	
Baseline SES-CD total score (p-value of the interaction test: 0,255)					
<12	69/120 (57,5)	29/58 (50,0)	1,15 [0,85; 1,55]	1,35 [0,72; 2,54]	7,50 [-8,11; 23,11]
				0,422	
≥12	54/82 (65,9)	22/31 (71,0)	0,93 [0,71; 1,22]	0,79 [0,32; 1,94]	-5,11 [-24,11; 13,88]
				0,659	
Baseline AP average (p-value of the interaction test: 0,058)					
<2	21/44 (47,7)	14/22 (63,6)	0,75 [0,48; 1,17]	0,52 [0,18; 1,49]	-15,91 [-40,85; 9,03]
				0,297	
≥2	102/157 (65,0)	37/69 (53,6)	1,21 [0,95; 1,55]	1,60 [0,90; 2,85]	11,34 [-2,59; 25,28]
				0,137	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline SF average (p-value of the interaction test: 0,755)					
<7	97/162 (59,9)	44/80 (55,0)	1,09 [0,86; 1,38]	1,22 [0,71; 2,10]	4,88 [-8,38; 18,14]
				0,491	
≥7	26/39 (66,7)	7/11 (63,6)	1,05 [0,64; 1,73]	1,14 [0,28; 4,62]	3,03 [-29,02; 35,08]
				1,000	
Baseline CDAI 1 (p-value of the interaction test: 0,768)					
<300	57/98 (58,2)	26/49 (53,1)	1,10 [0,80; 1,50]	1,23 [0,62; 2,45]	5,10 [-11,95; 22,15]
				0,599	
≥300	66/103 (64,1)	25/42 (59,5)	1,08 [0,81; 1,44]	1,21 [0,58; 2,53]	4,55 [-12,95; 22,05]
				0,705	
OECD Country (p-value of the interaction test: 0,850)					
Yes	85/135 (63,0)	33/56 (58,9)	1,07 [0,83; 1,38]	1,18 [0,63; 2,24]	4,03 [-11,21; 19,28]
				0,626	
No	38/67 (56,7)	18/35 (51,4)	1,10 [0,75; 1,62]	1,24 [0,54; 2,81]	5,29 [-15,08; 25,66]
				0,677	
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_wpaii15p_sub_empl_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Allgemeinbefinden - CDAI-GWP

Subgruppen für Reduction in General well being score by at least 0.6 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Subgruppe			p-Wert ^a		
Age 1 (p-value of the interaction test: 0,723)					
<65 years	224/322 (69,6)	103/160 (64,4)	1,08 [0,94; 1,24]	1,26 [0,85; 1,89]	5,19 [-3,77; 14,15]
			0,256		
≥65 years	6/9 (66,7)	3/4 (75,0)	0,89 [0,43; 1,85]	0,67 [0,05; 9,47]	-8,33 [-60,77; 44,10]
			1,000		
Age 2 (p-value of the interaction test: 0,831)					
<40 years	149/210 (71,0)	66/101 (65,3)	1,09 [0,92; 1,28]	1,30 [0,78; 2,15]	5,61 [-5,52; 16,73]
			0,359		
≥40 years	81/121 (66,9)	40/63 (63,5)	1,05 [0,84; 1,32]	1,16 [0,62; 2,20]	3,45 [-11,10; 18,00]
			0,744		
Sex (p-value of the interaction test: 0,545)					
Male	129/178 (72,5)	59/83 (71,1)	1,02 [0,86; 1,20]	1,07 [0,60; 1,91]	1,39 [-10,37; 13,14]
			0,882		
Female	101/153 (66,0)	47/81 (58,0)	1,14 [0,92; 1,41]	1,41 [0,81; 2,44]	7,99 [-5,12; 21,10]
			0,255		
Race (p-value of the interaction test: 0,387)					
White	181/268 (67,5)	89/137 (65,0)	1,04 [0,90; 1,21]	1,12 [0,73; 1,73]	2,57 [-7,19; 12,33]
			0,656		
Other	48/62 (77,4)	17/26 (65,4)	1,18 [0,87; 1,61]	1,82 [0,67; 4,95]	12,03 [-9,01; 33,08]
			0,291		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,338)					
Europe	153/224 (68,3)	81/121 (66,9)	1,02 [0,87; 1,19]	1,06 [0,66; 1,71]	1,36 [-9,00; 11,72]
				0,810	
North America	22/31 (71,0)	6/13 (46,2)	1,54 [0,82; 2,88]	2,85 [0,75; 10,87]	24,81 [-6,65; 56,27]
				0,172	
Other	55/76 (72,4)	19/30 (63,3)	1,14 [0,84; 1,55]	1,52 [0,62; 3,72]	9,04 [-10,93; 29,00]
				0,360	
Geographic region 2 (p-value of the interaction test: 0,470)					
Asia	42/58 (72,4)	14/23 (60,9)	1,19 [0,83; 1,71]	1,69 [0,61; 4,66]	11,54 [-11,48; 34,57]
				0,424	
Central America/South America	9/11 (81,8)	5/7 (71,4)	1,15 [0,66; 1,98]	1,80 [0,19; 16,98]	10,39 [-30,10; 50,88]
				1,000	
Europe and ROW	157/231 (68,0)	81/121 (66,9)	1,02 [0,87; 1,18]	1,05 [0,66; 1,67]	1,02 [-9,29; 11,34]
				0,905	
North America	22/31 (71,0)	6/13 (46,2)	1,54 [0,82; 2,88]	2,85 [0,75; 10,87]	24,81 [-6,65; 56,27]
				0,172	
Weight (p-value of the interaction test: 0,852)					
<100 kg	216/309 (69,9)	100/153 (65,4)	1,07 [0,93; 1,23]	1,23 [0,82; 1,86]	4,54 [-4,57; 13,65]
				0,340	
≥100 kg	14/22 (63,6)	6/11 (54,5)	1,17 [0,62; 2,18]	1,46 [0,34; 6,35]	9,09 [-26,54; 44,73]
				0,714	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
BMI (p-value of the interaction test: 0,471)					
Underweight (<18.5 kg/m ²)	37/59 (62,7)	13/23 (56,5)	1,11 [0,74; 1,67]	1,29 [0,49; 3,44]	6,19 [-17,53; 29,91]
				0,623	
Normal (≥18.5 and <25 kg/m ²)	116/157 (73,9)	59/92 (64,1)	1,15 [0,96; 1,38]	1,58 [0,91; 2,76]	9,75 [-2,21; 21,72]
				0,115	
Overweight (≥25 and <30 kg/m ²)	46/68 (67,6)	22/28 (78,6)	0,86 [0,67; 1,11]	0,57 [0,20; 1,61]	-10,92 [-29,76; 7,91]
				0,332	
Obese and Extreme obese (≥30 kg/m ²)	31/47 (66,0)	12/21 (57,1)	1,15 [0,76; 1,76]	1,45 [0,51; 4,17]	8,81 [-16,32; 33,94]
				0,588	
Tobacco use (p-value of the interaction test: 0,089)					
Current	53/76 (69,7)	16/32 (50,0)	1,39 [0,96; 2,03]	2,30 [0,99; 5,38]	19,74 [-0,43; 39,91]
				0,078	
Former	30/46 (65,2)	23/29 (79,3)	0,82 [0,62; 1,09]	0,49 [0,17; 1,45]	-14,09 [-34,26; 6,08]
				0,298	
Never	147/209 (70,3)	67/103 (65,0)	1,08 [0,92; 1,28]	1,27 [0,77; 2,10]	5,29 [-5,81; 16,38]
				0,366	
Prior biologic exposure (p-value of the interaction test: 0,053)					
Ever	29/36 (80,6)	6/12 (50,0)	1,61 [0,89; 2,90]	4,14 [1,02; 16,81]	30,56 [-0,55; 61,66]
				0,061	
Never	201/295 (68,1)	100/152 (65,8)	1,04 [0,90; 1,19]	1,11 [0,73; 1,68]	2,35 [-6,88; 11,57]
				0,670	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline corticosteroid use (p-value of the interaction test: 0,382)					
Yes	78/113 (69,0)	33/56 (58,9)	1,17 [0,91; 1,51]	1,55 [0,80; 3,02]	10,10 [-5,35; 25,55]
				0,229	
No	152/218 (69,7)	73/108 (67,6)	1,03 [0,88; 1,21]	1,10 [0,67; 1,81]	2,13 [-8,60; 12,86]
				0,704	
Baseline immunomodulator use (p-value of the interaction test: 0,777)					
Yes	76/102 (74,5)	37/53 (69,8)	1,07 [0,86; 1,32]	1,26 [0,61; 2,64]	4,70 [-10,28; 19,67]
				0,570	
No	154/229 (67,2)	69/111 (62,2)	1,08 [0,91; 1,28]	1,25 [0,78; 2,00]	5,09 [-5,79; 15,97]
				0,395	
Duration of CD (p-value of the interaction test: 0,954)					
<1 year	45/71 (63,4)	20/33 (60,6)	1,05 [0,75; 1,45]	1,13 [0,48; 2,63]	2,77 [-17,31; 22,86]
				0,830	
≥1 to <5 years	96/132 (72,7)	47/71 (66,2)	1,10 [0,90; 1,34]	1,36 [0,73; 2,54]	6,53 [-6,84; 19,90]
				0,338	
≥5 years	88/127 (69,3)	39/60 (65,0)	1,07 [0,86; 1,33]	1,21 [0,63; 2,33]	4,29 [-10,20; 18,78]
				0,616	
Baseline disease location (p-value of the interaction test: 0,975)					
Colonic	97/135 (71,9)	49/73 (67,1)	1,07 [0,88; 1,30]	1,25 [0,68; 2,31]	4,73 [-8,45; 17,91]
				0,526	
Ileal	26/41 (63,4)	15/24 (62,5)	1,01 [0,69; 1,49]	1,04 [0,37; 2,95]	0,91 [-23,43; 25,26]
				1,000	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Ileal-Colonic	107/155 (69,0)	42/65 (64,6)	1,07 [0,87; 1,32]	1,22 [0,66; 2,25]	4,42 [-9,30; 18,13]
0,531					
Baseline fecal calprotectin (p-value of the interaction test: 0,849)					
≤250	41/57 (71,9)	17/24 (70,8)	1,02 [0,75; 1,38]	1,06 [0,37; 3,02]	1,10 [-20,51; 22,70]
1,000					
>250	145/203 (71,4)	71/103 (68,9)	1,04 [0,89; 1,21]	1,13 [0,67; 1,89]	2,50 [-8,39; 13,38]
0,691					
Baseline CRP (p-value of the interaction test: 0,102)					
≤10	152/217 (70,0)	76/108 (70,4)	1,00 [0,86; 1,16]	0,98 [0,59; 1,63]	-0,32 [-10,87; 10,23]
1,000					
>10	78/114 (68,4)	30/56 (53,6)	1,28 [0,97; 1,68]	1,88 [0,97; 3,62]	14,85 [-0,75; 30,45]
0,064					
Baseline SES-CD total score (p-value of the interaction test: 0,652)					
<12	136/200 (68,0)	63/96 (65,6)	1,04 [0,87; 1,23]	1,11 [0,66; 1,86]	2,38 [-9,12; 13,87]
0,693					
≥12	94/131 (71,8)	43/66 (65,2)	1,10 [0,90; 1,35]	1,36 [0,72; 2,56]	6,60 [-7,24; 20,45]
0,412					
Baseline AP average (p-value of the interaction test: 0,063)					
<2	30/70 (42,9)	19/35 (54,3)	0,79 [0,53; 1,19]	0,63 [0,28; 1,43]	-11,43 [-31,60; 8,74]
0,304					
≥2	200/260 (76,9)	87/129 (67,4)	1,14 [0,99; 1,31]	1,61 [1,01; 2,57]	9,48 [-0,09; 19,05]
0,051					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline SF average (p-value of the interaction test: 0,579)					
<7	182/265 (68,7)	81/125 (64,8)	1,06 [0,91; 1,23]	1,19 [0,76; 1,87]	3,88 [-6,18; 13,94]
				0,488	
≥7	48/65 (73,8)	25/39 (64,1)	1,15 [0,87; 1,52]	1,58 [0,67; 3,72]	9,74 [-8,72; 28,20]
				0,376	
Baseline CDAI 1 (p-value of the interaction test: 0,348)					
<300	89/148 (60,1)	45/75 (60,0)	1,00 [0,80; 1,26]	1,01 [0,57; 1,77]	0,14 [-13,47; 13,74]
				1,000	
≥300	141/182 (77,5)	61/89 (68,5)	1,13 [0,96; 1,33]	1,58 [0,90; 2,78]	8,93 [-2,46; 20,33]
				0,137	
Baseline CDAI 2 (p-value of the interaction test: 0,766)					
<150	0/5 (0,0)	0/6 (0,0)	NB	NB	NB
				NB	
≥150 and <220	10/27 (37,0)	8/18 (44,4)	0,83 [0,41; 1,70]	0,74 [0,22; 2,48]	-7,41 [-36,71; 21,90]
				0,758	
≥220 and <450	202/275 (73,5)	85/125 (68,0)	1,08 [0,94; 1,24]	1,30 [0,82; 2,07]	5,45 [-4,25; 15,16]
				0,282	
≥450	18/23 (78,3)	13/15 (86,7)	0,90 [0,67; 1,21]	0,55 [0,09; 3,31]	-8,41 [-32,49; 15,68]
				0,681	
OECD Country (p-value of the interaction test: 0,397)					
Yes	147/209 (70,3)	58/94 (61,7)	1,14 [0,95; 1,37]	1,47 [0,88; 2,45]	8,63 [-2,98; 20,25]
				0,146	

Subgruppe	Mirikizumab Pat. mit Ereignis n/N (%)	Ustekinumab Pat. mit Ereignis n/N (%)	Mirikizumab vs. Ustekinumab		
			RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
No	83/122 (68,0)	48/70 (68,6)	0,99 [0,81; 1,21]	0,98 [0,52; 1,84]	-0,54 [-14,20; 13,13]
			1,000		

Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency.

RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald.
a: Exakter Test nach Fisher.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_gwbi0_6_sub_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Anhang 4-G.3.6.2 Gesundheitsbezogene Lebensqualität**Krankheitsspezifische Lebensqualität – IBDQ**

Subgruppen für Increase in IBDQ Total Score by at least 28.8 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,410)					
<65 years	205/322 (63,7)	96/160 (60,0)	1,06 [0,91; 1,23]	1,17 [0,79; 1,72]	3,66 [-5,57; 12,90]
			0,485		
≥65 years	2/9 (22,2)	2/4 (50,0)	0,44 [0,09; 2,13]	0,29 [0,02; 3,52]	-27,78 [-83,80; 28,25]
			0,530		
Age 2 (p-value of the interaction test: 0,492)					
<40 years	137/210 (65,2)	60/101 (59,4)	1,10 [0,91; 1,33]	1,28 [0,79; 2,09]	5,83 [-5,71; 17,37]
			0,318		
≥40 years	70/121 (57,9)	38/63 (60,3)	0,96 [0,75; 1,23]	0,90 [0,49; 1,68]	-2,47 [-17,41; 12,48]
			0,875		
Sex (p-value of the interaction test: 0,626)					
Male	118/178 (66,3)	51/83 (61,4)	1,08 [0,88; 1,32]	1,23 [0,72; 2,12]	4,85 [-7,72; 17,41]
			0,488		
Female	89/153 (58,2)	47/81 (58,0)	1,00 [0,80; 1,26]	1,01 [0,58; 1,74]	0,15 [-13,14; 13,43]
			1,000		
Race (p-value of the interaction test: 0,727)					
White	162/268 (60,4)	79/137 (57,7)	1,05 [0,88; 1,25]	1,12 [0,74; 1,70]	2,78 [-7,35; 12,92]
			0,595		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Other	45/62 (72,6)	19/26 (73,1)	0,99 [0,75; 1,31]	0,98 [0,35; 2,73]	-0,50 [-20,84; 19,85]
1,000					
Geographic region 1 (p-value of the interaction test: 0,628)					
Europe	140/224 (62,5)	71/121 (58,7)	1,07 [0,89; 1,28]	1,17 [0,75; 1,84]	3,82 [-7,00; 14,65]
0,490					
North America	18/31 (58,1)	6/13 (46,2)	1,26 [0,65; 2,43]	1,62 [0,44; 5,95]	11,91 [-20,28; 44,10]
0,522					
Other	49/76 (64,5)	21/30 (70,0)	0,92 [0,69; 1,23]	0,78 [0,31; 1,93]	-5,53 [-25,14; 14,09]
0,654					
Geographic region 2 (p-value of the interaction test: 0,856)					
Asia	40/58 (69,0)	16/23 (69,6)	0,99 [0,72; 1,37]	0,97 [0,34; 2,77]	-0,60 [-22,86; 21,66]
1,000					
Central America/South America	6/11 (54,5)	5/7 (71,4)	0,76 [0,37; 1,56]	0,48 [0,06; 3,63]	-16,88 [-61,45; 27,68]
0,637					
Europe and ROW	143/231 (61,9)	71/121 (58,7)	1,05 [0,88; 1,26]	1,14 [0,73; 1,79]	3,23 [-7,55; 14,01]
0,567					
North America	18/31 (58,1)	6/13 (46,2)	1,26 [0,65; 2,43]	1,62 [0,44; 5,95]	11,91 [-20,28; 44,10]
0,522					
Weight (p-value of the interaction test: 0,108)					
<100 kg	199/309 (64,4)	91/153 (59,5)	1,08 [0,93; 1,26]	1,23 [0,83; 1,84]	4,92 [-4,51; 14,36]
0,308					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
≥100 kg	8/22 (36,4)	7/11 (63,6)	0,57 [0,28; 1,16]	0,33 [0,07; 1,47]	-27,27 [-62,09; 7,54]
0,163					
BMI (p-value of the interaction test: 0,982)					
Underweight ($<18.5 \text{ kg/m}^2$)	38/59 (64,4)	14/23 (60,9)	1,06 [0,72; 1,55]	1,16 [0,43; 3,14]	3,54 [-19,85; 26,93]
0,802					
Normal (≥18.5 and <25 kg/m ²)	98/157 (62,4)	54/92 (58,7)	1,06 [0,86; 1,31]	1,17 [0,69; 1,98]	3,72 [-8,87; 16,32]
0,592					
Overweight (≥25 and <30 kg/m ²)	47/68 (69,1)	19/28 (67,9)	1,02 [0,75; 1,38]	1,06 [0,41; 2,73]	1,26 [-19,23; 21,75]
1,000					
Obese and Extreme obese (≥30 kg/m ²)	24/47 (51,1)	11/21 (52,4)	0,97 [0,59; 1,60]	0,95 [0,34; 2,66]	-1,32 [-27,02; 24,38]
1,000					
Tobacco use (p-value of the interaction test: 0,141)					
Current	50/76 (65,8)	15/32 (46,9)	1,40 [0,94; 2,10]	2,18 [0,94; 5,05]	18,91 [-1,40; 39,23]
0,086					
Former	26/46 (56,5)	17/29 (58,6)	0,96 [0,65; 1,43]	0,92 [0,36; 2,35]	-2,10 [-25,05; 20,85]
1,000					
Never	131/209 (62,7)	66/103 (64,1)	0,98 [0,82; 1,17]	0,94 [0,58; 1,54]	-1,40 [-12,75; 9,95]
0,901					
Prior biologic exposure (p-value of the interaction test: 0,599)					
Ever	24/36 (66,7)	9/12 (75,0)	0,89 [0,60; 1,33]	0,67 [0,15; 2,93]	-8,33 [-37,27; 20,60]
0,728					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Never	183/295 (62,0)	89/152 (58,6)	1,06 [0,90; 1,24]	1,16 [0,78; 1,72]	3,48 [-6,11; 13,07]
0,476					
Baseline corticosteroid use (p-value of the interaction test: 0,924)					
Yes	70/113 (61,9)	33/56 (58,9)	1,05 [0,81; 1,37]	1,13 [0,59; 2,18]	3,02 [-12,67; 18,71]
0,739					
No	137/218 (62,8)	65/108 (60,2)	1,04 [0,87; 1,26]	1,12 [0,70; 1,80]	2,66 [-8,58; 13,90]
0,716					
Baseline immunomodulator use (p-value of the interaction test: 0,106)					
Yes	63/102 (61,8)	38/53 (71,7)	0,86 [0,69; 1,08]	0,64 [0,31; 1,31]	-9,93 [-25,30; 5,43]
0,286					
No	144/229 (62,9)	60/111 (54,1)	1,16 [0,95; 1,42]	1,44 [0,91; 2,28]	8,83 [-2,36; 20,01]
0,126					
Duration of CD (p-value of the interaction test: 0,664)					
<1 year	41/71 (57,7)	21/33 (63,6)	0,91 [0,66; 1,26]	0,78 [0,33; 1,83]	-5,89 [-25,92; 14,14]
0,669					
≥1 to <5 years	88/132 (66,7)	45/71 (63,4)	1,05 [0,85; 1,30]	1,16 [0,63; 2,11]	3,29 [-10,51; 17,08]
0,646					
≥5 years	77/127 (60,6)	32/60 (53,3)	1,14 [0,86; 1,50]	1,35 [0,73; 2,50]	7,30 [-7,92; 22,51]
0,427					
Baseline disease location (p-value of the interaction test: 0,653)					
Colonic	88/135 (65,2)	50/73 (68,5)	0,95 [0,78; 1,16]	0,86 [0,47; 1,58]	-3,31 [-16,65; 10,04]
0,648					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Ileal	24/41 (58,5)	13/24 (54,2)	1,08 [0,69; 1,69]	1,19 [0,43; 3,30]	4,37 [-20,63; 29,37]
			0,798		
Ileal-Colonic	95/155 (61,3)	35/65 (53,8)	1,14 [0,88; 1,47]	1,36 [0,76; 2,44]	7,44 [-6,90; 21,79]
			0,367		
Baseline fecal calprotectin (p-value of the interaction test: 0,643)					
≤250	32/57 (56,1)	14/24 (58,3)	0,96 [0,64; 1,45]	0,91 [0,35; 2,40]	-2,19 [-25,75; 21,37]
			1,000		
>250	132/203 (65,0)	71/103 (68,9)	0,94 [0,80; 1,11]	0,84 [0,50; 1,39]	-3,91 [-14,99; 7,18]
			0,524		
Baseline CRP (p-value of the interaction test: 0,102)					
≤10	124/217 (57,1)	64/108 (59,3)	0,96 [0,79; 1,17]	0,92 [0,57; 1,46]	-2,12 [-13,48; 9,25]
			0,723		
>10	83/114 (72,8)	34/56 (60,7)	1,20 [0,94; 1,52]	1,73 [0,88; 3,41]	12,09 [-3,08; 27,27]
			0,117		
Baseline SES-CD total score (p-value of the interaction test: 0,218)					
<12	120/200 (60,0)	51/96 (53,1)	1,13 [0,91; 1,41]	1,32 [0,81; 2,16]	6,88 [-5,20; 18,95]
			0,315		
≥12	87/131 (66,4)	47/66 (71,2)	0,93 [0,77; 1,13]	0,80 [0,42; 1,52]	-4,80 [-18,39; 8,79]
			0,522		
Baseline AP average (p-value of the interaction test: 0,090)					
<2	31/70 (44,3)	20/35 (57,1)	0,78 [0,53; 1,14]	0,60 [0,26; 1,35]	-12,86 [-32,96; 7,25]
			0,223		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
≥2	176/260 (67,7)	78/129 (60,5)	1,12 [0,95; 1,32]	1,37 [0,88; 2,12]	7,23 [-2,95; 17,40]
0,175					
Baseline SF average (p-value of the interaction test: 1,000)					
<7	165/265 (62,3)	74/125 (59,2)	1,05 [0,88; 1,25]	1,14 [0,74; 1,76]	3,06 [-7,34; 13,47]
0,579					
≥7	42/65 (64,6)	24/39 (61,5)	1,05 [0,77; 1,43]	1,14 [0,50; 2,59]	3,08 [-16,11; 22,27]
0,834					
Baseline CDAI 1 (p-value of the interaction test: 0,949)					
<300	79/148 (53,4)	39/75 (52,0)	1,03 [0,79; 1,34]	1,06 [0,61; 1,84]	1,38 [-12,49; 15,25]
0,888					
≥300	128/182 (70,3)	59/89 (66,3)	1,06 [0,89; 1,26]	1,21 [0,70; 2,07]	4,04 [-7,82; 15,89]
0,576					
Baseline CDAI 2 (p-value of the interaction test: 0,696)					
<150	0/5 (0,0)	1/6 (16,7)	0,39 [0,02; 7,88]	0,33 [0,01; 10,11]	-16,67 [-46,49; 13,15]
1,000					
≥150 and <220	14/27 (51,9)	10/18 (55,6)	0,93 [0,54; 1,62]	0,86 [0,26; 2,85]	-3,70 [-33,40; 26,00]
1,000					
≥220 and <450	178/275 (64,7)	75/125 (60,0)	1,08 [0,91; 1,28]	1,22 [0,79; 1,89]	4,73 [-5,55; 15,01]
0,373					
≥450	15/23 (65,2)	12/15 (80,0)	0,82 [0,55; 1,21]	0,47 [0,10; 2,16]	-14,78 [-42,87; 13,30]
0,470					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
OECD Country (p-value of the interaction test: 0,102)					
Yes	128/209 (61,2)	48/94 (51,1)	1,20 [0,96; 1,50]	1,51 [0,93; 2,47]	10,18 [-1,89; 22,25]
			0,103		
No	79/122 (64,8)	50/70 (71,4)	0,91 [0,74; 1,10]	0,73 [0,39; 1,39]	-6,67 [-20,23; 6,89]
			0,425		
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_ibdqtsi28_8_sub_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba
20DEC2024 / 04:00

Subgruppen für Increase in IBDQ Emotional Function by at least 10.8 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,214)					
<65 years	183/322 (56,8)	87/160 (54,4)	1,05 [0,88; 1,24]	1,10 [0,75; 1,62]	2,46 [-6,97; 11,88]
			0,627		
≥65 years	1/9 (11,1)	2/4 (50,0)	0,22 [0,03; 1,80]	0,13 [0,01; 2,18]	-38,89 [-92,02; 14,24]
			0,203		
Age 2 (p-value of the interaction test: 0,677)					
<40 years	117/210 (55,7)	53/101 (52,5)	1,06 [0,85; 1,32]	1,14 [0,71; 1,83]	3,24 [-8,59; 15,07]
			0,628		
≥40 years	67/121 (55,4)	36/63 (57,1)	0,97 [0,74; 1,27]	0,93 [0,50; 1,72]	-1,77 [-16,86; 13,32]
			0,876		
Sex (p-value of the interaction test: 0,749)					
Male	98/178 (55,1)	46/83 (55,4)	0,99 [0,79; 1,26]	0,99 [0,58; 1,66]	-0,37 [-13,32; 12,59]
			1,000		
Female	86/153 (56,2)	43/81 (53,1)	1,06 [0,83; 1,36]	1,13 [0,66; 1,95]	3,12 [-10,29; 16,54]
			0,680		
Race (p-value of the interaction test: 0,856)					
White	144/268 (53,7)	72/137 (52,6)	1,02 [0,84; 1,24]	1,05 [0,69; 1,58]	1,18 [-9,10; 11,45]
			0,834		
Other	40/62 (64,5)	17/26 (65,4)	0,99 [0,71; 1,38]	0,96 [0,37; 2,52]	-0,87 [-22,69; 20,95]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,616)					
Europe	124/224 (55,4)	66/121 (54,5)	1,01 [0,83; 1,24]	1,03 [0,66; 1,61]	0,81 [-10,19; 11,82]
				0,910	
North America	17/31 (54,8)	5/13 (38,5)	1,43 [0,67; 3,04]	1,94 [0,52; 7,29]	16,38 [-15,34; 48,10]
				0,510	
Other	43/76 (56,6)	18/30 (60,0)	0,94 [0,66; 1,34]	0,87 [0,37; 2,05]	-3,42 [-24,19; 17,35]
				0,829	
Geographic region 2 (p-value of the interaction test: 0,801)					
Asia	35/58 (60,3)	14/23 (60,9)	0,99 [0,67; 1,46]	0,98 [0,36; 2,63]	-0,52 [-24,11; 23,06]
				1,000	
Central America/South America	5/11 (45,5)	4/7 (57,1)	0,80 [0,32; 1,98]	0,63 [0,09; 4,22]	-11,69 [-58,70; 35,32]
				1,000	
Europe and ROW	127/231 (55,0)	66/121 (54,5)	1,01 [0,83; 1,23]	1,02 [0,65; 1,58]	0,43 [-10,52; 11,38]
				1,000	
North America	17/31 (54,8)	5/13 (38,5)	1,43 [0,67; 3,04]	1,94 [0,52; 7,29]	16,38 [-15,34; 48,10]
				0,510	
Weight (p-value of the interaction test: 0,445)					
<100 kg	173/309 (56,0)	82/153 (53,6)	1,04 [0,87; 1,25]	1,10 [0,75; 1,63]	2,39 [-7,26; 12,04]
				0,691	
≥100 kg	11/22 (50,0)	7/11 (63,6)	0,79 [0,43; 1,45]	0,57 [0,13; 2,52]	-13,64 [-48,92; 21,64]
				0,712	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
BMI (p-value of the interaction test: 0,983)					
Underweight (<18.5 kg/m ²)	34/59 (57,6)	13/23 (56,5)	1,02 [0,67; 1,55]	1,05 [0,40; 2,77]	1,11 [-22,76; 24,97]
				1,000	
Normal (≥18.5 and <25 kg/m ²)	84/157 (53,5)	48/92 (52,2)	1,03 [0,80; 1,31]	1,05 [0,63; 1,77]	1,33 [-11,52; 14,18]
				0,896	
Overweight (≥25 and <30 kg/m ²)	40/68 (58,8)	17/28 (60,7)	0,97 [0,68; 1,39]	0,92 [0,38; 2,27]	-1,89 [-23,43; 19,65]
				1,000	
Obese and Extreme obese (≥30 kg/m ²)	26/47 (55,3)	11/21 (52,4)	1,06 [0,65; 1,71]	1,13 [0,40; 3,16]	2,94 [-22,72; 28,60]
				1,000	
Tobacco use (p-value of the interaction test: 0,144)					
Current	45/76 (59,2)	13/32 (40,6)	1,46 [0,92; 2,31]	2,12 [0,92; 4,92]	18,59 [-1,70; 38,87]
				0,093	
Former	22/46 (47,8)	15/29 (51,7)	0,92 [0,58; 1,47]	0,86 [0,34; 2,17]	-3,90 [-27,12; 19,32]
				0,815	
Never	117/209 (56,0)	61/103 (59,2)	0,95 [0,77; 1,15]	0,88 [0,54; 1,41]	-3,24 [-14,88; 8,39]
				0,628	
Prior biologic exposure (p-value of the interaction test: 0,767)					
Ever	22/36 (61,1)	8/12 (66,7)	0,92 [0,57; 1,48]	0,79 [0,20; 3,11]	-5,56 [-36,62; 25,51]
				1,000	
Never	162/295 (54,9)	81/152 (53,3)	1,03 [0,86; 1,24]	1,07 [0,72; 1,58]	1,63 [-8,13; 11,38]
				0,764	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline corticosteroid use (p-value of the interaction test: 0,945)					
Yes	64/113 (56,6)	31/56 (55,4)	1,02 [0,77; 1,36]	1,05 [0,55; 2,01]	1,28 [-14,63; 17,19]
				1,000	
No	120/218 (55,0)	58/108 (53,7)	1,02 [0,83; 1,27]	1,06 [0,66; 1,68]	1,34 [-10,15; 12,83]
				0,906	
Baseline immunomodulator use (p-value of the interaction test: 0,602)					
Yes	58/102 (56,9)	32/53 (60,4)	0,94 [0,71; 1,24]	0,87 [0,44; 1,70]	-3,51 [-19,82; 12,79]
				0,733	
No	126/229 (55,0)	57/111 (51,4)	1,07 [0,86; 1,33]	1,16 [0,74; 1,83]	3,67 [-7,64; 14,98]
				0,563	
Duration of CD (p-value of the interaction test: 0,307)					
<1 year	34/71 (47,9)	19/33 (57,6)	0,83 [0,57; 1,22]	0,68 [0,29; 1,56]	-9,69 [-30,17; 10,79]
				0,404	
≥1 to <5 years	83/132 (62,9)	38/71 (53,5)	1,17 [0,91; 1,51]	1,47 [0,82; 2,64]	9,36 [-4,87; 23,59]
				0,231	
≥5 years	66/127 (52,0)	32/60 (53,3)	0,97 [0,73; 1,30]	0,95 [0,51; 1,75]	-1,36 [-16,69; 13,96]
				0,877	
Baseline disease location (p-value of the interaction test: 0,623)					
Colonic	79/135 (58,5)	46/73 (63,0)	0,93 [0,74; 1,16]	0,83 [0,46; 1,49]	-4,50 [-18,34; 9,35]
				0,556	
Ileal	21/41 (51,2)	12/24 (50,0)	1,02 [0,62; 1,69]	1,05 [0,38; 2,88]	1,22 [-23,96; 26,40]
				1,000	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Ileal-Colonic	84/155 (54,2)	31/65 (47,7)	1,14 [0,85; 1,52]	1,30 [0,73; 2,32]	6,50 [-7,95; 20,96]
0,460					
Baseline fecal calprotectin (p-value of the interaction test: 0,976)					
≤250	33/57 (57,9)	15/24 (62,5)	0,93 [0,63; 1,36]	0,83 [0,31; 2,20]	-4,61 [-27,83; 18,62]
0,806					
>250	116/203 (57,1)	61/103 (59,2)	0,96 [0,79; 1,18]	0,92 [0,57; 1,49]	-2,08 [-13,76; 9,60]
0,807					
Baseline CRP (p-value of the interaction test: 0,129)					
≤10	115/217 (53,0)	61/108 (56,5)	0,94 [0,76; 1,15]	0,87 [0,55; 1,38]	-3,49 [-14,95; 7,98]
0,557					
>10	69/114 (60,5)	28/56 (50,0)	1,21 [0,90; 1,64]	1,53 [0,80; 2,92]	10,53 [-5,35; 26,40]
0,248					
Baseline SES-CD total score (p-value of the interaction test: 0,566)					
<12	108/200 (54,0)	49/96 (51,0)	1,06 [0,84; 1,34]	1,13 [0,69; 1,83]	2,96 [-9,20; 15,11]
0,709					
≥12	76/131 (58,0)	40/66 (60,6)	0,96 [0,75; 1,22]	0,90 [0,49; 1,64]	-2,59 [-17,10; 11,91]
0,761					
Baseline AP average (p-value of the interaction test: 0,134)					
<2	27/70 (38,6)	18/35 (51,4)	0,75 [0,48; 1,16]	0,59 [0,26; 1,35]	-12,86 [-32,96; 7,25]
0,219					
≥2	157/260 (60,4)	71/129 (55,0)	1,10 [0,91; 1,32]	1,25 [0,81; 1,91]	5,35 [-5,10; 15,79]
0,327					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline SF average (p-value of the interaction test: 0,905)					
<7	149/265 (56,2)	69/125 (55,2)	1,02 [0,84; 1,23]	1,04 [0,68; 1,60]	1,03 [-9,54; 11,59]
				0,913	
≥7	35/65 (53,8)	20/39 (51,3)	1,05 [0,72; 1,54]	1,11 [0,50; 2,45]	2,56 [-17,26; 22,39]
				0,841	
Baseline CDAI 1 (p-value of the interaction test: 0,964)					
<300	74/148 (50,0)	37/75 (49,3)	1,01 [0,77; 1,34]	1,03 [0,59; 1,79]	0,67 [-13,22; 14,56]
				1,000	
≥300	110/182 (60,4)	52/89 (58,4)	1,03 [0,84; 1,28]	1,09 [0,65; 1,82]	2,01 [-10,45; 14,47]
				0,793	
Baseline CDAI 2 (p-value of the interaction test: 0,878)					
<150	0/5 (0,0)	1/6 (16,7)	0,39 [0,02; 7,88]	0,33 [0,01; 10,11]	-16,67 [-46,49; 13,15]
				1,000	
≥150 and <220	13/27 (48,1)	8/18 (44,4)	1,08 [0,57; 2,07]	1,16 [0,35; 3,84]	3,70 [-26,00; 33,40]
				1,000	
≥220 and <450	158/275 (57,5)	70/125 (56,0)	1,03 [0,85; 1,24]	1,06 [0,69; 1,63]	1,45 [-9,03; 11,94]
				0,828	
≥450	13/23 (56,5)	10/15 (66,7)	0,85 [0,51; 1,41]	0,65 [0,17; 2,52]	-10,14 [-41,44; 21,15]
				0,736	
OECD Country (p-value of the interaction test: 0,057)					
Yes	116/209 (55,5)	43/94 (45,7)	1,21 [0,94; 1,56]	1,48 [0,91; 2,41]	9,76 [-2,36; 21,87]
				0,136	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
No	68/122 (55,7)	46/70 (65,7)	0,85 [0,67; 1,07]	0,66 [0,36; 1,21]	-9,98 [-24,17; 4,21]
0,222					
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_ibdqefi10_8_sub_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

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Subgruppen für Increase in IBDQ Social Function by at least 4.5 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,353)					
<65 years	200/322 (62,1)	101/160 (63,1)	0,98 [0,85; 1,14]	0,96 [0,65; 1,42]	-1,01 [-10,18; 8,15]
			0,842		
≥65 years	3/9 (33,3)	3/4 (75,0)	0,44 [0,15; 1,31]	0,17 [0,01; 2,37]	-41,67 [-94,10; 10,77]
			0,266		
Age 2 (p-value of the interaction test: 0,689)					
<40 years	129/210 (61,4)	65/101 (64,4)	0,95 [0,80; 1,14]	0,88 [0,54; 1,44]	-2,93 [-14,36; 8,50]
			0,708		
≥40 years	74/121 (61,2)	39/63 (61,9)	0,99 [0,78; 1,26]	0,97 [0,52; 1,81]	-0,75 [-15,55; 14,06]
			1,000		
Sex (p-value of the interaction test: 0,589)					
Male	114/178 (64,0)	57/83 (68,7)	0,93 [0,78; 1,12]	0,81 [0,47; 1,42]	-4,63 [-16,85; 7,59]
			0,488		
Female	89/153 (58,2)	47/81 (58,0)	1,00 [0,80; 1,26]	1,01 [0,58; 1,74]	0,15 [-13,14; 13,43]
			1,000		
Race (p-value of the interaction test: 0,873)					
White	162/268 (60,4)	86/137 (62,8)	0,96 [0,82; 1,13]	0,91 [0,59; 1,39]	-2,33 [-12,32; 7,66]
			0,668		
Other	41/62 (66,1)	18/26 (69,2)	0,96 [0,70; 1,31]	0,87 [0,32; 2,32]	-3,10 [-24,40; 18,19]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,801)					
Europe	140/224 (62,5)	77/121 (63,6)	0,98 [0,83; 1,16]	0,95 [0,60; 1,51]	-1,14 [-11,80; 9,52]
				0,907	
North America	18/31 (58,1)	7/13 (53,8)	1,08 [0,60; 1,94]	1,19 [0,32; 4,37]	4,22 [-27,97; 36,41]
				1,000	
Other	45/76 (59,2)	20/30 (66,7)	0,89 [0,65; 1,22]	0,73 [0,30; 1,76]	-7,46 [-27,62; 12,71]
				0,515	
Geographic region 2 (p-value of the interaction test: 0,872)					
Asia	37/58 (63,8)	15/23 (65,2)	0,98 [0,69; 1,40]	0,94 [0,34; 2,58]	-1,42 [-24,49; 21,64]
				1,000	
Central America/South America	5/11 (45,5)	5/7 (71,4)	0,64 [0,29; 1,41]	0,33 [0,04; 2,52]	-25,97 [-70,54; 18,59]
				0,367	
Europe and ROW	143/231 (61,9)	77/121 (63,6)	0,97 [0,82; 1,15]	0,93 [0,59; 1,46]	-1,73 [-12,35; 8,88]
				0,817	
North America	18/31 (58,1)	7/13 (53,8)	1,08 [0,60; 1,94]	1,19 [0,32; 4,37]	4,22 [-27,97; 36,41]
				1,000	
Weight (p-value of the interaction test: 0,740)					
<100 kg	191/309 (61,8)	97/153 (63,4)	0,97 [0,84; 1,13]	0,93 [0,63; 1,40]	-1,59 [-10,95; 7,77]
				0,760	
≥100 kg	12/22 (54,5)	7/11 (63,6)	0,86 [0,48; 1,54]	0,69 [0,15; 3,04]	-9,09 [-44,32; 26,14]
				0,719	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
BMI (p-value of the interaction test: 0,996)					
Underweight (<18.5 kg/m ²)	32/59 (54,2)	13/23 (56,5)	0,96 [0,63; 1,47]	0,91 [0,35; 2,41]	-2,28 [-26,20; 21,63]
				1,000	
Normal (≥18.5 and <25 kg/m ²)	96/157 (61,1)	58/92 (63,0)	0,97 [0,79; 1,18]	0,92 [0,54; 1,57]	-1,90 [-14,36; 10,57]
				0,788	
Overweight (≥25 and <30 kg/m ²)	48/68 (70,6)	20/28 (71,4)	0,99 [0,75; 1,31]	0,96 [0,36; 2,54]	-0,84 [-20,77; 19,09]
				1,000	
Obese and Extreme obese (≥30 kg/m ²)	27/47 (57,4)	13/21 (61,9)	0,93 [0,61; 1,41]	0,83 [0,29; 2,38]	-4,46 [-29,58; 20,67]
				0,794	
Tobacco use (p-value of the interaction test: 0,158)					
Current	52/76 (68,4)	18/32 (56,3)	1,22 [0,86; 1,71]	1,69 [0,72; 3,94]	12,17 [-7,94; 32,29]
				0,272	
Former	30/46 (65,2)	19/29 (65,5)	1,00 [0,71; 1,40]	0,99 [0,37; 2,62]	-0,30 [-22,41; 21,81]
				1,000	
Never	121/209 (57,9)	67/103 (65,0)	0,89 [0,74; 1,07]	0,74 [0,45; 1,21]	-7,15 [-18,54; 4,23]
				0,268	
Prior biologic exposure (p-value of the interaction test: 0,545)					
Ever	22/36 (61,1)	9/12 (75,0)	0,81 [0,54; 1,24]	0,52 [0,12; 2,27]	-13,89 [-43,11; 15,33]
				0,497	
Never	181/295 (61,4)	95/152 (62,5)	0,98 [0,84; 1,14]	0,95 [0,64; 1,43]	-1,14 [-10,64; 8,35]
				0,838	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline corticosteroid use (p-value of the interaction test: 0,815)					
Yes	70/113 (61,9)	37/56 (66,1)	0,94 [0,74; 1,19]	0,84 [0,43; 1,64]	-4,12 [-19,42; 11,17]
				0,616	
No	133/218 (61,0)	67/108 (62,0)	0,98 [0,82; 1,18]	0,96 [0,60; 1,54]	-1,03 [-12,24; 10,18]
				0,904	
Baseline immunomodulator use (p-value of the interaction test: 0,053)					
Yes	60/102 (58,8)	40/53 (75,5)	0,78 [0,62; 0,97]	0,46 [0,22; 0,97]	-16,65 [-31,66; -1,63]
				0,051	
No	143/229 (62,4)	64/111 (57,7)	1,08 [0,90; 1,31]	1,22 [0,77; 1,94]	4,79 [-6,34; 15,92]
				0,409	
Duration of CD (p-value of the interaction test: 0,892)					
<1 year	42/71 (59,2)	21/33 (63,6)	0,93 [0,67; 1,28]	0,83 [0,35; 1,94]	-4,48 [-24,48; 15,52]
				0,830	
≥1 to <5 years	84/132 (63,6)	48/71 (67,6)	0,94 [0,77; 1,16]	0,84 [0,46; 1,54]	-3,97 [-17,60; 9,66]
				0,644	
≥5 years	76/127 (59,8)	35/60 (58,3)	1,03 [0,79; 1,33]	1,06 [0,57; 1,99]	1,51 [-13,60; 16,62]
				0,874	
Baseline disease location (p-value of the interaction test: 0,193)					
Colonic	93/135 (68,9)	49/73 (67,1)	1,03 [0,84; 1,25]	1,08 [0,59; 1,99]	1,77 [-11,54; 15,07]
				0,876	
Ileal	23/41 (56,1)	11/24 (45,8)	1,22 [0,73; 2,04]	1,51 [0,55; 4,16]	10,26 [-14,80; 35,33]
				0,452	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Ileal-Colonic	87/155 (56,1)	44/65 (67,7)	0,83 [0,67; 1,03]	0,61 [0,33; 1,12]	-11,56 [-25,36; 2,23]
0,133					
Baseline fecal calprotectin (p-value of the interaction test: 0,631)					
≤250	29/57 (50,9)	16/24 (66,7)	0,76 [0,52; 1,12]	0,52 [0,19; 1,40]	-15,79 [-38,68; 7,10]
0,227					
>250	132/203 (65,0)	72/103 (69,9)	0,93 [0,79; 1,09]	0,80 [0,48; 1,33]	-4,88 [-15,90; 6,14]
0,442					
Baseline SES-CD total score (p-value of the interaction test: 0,414)					
<12	117/200 (58,5)	56/96 (58,3)	1,00 [0,82; 1,23]	1,01 [0,61; 1,65]	0,17 [-11,83; 12,16]
1,000					
≥12	86/131 (65,6)	48/66 (72,7)	0,90 [0,74; 1,09]	0,72 [0,37; 1,37]	-7,08 [-20,55; 6,40]
0,336					
Baseline SF average (p-value of the interaction test: 0,806)					
<7	162/265 (61,1)	78/125 (62,4)	0,98 [0,83; 1,16]	0,95 [0,61; 1,47]	-1,27 [-11,59; 9,05]
0,824					
≥7	41/65 (63,1)	26/39 (66,7)	0,95 [0,71; 1,26]	0,85 [0,37; 1,97]	-3,59 [-22,47; 15,29]
0,833					
Baseline CDAI 1 (p-value of the interaction test: 0,633)					
<300	80/148 (54,1)	45/75 (60,0)	0,90 [0,71; 1,14]	0,78 [0,45; 1,38]	-5,95 [-19,63; 7,74]
0,475					
≥300	123/182 (67,6)	59/89 (66,3)	1,02 [0,85; 1,22]	1,06 [0,62; 1,82]	1,29 [-10,66; 13,24]
0,891					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline CDAI 2 (p-value of the interaction test: 0,641)					
<150	0/5 (0,0)	1/6 (16,7)	0,39 [0,02; 7,88]	0,33 [0,01; 10,11]	-16,67 [-46,49; 13,15]
				1,000	
≥150 and <220	14/27 (51,9)	12/18 (66,7)	0,78 [0,48; 1,27]	0,54 [0,16; 1,86]	-14,81 [-43,62; 13,99]
				0,371	
≥220 and <450	175/275 (63,6)	79/125 (63,2)	1,01 [0,86; 1,18]	1,02 [0,66; 1,58]	0,44 [-9,75; 10,62]
				1,000	
≥450	14/23 (60,9)	12/15 (80,0)	0,76 [0,50; 1,15]	0,39 [0,09; 1,77]	-19,13 [-47,55; 9,29]
				0,294	
OECD Country (p-value of the interaction test: 0,602)					
Yes	126/209 (60,3)	56/94 (59,6)	1,01 [0,83; 1,24]	1,03 [0,63; 1,69]	0,71 [-11,22; 12,65]
				1,000	
No	77/122 (63,1)	48/70 (68,6)	0,92 [0,75; 1,13]	0,78 [0,42; 1,46]	-5,46 [-19,30; 8,38]
				0,530	
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba
20DEC2024 / 04:00

Gesundheitsbezogene Lebensqualität – SF-36

Subgruppen für Increase in SF-36 PCS Score by at least 9.4 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,211)					
<65 years	151/322 (46,9)	69/160 (43,1)	1,09 [0,88; 1,34]	1,16 [0,79; 1,71]	3,77 [-5,64; 13,18]
			0,439		
≥65 years	1/9 (11,1)	2/4 (50,0)	0,22 [0,03; 1,80]	0,13 [0,01; 2,18]	-38,89 [-92,02; 14,24]
			0,203		
Age 2 (p-value of the interaction test: 0,109)					
<40 years	108/210 (51,4)	43/101 (42,6)	1,21 [0,93; 1,57]	1,43 [0,89; 2,30]	8,85 [-2,92; 20,63]
			0,148		
≥40 years	44/121 (36,4)	28/63 (44,4)	0,82 [0,57; 1,18]	0,71 [0,38; 1,33]	-8,08 [-23,05; 6,89]
			0,340		
Sex (p-value of the interaction test: 0,309)					
Male	86/178 (48,3)	34/83 (41,0)	1,18 [0,87; 1,59]	1,35 [0,80; 2,28]	7,35 [-5,53; 20,23]
			0,288		
Female	66/153 (43,1)	37/81 (45,7)	0,94 [0,70; 1,27]	0,90 [0,52; 1,55]	-2,54 [-15,93; 10,85]
			0,782		
Race (p-value of the interaction test: 0,777)					
White	117/268 (43,7)	58/137 (42,3)	1,03 [0,81; 1,31]	1,06 [0,70; 1,60]	1,32 [-8,86; 11,50]
			0,833		
Other	35/62 (56,5)	13/26 (50,0)	1,13 [0,73; 1,76]	1,30 [0,52; 3,25]	6,45 [-16,39; 29,29]
			0,643		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,861)					
Europe	104/224 (46,4)	52/121 (43,0)	1,08 [0,84; 1,39]	1,15 [0,74; 1,80]	3,45 [-7,52; 14,43]
				0,572	
North America	10/31 (32,3)	5/13 (38,5)	0,84 [0,36; 1,97]	0,76 [0,20; 2,93]	-6,20 [-37,35; 24,94]
				0,737	
Other	38/76 (50,0)	14/30 (46,7)	1,07 [0,69; 1,67]	1,14 [0,49; 2,66]	3,33 [-17,76; 24,43]
				0,831	
Geographic region 2 (p-value of the interaction test: 0,727)					
Asia	30/58 (51,7)	12/23 (52,2)	0,99 [0,62; 1,58]	0,98 [0,37; 2,58]	-0,45 [-24,58; 23,68]
				1,000	
Central America/South America	6/11 (54,5)	2/7 (28,6)	1,91 [0,53; 6,93]	3,00 [0,40; 22,71]	25,97 [-18,59; 70,54]
				0,367	
Europe and ROW	106/231 (45,9)	52/121 (43,0)	1,07 [0,83; 1,37]	1,13 [0,72; 1,75]	2,91 [-8,00; 13,83]
				0,652	
North America	10/31 (32,3)	5/13 (38,5)	0,84 [0,36; 1,97]	0,76 [0,20; 2,93]	-6,20 [-37,35; 24,94]
				0,737	
Weight (p-value of the interaction test: 0,332)					
<100 kg	147/309 (47,6)	67/153 (43,8)	1,09 [0,88; 1,35]	1,16 [0,79; 1,72]	3,78 [-5,85; 13,42]
				0,488	
≥100 kg	5/22 (22,7)	4/11 (36,4)	0,63 [0,21; 1,87]	0,51 [0,11; 2,50]	-13,64 [-47,02; 19,75]
				0,438	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
BMI (p-value of the interaction test: 0,403)					
Underweight (<18.5 kg/m ²)	32/59 (54,2)	12/23 (52,2)	1,04 [0,66; 1,64]	1,09 [0,41; 2,85]	2,06 [-21,99; 26,11]
				1,000	
Normal (≥18.5 and <25 kg/m ²)	68/157 (43,3)	34/92 (37,0)	1,17 [0,85; 1,62]	1,30 [0,77; 2,21]	6,36 [-6,19; 18,90]
				0,352	
Overweight (≥25 and <30 kg/m ²)	31/68 (45,6)	17/28 (60,7)	0,75 [0,51; 1,11]	0,54 [0,22; 1,33]	-15,13 [-36,74; 6,49]
				0,261	
Obese and Extreme obese (≥30 kg/m ²)	21/47 (44,7)	8/21 (38,1)	1,17 [0,62; 2,20]	1,31 [0,46; 3,76]	6,59 [-18,58; 31,75]
				0,791	
Tobacco use (p-value of the interaction test: 0,111)					
Current	39/76 (51,3)	10/32 (31,3)	1,64 [0,94; 2,87]	2,32 [0,97; 5,55]	20,07 [0,47; 39,67]
				0,061	
Former	16/46 (34,8)	13/29 (44,8)	0,78 [0,44; 1,37]	0,66 [0,25; 1,70]	-10,04 [-32,78; 12,69]
				0,467	
Never	97/209 (46,4)	48/103 (46,6)	1,00 [0,77; 1,28]	0,99 [0,62; 1,59]	-0,19 [-11,96; 11,58]
				1,000	
Prior biologic exposure (p-value of the interaction test: 0,963)					
Ever	16/36 (44,4)	5/12 (41,7)	1,07 [0,50; 2,29]	1,12 [0,30; 4,20]	2,78 [-29,50; 35,05]
				1,000	
Never	136/295 (46,1)	66/152 (43,4)	1,06 [0,85; 1,32]	1,11 [0,75; 1,65]	2,68 [-7,04; 12,40]
				0,617	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline corticosteroid use (p-value of the interaction test: 0,675)					
Yes	52/113 (46,0)	26/56 (46,4)	0,99 [0,70; 1,40]	0,98 [0,52; 1,87]	-0,41 [-16,38; 15,56]
				1,000	
No	100/218 (45,9)	45/108 (41,7)	1,10 [0,84; 1,44]	1,19 [0,74; 1,89]	4,20 [-7,21; 15,62]
				0,480	
Baseline immunomodulator use (p-value of the interaction test: 0,958)					
Yes	46/102 (45,1)	23/53 (43,4)	1,04 [0,71; 1,51]	1,07 [0,55; 2,09]	1,70 [-14,77; 18,17]
				0,866	
No	106/229 (46,3)	48/111 (43,2)	1,07 [0,83; 1,38]	1,13 [0,72; 1,79]	3,04 [-8,21; 14,30]
				0,643	
Duration of CD (p-value of the interaction test: 0,215)					
<1 year	31/71 (43,7)	18/33 (54,5)	0,80 [0,53; 1,20]	0,65 [0,28; 1,48]	-10,88 [-31,42; 9,65]
				0,399	
≥1 to <5 years	67/132 (50,8)	28/71 (39,4)	1,29 [0,92; 1,80]	1,58 [0,88; 2,84]	11,32 [-2,89; 25,53]
				0,141	
≥5 years	54/127 (42,5)	25/60 (41,7)	1,02 [0,71; 1,46]	1,04 [0,56; 1,93]	0,85 [-14,30; 16,00]
				1,000	
Baseline disease location (p-value of the interaction test: 0,927)					
Colonic	63/135 (46,7)	33/73 (45,2)	1,03 [0,76; 1,41]	1,06 [0,60; 1,88]	1,46 [-12,72; 15,64]
				0,885	
Ileal	16/41 (39,0)	8/24 (33,3)	1,17 [0,59; 2,32]	1,28 [0,45; 3,68]	5,69 [-18,36; 29,75]
				0,791	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Ileal-Colonic	73/155 (47,1)	30/65 (46,2)	1,02 [0,75; 1,39]	1,04 [0,58; 1,86]	0,94 [-13,50; 15,39]
1,000					
Baseline fecal calprotectin (p-value of the interaction test: 0,112)					
≤250	22/57 (38,6)	13/24 (54,2)	0,71 [0,44; 1,17]	0,53 [0,20; 1,39]	-15,57 [-39,17; 8,03]
0,226					
>250	105/203 (51,7)	44/103 (42,7)	1,21 [0,93; 1,57]	1,44 [0,89; 2,32]	9,01 [-2,76; 20,77]
0,148					
Baseline SES-CD total score (p-value of the interaction test: 0,953)					
<12	85/200 (42,5)	39/96 (40,6)	1,05 [0,78; 1,40]	1,08 [0,66; 1,77]	1,88 [-10,10; 13,85]
0,802					
≥12	67/131 (51,1)	32/66 (48,5)	1,05 [0,78; 1,42]	1,11 [0,62; 2,01]	2,66 [-12,13; 17,45]
0,764					
Baseline AP average (p-value of the interaction test: 0,276)					
<2	19/70 (27,1)	12/35 (34,3)	0,79 [0,44; 1,44]	0,71 [0,30; 1,71]	-7,14 [-26,01; 11,72]
0,500					
≥2	133/260 (51,2)	59/129 (45,7)	1,12 [0,90; 1,40]	1,24 [0,81; 1,90]	5,42 [-5,11; 15,94]
0,334					
Baseline SF average (p-value of the interaction test: 0,295)					
<7	119/265 (44,9)	56/125 (44,8)	1,00 [0,79; 1,27]	1,00 [0,65; 1,54]	0,11 [-10,47; 10,68]
1,000					
≥7	33/65 (50,8)	15/39 (38,5)	1,32 [0,83; 2,10]	1,65 [0,74; 3,70]	12,31 [-7,21; 31,82]
0,310					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline CDAI 1 (p-value of the interaction test: 0,467)					
<300	60/148 (40,5)	32/75 (42,7)	0,95 [0,69; 1,32]	0,92 [0,52; 1,61]	-2,13 [-15,83; 11,58]
				0,775	
≥300	92/182 (50,5)	39/89 (43,8)	1,15 [0,88; 1,52]	1,31 [0,79; 2,18]	6,73 [-5,88; 19,34]
				0,304	
Baseline CDAI 2 (p-value of the interaction test: 0,534)					
<150	0/5 (0,0)	2/6 (33,3)	0,23 [0,01; 3,97]	0,16 [0,01; 4,36]	-33,33 [-71,05; 4,39]
				0,455	
≥150 and <220	8/27 (29,6)	7/18 (38,9)	0,76 [0,34; 1,73]	0,66 [0,19; 2,33]	-9,26 [-37,61; 19,09]
				0,538	
≥220 and <450	132/275 (48,0)	53/125 (42,4)	1,13 [0,89; 1,44]	1,25 [0,82; 1,92]	5,60 [-4,88; 16,08]
				0,331	
≥450	12/23 (52,2)	9/15 (60,0)	0,87 [0,49; 1,54]	0,73 [0,19; 2,72]	-7,83 [-39,94; 24,29]
				0,744	
OECD Country (p-value of the interaction test: 0,657)					
Yes	92/209 (44,0)	40/94 (42,6)	1,03 [0,78; 1,37]	1,06 [0,65; 1,74]	1,47 [-10,58; 13,52]
				0,900	
No	60/122 (49,2)	31/70 (44,3)	1,11 [0,81; 1,53]	1,22 [0,67; 2,20]	4,89 [-9,74; 19,53]
				0,550	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Datenschnitt: 23. August 2023; Conventional-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PCS: Physical Health Component Summary Score; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF-36: 36-Item Short Form Health Survey; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

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20DEC2024 / 04:00

Subgruppen für Increase in SF-36 MCS Score by at least 9.6 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,140)					
<65 years	96/322 (29,8)	49/160 (30,6)	0,97 [0,73; 1,30]	0,96 [0,64; 1,45]	-0,81 [-9,53; 7,90]
			0,916		
≥65 years	0/9 (0,0)	2/4 (50,0)	0,10 [0,01; 1,71]	0,05 [0,00; 1,49]	-50,00 [-99,00; -1,00]
			0,077		
Age 2 (p-value of the interaction test: 0,064)					
<40 years	66/210 (31,4)	27/101 (26,7)	1,18 [0,80; 1,72]	1,26 [0,74; 2,13]	4,70 [-5,98; 15,37]
			0,430		
≥40 years	30/121 (24,8)	24/63 (38,1)	0,65 [0,42; 1,01]	0,54 [0,28; 1,03]	-13,30 [-27,55; 0,95]
			0,064		
Sex (p-value of the interaction test: 0,864)					
Male	47/178 (26,4)	24/83 (28,9)	0,91 [0,60; 1,39]	0,88 [0,49; 1,58]	-2,51 [-14,22; 9,20]
			0,765		
Female	49/153 (32,0)	27/81 (33,3)	0,96 [0,65; 1,41]	0,94 [0,53; 1,67]	-1,31 [-13,96; 11,34]
			0,884		
Race (p-value of the interaction test: 0,523)					
White	77/268 (28,7)	41/137 (29,9)	0,96 [0,70; 1,32]	0,94 [0,60; 1,48]	-1,20 [-10,58; 8,19]
			0,818		
Other	19/62 (30,6)	10/26 (38,5)	0,80 [0,43; 1,47]	0,71 [0,27; 1,84]	-7,82 [-29,76; 14,12]
			0,620		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Geographic region 1 (p-value of the interaction test: 0,870)					
Europe	65/224 (29,0)	37/121 (30,6)	0,95 [0,68; 1,33]	0,93 [0,57; 1,50]	-1,56 [-11,70; 8,57]
			0,805		
North America	8/31 (25,8)	3/13 (23,1)	1,12 [0,35; 3,56]	1,16 [0,25; 5,30]	2,73 [-24,87; 30,33]
			1,000		
Other	23/76 (30,3)	11/30 (36,7)	0,83 [0,46; 1,48]	0,75 [0,31; 1,82]	-6,40 [-26,50; 13,70]
			0,645		
Geographic region 2 (p-value of the interaction test: 0,806)					
Asia	18/58 (31,0)	7/23 (30,4)	1,02 [0,49; 2,11]	1,03 [0,36; 2,93]	0,60 [-21,66; 22,86]
			1,000		
Central America/South America	3/11 (27,3)	4/7 (57,1)	0,48 [0,15; 1,52]	0,28 [0,04; 2,08]	-29,87 [-75,00; 15,26]
			0,332		
Europe and ROW	67/231 (29,0)	37/121 (30,6)	0,95 [0,68; 1,33]	0,93 [0,57; 1,50]	-1,57 [-11,66; 8,51]
			0,806		
North America	8/31 (25,8)	3/13 (23,1)	1,12 [0,35; 3,56]	1,16 [0,25; 5,30]	2,73 [-24,87; 30,33]
			1,000		
Weight (p-value of the interaction test: 0,738)					
<100 kg	93/309 (30,1)	50/153 (32,7)	0,92 [0,69; 1,22]	0,89 [0,58; 1,34]	-2,58 [-11,60; 6,44]
			0,594		
≥100 kg	3/22 (13,6)	1/11 (9,1)	1,50 [0,18; 12,80]	1,58 [0,14; 17,22]	4,55 [-17,69; 26,78]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
BMI (p-value of the interaction test: 0,570)					
Underweight ($<18.5 \text{ kg/m}^2$)	18/59 (30,5)	7/23 (30,4)	1,00 [0,48; 2,08]	1,00 [0,35; 2,86]	0,07 [-22,10; 22,25]
				1,000	
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	42/157 (26,8)	28/92 (30,4)	0,88 [0,59; 1,32]	0,83 [0,47; 1,47]	-3,68 [-15,36; 7,99]
				0,561	
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	22/68 (32,4)	12/28 (42,9)	0,75 [0,44; 1,31]	0,64 [0,26; 1,58]	-10,50 [-31,94; 10,93]
				0,355	
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	14/47 (29,8)	4/21 (19,0)	1,56 [0,58; 4,19]	1,80 [0,51; 6,33]	10,74 [-10,54; 32,02]
				0,553	
Tobacco use (p-value of the interaction test: 0,479)					
Current	27/76 (35,5)	9/32 (28,1)	1,26 [0,67; 2,37]	1,41 [0,57; 3,47]	7,40 [-11,53; 26,33]
				0,509	
Former	11/46 (23,9)	8/29 (27,6)	0,87 [0,40; 1,90]	0,83 [0,29; 2,38]	-3,67 [-24,08; 16,74]
				0,788	
Never	58/209 (27,8)	34/103 (33,0)	0,84 [0,59; 1,19]	0,78 [0,47; 1,30]	-5,26 [-16,18; 5,67]
				0,357	
Prior biologic exposure (p-value of the interaction test: 0,696)					
Ever	12/36 (33,3)	5/12 (41,7)	0,80 [0,35; 1,80]	0,70 [0,18; 2,67]	-8,33 [-40,20; 23,53]
				0,731	
Never	84/295 (28,5)	46/152 (30,3)	0,94 [0,70; 1,27]	0,92 [0,60; 1,41]	-1,79 [-10,72; 7,15]
				0,742	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline corticosteroid use (p-value of the interaction test: 0,120)					
Yes	27/113 (23,9)	20/56 (35,7)	0,67 [0,41; 1,08]	0,57 [0,28; 1,13]	-11,82 [-26,63; 2,99]
				0,144	
No	69/218 (31,7)	31/108 (28,7)	1,10 [0,77; 1,57]	1,15 [0,69; 1,91]	2,95 [-7,58; 13,48]
				0,612	
Baseline immunomodulator use (p-value of the interaction test: 0,984)					
Yes	30/102 (29,4)	17/53 (32,1)	0,92 [0,56; 1,50]	0,88 [0,43; 1,81]	-2,66 [-18,03; 12,70]
				0,854	
No	66/229 (28,8)	34/111 (30,6)	0,94 [0,67; 1,33]	0,92 [0,56; 1,50]	-1,81 [-12,20; 8,58]
				0,800	
Duration of CD (p-value of the interaction test: 0,923)					
<1 year	18/71 (25,4)	10/33 (30,3)	0,84 [0,44; 1,61]	0,78 [0,31; 1,95]	-4,95 [-23,61; 13,71]
				0,639	
≥1 to <5 years	44/132 (33,3)	25/71 (35,2)	0,95 [0,64; 1,41]	0,92 [0,50; 1,69]	-1,88 [-15,59; 11,84]
				0,877	
≥5 years	34/127 (26,8)	16/60 (26,7)	1,00 [0,60; 1,67]	1,01 [0,50; 2,01]	0,10 [-13,48; 13,69]
				1,000	
Baseline disease location (p-value of the interaction test: 0,398)					
Colonic	47/135 (34,8)	30/73 (41,1)	0,85 [0,59; 1,21]	0,77 [0,43; 1,37]	-6,28 [-20,14; 7,57]
				0,372	
Ileal	6/41 (14,6)	6/24 (25,0)	0,59 [0,21; 1,61]	0,51 [0,14; 1,82]	-10,37 [-30,79; 10,06]
				0,335	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Ileal-Colonic	43/155 (27,7)	15/65 (23,1)	1,20 [0,72; 2,00]	1,28 [0,65; 2,52]	4,67 [-7,77; 17,10]
0,507					
Baseline fecal calprotectin (p-value of the interaction test: 0,408)					
≤250	20/57 (35,1)	7/24 (29,2)	1,20 [0,59; 2,46]	1,31 [0,47; 3,69]	5,92 [-16,08; 27,93]
0,797					
>250	60/203 (29,6)	34/103 (33,0)	0,90 [0,63; 1,27]	0,85 [0,51; 1,42]	-3,45 [-14,49; 7,59]
0,600					
Baseline CRP (p-value of the interaction test: 0,592)					
≤10	61/217 (28,1)	34/108 (31,5)	0,89 [0,63; 1,27]	0,85 [0,51; 1,41]	-3,37 [-13,98; 7,24]
0,605					
>10	35/114 (30,7)	17/56 (30,4)	1,01 [0,62; 1,64]	1,02 [0,51; 2,04]	0,34 [-14,38; 15,07]
1,000					
Baseline SES-CD total score (p-value of the interaction test: 0,553)					
<12	54/200 (27,0)	26/96 (27,1)	1,00 [0,67; 1,49]	1,00 [0,58; 1,72]	-0,08 [-10,89; 10,73]
1,000					
≥12	42/131 (32,1)	25/66 (37,9)	0,85 [0,57; 1,26]	0,77 [0,42; 1,44]	-5,82 [-19,99; 8,35]
0,430					
Baseline AP average (p-value of the interaction test: 0,454)					
<2	11/70 (15,7)	8/35 (22,9)	0,69 [0,30; 1,55]	0,63 [0,23; 1,74]	-7,14 [-23,46; 9,17]
0,424					
≥2	85/260 (32,7)	43/129 (33,3)	0,98 [0,73; 1,32]	0,97 [0,62; 1,52]	-0,64 [-10,58; 9,29]
0,909					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Baseline SF average (p-value of the interaction test: 0,481)					
<7	81/265 (30,6)	39/125 (31,2)	0,98 [0,71; 1,35]	0,97 [0,61; 1,54]	-0,63 [-10,47; 9,20]
				0,907	
≥7	15/65 (23,1)	12/39 (30,8)	0,75 [0,39; 1,43]	0,68 [0,28; 1,65]	-7,69 [-25,43; 10,05]
				0,489	
Baseline CDAI 1 (p-value of the interaction test: 0,372)					
<300	36/148 (24,3)	17/75 (22,7)	1,07 [0,65; 1,78]	1,10 [0,57; 2,12]	1,66 [-10,07; 13,39]
				0,868	
≥300	60/182 (33,0)	34/89 (38,2)	0,86 [0,62; 1,21]	0,80 [0,47; 1,35]	-5,24 [-17,42; 6,95]
				0,417	
Baseline CDAI 2 (p-value of the interaction test: 0,296)					
<150	1/5 (20,0)	0/6 (0,0)	3,50 [0,17; 70,94]	4,33 [0,14; >100]	20,00 [-15,06; 55,06]
				0,455	
≥150 and <220	6/27 (22,2)	1/18 (5,6)	4,00 [0,52; 30,49]	4,86 [0,53; 44,34]	16,67 [-2,25; 35,58]
				0,215	
≥220 and <450	83/275 (30,2)	43/125 (34,4)	0,88 [0,65; 1,19]	0,82 [0,53; 1,29]	-4,22 [-14,16; 5,72]
				0,418	
≥450	6/23 (26,1)	7/15 (46,7)	0,56 [0,23; 1,34]	0,40 [0,10; 1,60]	-20,58 [-51,55; 10,40]
				0,295	
OECD Country (p-value of the interaction test: 0,392)					
Yes	61/209 (29,2)	26/94 (27,7)	1,06 [0,72; 1,56]	1,08 [0,63; 1,85]	1,53 [-9,42; 12,47]
				0,891	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
No	35/122 (28,7)	25/70 (35,7)	0,80 [0,53; 1,22]	0,72 [0,39; 1,36]	-7,03 [-20,82; 6,77]
0,335					

Datenschnitt: 23. August 2023; Conventional-failed ITT Population.

Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; MCS: Mental Health Component Summary Score; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF-36: 36-Item Short Form Health Survey; SF: Stool Frequency.

RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm.

a: Exakter Test nach Fisher.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_sf36mcsi9_6_sub_itta_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Anhang 4-G.3.6.3 Sicherheit**Anhang 4-G.3.6.3.1 Unerwünschte Ereignisse (UE) Gesamtraten**

Subgruppen für Jegliche unerwünschte Ereignisse: Gesamtrate in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,306)					
<65 years	239/322 (74,2)	114/160 (71,3)	1,04 [0,93; 1,17]	1,16 [0,76; 1,78]	2,97 [-5,51; 11,46]
			0,513		
≥65 years	6/9 (66,7)	4/4 (100)	0,72 [0,42; 1,24]	0,21 [0,01; 5,05]	-33,33 [-64,13; -2,54]
			0,497		
Age 2 (p-value of the interaction test: 0,531)					
<40 years	153/210 (72,9)	70/101 (69,3)	1,05 [0,90; 1,23]	1,19 [0,71; 2,00]	3,55 [-7,27; 14,37]
			0,591		
≥40 years	92/121 (76,0)	48/63 (76,2)	1,00 [0,84; 1,18]	0,99 [0,49; 2,03]	-0,16 [-13,14; 12,82]
			1,000		
Sex (p-value of the interaction test: 0,630)					
Male	129/178 (72,5)	57/83 (68,7)	1,06 [0,89; 1,25]	1,20 [0,68; 2,12]	3,80 [-8,15; 15,74]
			0,558		
Female	116/153 (75,8)	61/81 (75,3)	1,01 [0,86; 1,17]	1,03 [0,55; 1,92]	0,51 [-11,08; 12,09]
			1,000		
Race (p-value of the interaction test: 0,970)					
White	194/268 (72,4)	96/137 (70,1)	1,03 [0,91; 1,18]	1,12 [0,71; 1,76]	2,32 [-7,04; 11,67]
			0,642		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Other	50/62 (80,6)	21/26 (80,8)	1,00 [0,80; 1,25]	0,99 [0,31; 3,17]	-0,12 [-18,19; 17,94]
1,000					
Geographic region 1 (p-value of the interaction test: 0,776)					
Europe	157/224 (70,1)	81/121 (66,9)	1,05 [0,90; 1,22]	1,16 [0,72; 1,86]	3,15 [-7,16; 13,45]
0,545					
North America	26/31 (83,9)	12/13 (92,3)	0,91 [0,73; 1,13]	0,43 [0,05; 4,13]	-8,44 [-27,86; 10,99]
0,652					
Other	62/76 (81,6)	25/30 (83,3)	0,98 [0,81; 1,19]	0,89 [0,29; 2,72]	-1,75 [-17,69; 14,18]
1,000					
Geographic region 2 (p-value of the interaction test: 0,596)					
Asia	47/58 (81,0)	18/23 (78,3)	1,04 [0,81; 1,33]	1,19 [0,36; 3,90]	2,77 [-16,87; 22,42]
0,765					
Central America/South America	8/11 (72,7)	7/7 (100)	0,76 [0,50; 1,13]	0,16 [0,01; 3,67]	-27,27 [-53,59; -0,95]
0,245					
Europe and ROW	164/231 (71,0)	81/121 (66,9)	1,06 [0,91; 1,23]	1,21 [0,75; 1,94]	4,05 [-6,17; 14,28]
0,465					
North America	26/31 (83,9)	12/13 (92,3)	0,91 [0,73; 1,13]	0,43 [0,05; 4,13]	-8,44 [-27,86; 10,99]
0,652					
Weight (p-value of the interaction test: 0,274)					
<100 kg	231/309 (74,8)	109/153 (71,2)	1,05 [0,93; 1,18]	1,20 [0,77; 1,85]	3,52 [-5,14; 12,17]
0,434					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
≥100 kg	14/22 (63,6)	9/11 (81,8)	0,78 [0,51; 1,19]	0,39 [0,07; 2,26]	-18,18 [-48,57; 12,21]
0,430					
BMI (p-value of the interaction test: 0,685)					
Underweight ($<18.5 \text{ kg/m}^2$)	48/59 (81,4)	18/23 (78,3)	1,04 [0,81; 1,33]	1,21 [0,37; 3,98]	3,10 [-16,47; 22,66]
0,762					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	109/157 (69,4)	61/92 (66,3)	1,05 [0,88; 1,25]	1,15 [0,67; 2,00]	3,12 [-8,93; 15,17]
0,673					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	51/68 (75,0)	20/28 (71,4)	1,05 [0,80; 1,38]	1,20 [0,45; 3,22]	3,57 [-16,07; 23,22]
0,799					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	37/47 (78,7)	19/21 (90,5)	0,87 [0,71; 1,07]	0,39 [0,08; 1,96]	-11,75 [-28,91; 5,41]
0,317					
Tobacco use (p-value of the interaction test: 0,545)					
Current	57/76 (75,0)	23/32 (71,9)	1,04 [0,81; 1,34]	1,17 [0,46; 2,97]	3,13 [-15,24; 21,49]
0,811					
Former	34/46 (73,9)	24/29 (82,8)	0,89 [0,70; 1,13]	0,59 [0,18; 1,90]	-8,85 [-27,55; 9,86]
0,413					
Never	154/209 (73,7)	71/103 (68,9)	1,07 [0,92; 1,25]	1,26 [0,75; 2,12]	4,75 [-6,00; 15,50]
0,421					
Prior biologic exposure (p-value of the interaction test: 0,941)					
Ever	30/36 (83,3)	10/12 (83,3)	1,00 [0,75; 1,34]	1,00 [0,17; 5,77]	0,00 [-24,35; 24,35]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Never	215/295 (72,9)	108/152 (71,1)	1,03 [0,91; 1,16]	1,09 [0,71; 1,69]	1,83 [-6,99; 10,64]
0,738					
Baseline corticosteroid use (p-value of the interaction test: 0,680)					
Yes	80/113 (70,8)	40/56 (71,4)	0,99 [0,81; 1,21]	0,97 [0,48; 1,97]	-0,63 [-15,13; 13,87]
1,000					
No	165/218 (75,7)	78/108 (72,2)	1,05 [0,91; 1,20]	1,20 [0,71; 2,02]	3,47 [-6,72; 13,65]
0,502					
Baseline immunomodulator use (p-value of the interaction test: 0,985)					
Yes	77/102 (75,5)	39/53 (73,6)	1,03 [0,84; 1,25]	1,11 [0,52; 2,36]	1,91 [-12,61; 16,42]
0,846					
No	168/229 (73,4)	79/111 (71,2)	1,03 [0,89; 1,19]	1,12 [0,67; 1,85]	2,19 [-8,00; 12,38]
0,698					
Baseline disease location (p-value of the interaction test: 0,875)					
Colonic	98/135 (72,6)	53/73 (72,6)	1,00 [0,84; 1,19]	1,00 [0,53; 1,89]	-0,01 [-12,71; 12,69]
1,000					
Ileal	29/41 (70,7)	17/24 (70,8)	1,00 [0,72; 1,38]	1,00 [0,33; 3,01]	-0,10 [-23,01; 22,80]
1,000					
Ileal-Colonic	118/155 (76,1)	47/65 (72,3)	1,05 [0,88; 1,25]	1,22 [0,63; 2,36]	3,82 [-8,96; 16,60]
0,609					
Baseline fecal calprotectin (p-value of the interaction test: 0,245)					
≤250	43/57 (75,4)	14/24 (58,3)	1,29 [0,89; 1,87]	2,19 [0,80; 6,03]	17,11 [-5,56; 39,77]
0,182					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
>250	150/203 (73,9)	74/103 (71,8)	1,03 [0,89; 1,19]	1,11 [0,65; 1,89]	2,05 [-8,53; 12,63]
0,785					
Baseline CRP (p-value of the interaction test: 0,382)					
≤10	161/217 (74,2)	75/108 (69,4)	1,07 [0,92; 1,24]	1,27 [0,76; 2,11]	4,75 [-5,71; 15,21]
0,428					
>10	84/114 (73,7)	43/56 (76,8)	0,96 [0,80; 1,15]	0,85 [0,40; 1,79]	-3,10 [-16,80; 10,60]
0,711					
Baseline SES-CD total score (p-value of the interaction test: 0,413)					
<12	153/200 (76,5)	69/96 (71,9)	1,06 [0,92; 1,23]	1,27 [0,73; 2,21]	4,63 [-6,12; 15,37]
0,393					
≥12	92/131 (70,2)	48/66 (72,7)	0,97 [0,80; 1,16]	0,88 [0,46; 1,71]	-2,50 [-15,79; 10,80]
0,742					
Baseline AP average (p-value of the interaction test: 0,550)					
<2	58/70 (82,9)	27/35 (77,1)	1,07 [0,87; 1,32]	1,43 [0,52; 3,91]	5,71 [-10,76; 22,19]
0,599					
≥2	186/260 (71,5)	91/129 (70,5)	1,01 [0,89; 1,16]	1,05 [0,66; 1,67]	1,00 [-8,59; 10,59]
0,905					
Baseline SF average (p-value of the interaction test: 0,934)					
<7	200/265 (75,5)	92/125 (73,6)	1,03 [0,90; 1,16]	1,10 [0,68; 1,79]	1,87 [-7,43; 11,17]
0,709					
≥7	44/65 (67,7)	26/39 (66,7)	1,02 [0,77; 1,34]	1,05 [0,45; 2,44]	1,03 [-17,63; 19,68]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline CDAI 1 (p-value of the interaction test: 0,430)					
<300	113/148 (76,4)	53/75 (70,7)	1,08 [0,91; 1,28]	1,34 [0,72; 2,50]	5,68 [-6,69; 18,06]
			0,417		
≥300	131/182 (72,0)	65/89 (73,0)	0,99 [0,84; 1,15]	0,95 [0,54; 1,68]	-1,06 [-12,35; 10,24]
			0,886		
Baseline CDAI 2 (p-value of the interaction test: 0,794)					
<150	4/5 (80,0)	3/6 (50,0)	1,60 [0,64; 3,98]	4,00 [0,27; 60,32]	30,00 [-23,20; 83,20]
			0,545		
≥150 and <220	21/27 (77,8)	14/18 (77,8)	1,00 [0,73; 1,38]	1,00 [0,24; 4,20]	0,00 [-24,79; 24,79]
			1,000		
≥220 and <450	204/275 (74,2)	93/125 (74,4)	1,00 [0,88; 1,13]	0,99 [0,61; 1,60]	-0,22 [-9,45; 9,02]
			1,000		
≥450	15/23 (65,2)	8/15 (53,3)	1,22 [0,70; 2,14]	1,64 [0,43; 6,19]	11,88 [-19,99; 43,76]
			0,514		
OECD Country (p-value of the interaction test: 0,843)					
Yes	160/209 (76,6)	71/94 (75,5)	1,01 [0,88; 1,16]	1,06 [0,60; 1,87]	1,02 [-9,39; 11,44]
			0,884		
No	85/122 (69,7)	47/70 (67,1)	1,04 [0,85; 1,27]	1,12 [0,60; 2,11]	2,53 [-11,17; 16,23]
			0,748		

	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Subgruppe			p-Wert ^a		
Datenschnitt: 23. August 2023; Conventional-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_teae_sub_safa_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
20DEC2024 / 04:00

Subgruppen für Jegliche unerwünschte Ereignisse: Nicht schwer in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,219)					
<65 years	216/322 (67,1)	103/160 (64,4)	1,04 [0,91; 1,20]	1,13 [0,76; 1,68]	2,71 [-6,32; 11,73]
			0,609		
≥65 years	5/9 (55,6)	4/4 (100)	0,61 [0,32; 1,15]	0,14 [0,01; 3,25]	-44,44 [-76,91; -11,98]
			0,228		
Age 2 (p-value of the interaction test: 0,892)					
<40 years	136/210 (64,8)	65/101 (64,4)	1,01 [0,84; 1,20]	1,02 [0,62; 1,67]	0,41 [-10,95; 11,76]
			1,000		
≥40 years	85/121 (70,2)	42/63 (66,7)	1,05 [0,85; 1,30]	1,18 [0,61; 2,27]	3,58 [-10,63; 17,79]
			0,619		
Sex (p-value of the interaction test: 0,667)					
Male	119/178 (66,9)	53/83 (63,9)	1,05 [0,86; 1,27]	1,14 [0,66; 1,97]	3,00 [-9,44; 15,43]
			0,675		
Female	102/153 (66,7)	54/81 (66,7)	1,00 [0,83; 1,21]	1,00 [0,56; 1,77]	0,00 [-12,70; 12,70]
			1,000		
Race (p-value of the interaction test: 0,355)					
White	172/268 (64,2)	89/137 (65,0)	0,99 [0,85; 1,15]	0,97 [0,63; 1,49]	-0,78 [-10,62; 9,05]
			0,913		
Other	48/62 (77,4)	18/26 (69,2)	1,12 [0,84; 1,49]	1,52 [0,55; 4,24]	8,19 [-12,38; 28,76]
			0,430		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,931)					
Europe	139/224 (62,1)	75/121 (62,0)	1,00 [0,84; 1,19]	1,00 [0,64; 1,58]	0,07 [-10,66; 10,80]
				1,000	
North America	25/31 (80,6)	10/13 (76,9)	1,05 [0,74; 1,48]	1,25 [0,26; 6,00]	3,72 [-23,07; 30,52]
				1,000	
Other	57/76 (75,0)	22/30 (73,3)	1,02 [0,80; 1,32]	1,09 [0,42; 2,85]	1,67 [-16,91; 20,25]
				1,000	
Geographic region 2 (p-value of the interaction test: 0,746)					
Asia	44/58 (75,9)	16/23 (69,6)	1,09 [0,80; 1,48]	1,38 [0,47; 4,02]	6,30 [-15,50; 28,09]
				0,582	
Central America/South America	7/11 (63,6)	6/7 (85,7)	0,74 [0,43; 1,27]	0,29 [0,03; 3,37]	-22,08 [-60,55; 16,39]
				0,596	
Europe and ROW	145/231 (62,8)	75/121 (62,0)	1,01 [0,85; 1,20]	1,03 [0,66; 1,63]	0,79 [-9,87; 11,45]
				0,908	
North America	25/31 (80,6)	10/13 (76,9)	1,05 [0,74; 1,48]	1,25 [0,26; 6,00]	3,72 [-23,07; 30,52]
				1,000	
Weight (p-value of the interaction test: 0,591)					
<100 kg	207/309 (67,0)	99/153 (64,7)	1,04 [0,90; 1,19]	1,11 [0,74; 1,66]	2,28 [-6,93; 11,49]
				0,676	
≥100 kg	14/22 (63,6)	8/11 (72,7)	0,88 [0,54; 1,41]	0,66 [0,13; 3,21]	-9,09 [-42,21; 24,03]
				0,709	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
BMI (p-value of the interaction test: 0,679)					
Underweight ($<18.5 \text{ kg/m}^2$)	44/59 (74,6)	15/23 (65,2)	1,14 [0,82; 1,60]	1,56 [0,55; 4,42]	9,36 [-13,05; 31,77]
				0,422	
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	96/157 (61,1)	55/92 (59,8)	1,02 [0,83; 1,26]	1,06 [0,63; 1,79]	1,36 [-11,23; 13,95]
				0,893	
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	46/68 (67,6)	19/28 (67,9)	1,00 [0,74; 1,35]	0,99 [0,39; 2,54]	-0,21 [-20,77; 20,35]
				1,000	
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	35/47 (74,5)	18/21 (85,7)	0,87 [0,68; 1,11]	0,49 [0,12; 1,95]	-11,25 [-30,72; 8,23]
				0,361	
Tobacco use (p-value of the interaction test: 0,307)					
Current	54/76 (71,1)	19/32 (59,4)	1,20 [0,87; 1,65]	1,68 [0,71; 3,98]	11,68 [-8,16; 31,52]
				0,265	
Former	31/46 (67,4)	23/29 (79,3)	0,85 [0,65; 1,12]	0,54 [0,18; 1,60]	-11,92 [-31,94; 8,10]
				0,302	
Never	136/209 (65,1)	65/103 (63,1)	1,03 [0,86; 1,23]	1,09 [0,67; 1,78]	1,96 [-9,38; 13,31]
				0,802	
Prior biologic exposure (p-value of the interaction test: 0,984)					
Ever	27/36 (75,0)	9/12 (75,0)	1,00 [0,69; 1,46]	1,00 [0,22; 4,52]	0,00 [-28,29; 28,29]
				1,000	
Never	194/295 (65,8)	98/152 (64,5)	1,02 [0,88; 1,18]	1,06 [0,70; 1,59]	1,29 [-8,05; 10,63]
				0,834	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline corticosteroid use (p-value of the interaction test: 0,327)					
Yes	69/113 (61,1)	37/56 (66,1)	0,92 [0,73; 1,17]	0,81 [0,41; 1,57]	-5,01 [-20,33; 10,31]
				0,613	
No	152/218 (69,7)	70/108 (64,8)	1,08 [0,91; 1,27]	1,25 [0,77; 2,04]	4,91 [-5,97; 15,79]
				0,379	
Baseline immunomodulator use (p-value of the interaction test: 0,378)					
Yes	73/102 (71,6)	34/53 (64,2)	1,12 [0,88; 1,41]	1,41 [0,69; 2,85]	7,42 [-8,18; 23,02]
				0,364	
No	148/229 (64,6)	73/111 (65,8)	0,98 [0,83; 1,16]	0,95 [0,59; 1,53]	-1,14 [-11,92; 9,65]
				0,904	
Duration of CD (p-value of the interaction test: 0,206)					
<1 year	43/71 (60,6)	15/33 (45,5)	1,33 [0,88; 2,02]	1,84 [0,80; 4,24]	15,11 [-5,33; 35,55]
				0,203	
≥1 to <5 years	83/132 (62,9)	49/71 (69,0)	0,91 [0,74; 1,12]	0,76 [0,41; 1,41]	-6,14 [-19,69; 7,42]
				0,441	
≥5 years	94/127 (74,0)	43/60 (71,7)	1,03 [0,85; 1,25]	1,13 [0,57; 2,24]	2,35 [-11,37; 16,07]
				0,727	
Baseline disease location (p-value of the interaction test: 0,863)					
Colonic	86/135 (63,7)	47/73 (64,4)	0,99 [0,80; 1,22]	0,97 [0,54; 1,76]	-0,68 [-14,34; 12,98]
				1,000	
Ileal	25/41 (61,0)	15/24 (62,5)	0,98 [0,66; 1,45]	0,94 [0,33; 2,65]	-1,52 [-25,98; 22,93]
				1,000	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Ileal-Colonic	110/155 (71,0)	44/65 (67,7)	1,05 [0,86; 1,28]	1,17 [0,62; 2,18]	3,28 [-10,15; 16,70]
0,632					
Baseline fecal calprotectin (p-value of the interaction test: 0,272)					
≤250	38/57 (66,7)	12/24 (50,0)	1,33 [0,86; 2,07]	2,00 [0,76; 5,28]	16,67 [-6,78; 40,12]
0,212					
>250	137/203 (67,5)	68/103 (66,0)	1,02 [0,86; 1,21]	1,07 [0,65; 1,77]	1,47 [-9,72; 12,66]
0,798					
Baseline CRP (p-value of the interaction test: 0,337)					
≤10	151/217 (69,6)	70/108 (64,8)	1,07 [0,91; 1,27]	1,24 [0,76; 2,03]	4,77 [-6,12; 15,66]
0,449					
>10	70/114 (61,4)	37/56 (66,1)	0,93 [0,73; 1,18]	0,82 [0,42; 1,60]	-4,67 [-19,95; 10,62]
0,614					
Baseline SES-CD total score (p-value of the interaction test: 0,340)					
<12	139/200 (69,5)	62/96 (64,6)	1,08 [0,90; 1,28]	1,25 [0,75; 2,09]	4,92 [-6,58; 16,42]
0,426					
≥12	82/131 (62,6)	44/66 (66,7)	0,94 [0,76; 1,17]	0,84 [0,45; 1,56]	-4,07 [-18,14; 10,00]
0,638					
Baseline AP average (p-value of the interaction test: 0,664)					
<2	55/70 (78,6)	26/35 (74,3)	1,06 [0,84; 1,33]	1,27 [0,49; 3,28]	4,29 [-13,09; 21,67]
0,630					
≥2	165/260 (63,5)	81/129 (62,8)	1,01 [0,86; 1,19]	1,03 [0,66; 1,59]	0,67 [-9,52; 10,86]
0,911					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Baseline SF average (p-value of the interaction test: 0,746)					
<7	182/265 (68,7)	83/125 (66,4)	1,03 [0,89; 1,20]	1,11 [0,71; 1,75]	2,28 [-7,71; 12,27]
				0,727	
≥7	38/65 (58,5)	24/39 (61,5)	0,95 [0,69; 1,31]	0,88 [0,39; 1,98]	-3,08 [-22,48; 16,33]
				0,838	
Baseline CDAI 1 (p-value of the interaction test: 0,876)					
<300	102/148 (68,9)	50/75 (66,7)	1,03 [0,85; 1,25]	1,11 [0,61; 2,01]	2,25 [-10,76; 15,27]
				0,762	
≥300	118/182 (64,8)	57/89 (64,0)	1,01 [0,84; 1,22]	1,04 [0,61; 1,76]	0,79 [-11,36; 12,94]
				0,893	
Baseline CDAI 2 (p-value of the interaction test: 0,710)					
<150	4/5 (80,0)	3/6 (50,0)	1,60 [0,64; 3,98]	4,00 [0,27; 60,32]	30,00 [-23,20; 83,20]
				0,545	
≥150 and <220	18/27 (66,7)	14/18 (77,8)	0,86 [0,60; 1,23]	0,57 [0,15; 2,25]	-11,11 [-37,28; 15,06]
				0,514	
≥220 and <450	185/275 (67,3)	82/125 (65,6)	1,03 [0,88; 1,19]	1,08 [0,69; 1,69]	1,67 [-8,33; 11,68]
				0,819	
≥450	13/23 (56,5)	8/15 (53,3)	1,06 [0,59; 1,92]	1,14 [0,31; 4,20]	3,19 [-29,18; 35,56]
				1,000	
OECD Country (p-value of the interaction test: 0,894)					
Yes	142/209 (67,9)	63/94 (67,0)	1,01 [0,86; 1,20]	1,04 [0,62; 1,75]	0,92 [-10,50; 12,34]
				0,895	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
No	79/122 (64,8)	44/70 (62,9)	1,03 [0,82; 1,29]	1,09 [0,59; 2,00]	1,90 [-12,24; 16,04]
0,876					
Datenschnitt: 23. August 2023; Conventional-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_aemaxns_sub_safa_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
20DEC2024 / 04:00

Subgruppen für Jegliche unerwünschte Ereignisse: Schwer in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,833)					
<65 years	23/322 (7,1)	11/160 (6,9)	1,04 [0,52; 2,08]	1,04 [0,49; 2,19]	0,27 [-4,56; 5,09]
			1,000		
≥65 years	1/9 (11,1)	0/4 (0,0)	1,50 [0,07; 30,59]	1,59 [0,05; 47,52]	11,11 [-9,42; 31,64]
			1,000		
Age 2 (p-value of the interaction test: 0,181)					
<40 years	17/210 (8,1)	5/101 (5,0)	1,64 [0,62; 4,31]	1,69 [0,61; 4,72]	3,14 [-2,47; 8,76]
			0,356		
≥40 years	7/121 (5,8)	6/63 (9,5)	0,61 [0,21; 1,73]	0,58 [0,19; 1,82]	-3,74 [-12,10; 4,62]
			0,373		
Sex (p-value of the interaction test: 0,920)					
Male	10/178 (5,6)	4/83 (4,8)	1,17 [0,38; 3,61]	1,18 [0,36; 3,86]	0,80 [-4,92; 6,51]
			1,000		
Female	14/153 (9,2)	7/81 (8,6)	1,06 [0,45; 2,52]	1,06 [0,41; 2,75]	0,51 [-7,13; 8,14]
			1,000		
Race (p-value of the interaction test: 0,069)					
White	22/268 (8,2)	7/137 (5,1)	1,61 [0,70; 3,67]	1,66 [0,69; 3,99]	3,10 [-1,84; 8,04]
			0,311		
Other	2/62 (3,2)	3/26 (11,5)	0,28 [0,05; 1,58]	0,26 [0,04; 1,63]	-8,31 [-21,36; 4,73]
			0,151		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,200)					
Europe	18/224 (8,0)	6/121 (5,0)	1,62 [0,66; 3,97]	1,67 [0,65; 4,34]	3,08 [-2,18; 8,33]
				0,376	
North America	1/31 (3,2)	2/13 (15,4)	0,21 [0,02; 2,12]	0,18 [0,02; 2,23]	-12,16 [-32,73; 8,42]
				0,204	
Other	5/76 (6,6)	3/30 (10,0)	0,66 [0,17; 2,58]	0,63 [0,14; 2,84]	-3,42 [-15,52; 8,67]
				0,685	
Geographic region 2 (p-value of the interaction test: 0,327)					
Asia	3/58 (5,2)	2/23 (8,7)	0,59 [0,11; 3,33]	0,57 [0,09; 3,67]	-3,52 [-16,37; 9,33]
				0,619	
Central America/South America	1/11 (9,1)	1/7 (14,3)	0,64 [0,05; 8,61]	0,60 [0,03; 11,47]	-5,19 [-36,19; 25,80]
				1,000	
Europe and ROW	19/231 (8,2)	6/121 (5,0)	1,66 [0,68; 4,04]	1,72 [0,67; 4,42]	3,27 [-1,98; 8,51]
				0,285	
North America	1/31 (3,2)	2/13 (15,4)	0,21 [0,02; 2,12]	0,18 [0,02; 2,23]	-12,16 [-32,73; 8,42]
				0,204	
Weight (p-value of the interaction test: 0,243)					
<100 kg	24/309 (7,8)	10/153 (6,5)	1,19 [0,58; 2,42]	1,20 [0,56; 2,59]	1,23 [-3,69; 6,15]
				0,708	
≥100 kg	0/22 (0,0)	1/11 (9,1)	0,17 [0,01; 3,95]	0,16 [0,01; 4,15]	-9,09 [-26,08; 7,90]
				0,333	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
BMI (p-value of the interaction test: 0,766)					
Underweight ($<18.5 \text{ kg/m}^2$)	4/59 (6,8)	3/23 (13,0)	0,52 [0,13; 2,14]	0,48 [0,10; 2,36]	-6,26 [-21,45; 8,92]
			0,394		
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	13/157 (8,3)	6/92 (6,5)	1,27 [0,50; 3,23]	1,29 [0,47; 3,53]	1,76 [-4,88; 8,39]
			0,805		
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	5/68 (7,4)	1/28 (3,6)	2,06 [0,25; 16,84]	2,14 [0,24; 19,22]	3,78 [-5,48; 13,04]
			0,668		
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	2/47 (4,3)	1/21 (4,8)	0,89 [0,09; 9,32]	0,89 [0,08; 10,38]	-0,51 [-11,29; 10,28]
			1,000		
Tobacco use (p-value of the interaction test: 0,206)					
Current	3/76 (3,9)	4/32 (12,5)	0,32 [0,07; 1,33]	0,29 [0,06; 1,37]	-8,55 [-20,82; 3,71]
			0,192		
Former	3/46 (6,5)	1/29 (3,4)	1,89 [0,21; 17,33]	1,95 [0,19; 19,73]	3,07 [-6,67; 12,82]
			1,000		
Never	18/209 (8,6)	6/103 (5,8)	1,48 [0,61; 3,61]	1,52 [0,59; 3,96]	2,79 [-3,12; 8,70]
			0,500		
Prior biologic exposure (p-value of the interaction test: 0,879)					
Ever	3/36 (8,3)	1/12 (8,3)	1,00 [0,11; 8,73]	1,00 [0,09; 10,63]	0,00 [-18,06; 18,06]
			1,000		
Never	21/295 (7,1)	10/152 (6,6)	1,08 [0,52; 2,24]	1,09 [0,50; 2,37]	0,54 [-4,37; 5,45]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline corticosteroid use (p-value of the interaction test: 0,308)					
Yes	11/113 (9,7)	3/56 (5,4)	1,82 [0,53; 6,25]	1,91 [0,51; 7,13]	4,38 [-3,66; 12,42]
				0,391	
No	13/218 (6,0)	8/108 (7,4)	0,81 [0,34; 1,88]	0,79 [0,32; 1,97]	-1,44 [-7,30; 4,41]
				0,636	
Baseline immunomodulator use (p-value of the interaction test: 0,104)					
Yes	4/102 (3,9)	5/53 (9,4)	0,42 [0,12; 1,48]	0,39 [0,10; 1,53]	-5,51 [-14,24; 3,21]
				0,275	
No	20/229 (8,7)	6/111 (5,4)	1,62 [0,67; 3,91]	1,67 [0,65; 4,30]	3,33 [-2,25; 8,90]
				0,384	
Duration of CD (p-value of the interaction test: 0,465)					
<1 year	6/71 (8,5)	2/33 (6,1)	1,39 [0,30; 6,54]	1,43 [0,27; 7,50]	2,39 [-8,01; 12,79]
				1,000	
≥1 to <5 years	7/132 (5,3)	6/71 (8,5)	0,63 [0,22; 1,80]	0,61 [0,20; 1,88]	-3,15 [-10,66; 4,37]
				0,384	
≥5 years	11/127 (8,7)	3/60 (5,0)	1,73 [0,50; 5,98]	1,80 [0,48; 6,71]	3,66 [-3,71; 11,03]
				0,554	
Baseline disease location (p-value of the interaction test: 0,995)					
Colonic	12/135 (8,9)	6/73 (8,2)	1,08 [0,42; 2,76]	1,09 [0,39; 3,03]	0,67 [-7,25; 8,59]
				1,000	
Ileal	4/41 (9,8)	2/24 (8,3)	1,17 [0,23; 5,92]	1,19 [0,20; 7,03]	1,42 [-12,89; 15,73]
				1,000	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Ileal-Colonic	8/155 (5,2)	3/65 (4,6)	1,12 [0,31; 4,08]	1,12 [0,29; 4,38]	0,55 [-5,63; 6,72]
1,000					
Baseline fecal calprotectin (p-value of the interaction test: 0,926)					
≤250	5/57 (8,8)	2/24 (8,3)	1,05 [0,22; 5,05]	1,06 [0,19; 5,87]	0,44 [-12,84; 13,71]
1,000					
>250	13/203 (6,4)	6/103 (5,8)	1,10 [0,43; 2,81]	1,11 [0,41; 3,00]	0,58 [-5,06; 6,22]
1,000					
Baseline CRP (p-value of the interaction test: 0,887)					
≤10	10/217 (4,6)	5/108 (4,6)	1,00 [0,35; 2,84]	1,00 [0,33; 2,99]	-0,02 [-4,87; 4,82]
1,000					
>10	14/114 (12,3)	6/56 (10,7)	1,15 [0,47; 2,82]	1,17 [0,42; 3,22]	1,57 [-8,53; 11,66]
1,000					
Baseline SES-CD total score (p-value of the interaction test: 0,740)					
<12	14/200 (7,0)	7/96 (7,3)	0,96 [0,40; 2,30]	0,96 [0,37; 2,45]	-0,29 [-6,58; 6,00]
1,000					
≥12	10/131 (7,6)	4/66 (6,1)	1,26 [0,41; 3,86]	1,28 [0,39; 4,25]	1,57 [-5,76; 8,91]
0,777					
Baseline AP average (p-value of the interaction test: 0,877)					
<2	3/70 (4,3)	1/35 (2,9)	1,50 [0,16; 13,90]	1,52 [0,15; 15,19]	1,43 [-5,85; 8,71]
1,000					
≥2	21/260 (8,1)	10/129 (7,8)	1,04 [0,51; 2,15]	1,05 [0,48; 2,29]	0,32 [-5,36; 6,01]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline SF average (p-value of the interaction test: 0,496)					
<7	18/265 (6,8)	9/125 (7,2)	0,94 [0,44; 2,04]	0,94 [0,41; 2,15]	-0,41 [-5,86; 5,04]
			1,000		
≥7	6/65 (9,2)	2/39 (5,1)	1,80 [0,38; 8,48]	1,88 [0,36; 9,82]	4,10 [-5,77; 13,97]
			0,707		
Baseline CDAI 1 (p-value of the interaction test: 0,283)					
<300	11/148 (7,4)	3/75 (4,0)	1,86 [0,53; 6,46]	1,93 [0,52; 7,13]	3,43 [-2,69; 9,56]
			0,393		
≥300	13/182 (7,1)	8/89 (9,0)	0,79 [0,34; 1,85]	0,78 [0,31; 1,95]	-1,85 [-8,87; 5,18]
			0,632		
Baseline CDAI 2 (p-value of the interaction test: 0,530)					
<150	0/5 (0,0)	0/6 (0,0)	NB	NB	NB
			NB		
≥150 and <220	3/27 (11,1)	0/18 (0,0)	4,75 [0,26; 86,79]	5,29 [0,26; >100]	11,11 [-0,74; 22,97]
			0,264		
≥220 and <450	19/275 (6,9)	11/125 (8,8)	0,79 [0,39; 1,60]	0,77 [0,35; 1,67]	-1,89 [-7,69; 3,91]
			0,541		
≥450	2/23 (8,7)	0/15 (0,0)	3,33 [0,17; 64,96]	3,60 [0,16; 80,48]	8,70 [-2,82; 20,21]
			0,509		
OECD Country (p-value of the interaction test: 0,888)					
Yes	18/209 (8,6)	8/94 (8,5)	1,01 [0,46; 2,24]	1,01 [0,42; 2,42]	0,10 [-6,70; 6,91]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
No	6/122 (4,9)	3/70 (4,3)	1,15 [0,30; 4,45]	1,16 [0,28; 4,77]	0,63 [-5,47; 6,73]
			1,000		
Datenschnitt: 23. August 2023; Conventional-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_aemaxse_sub_safa_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
20DEC2024 / 04:00

Subgruppen für Abbruch der Behandlung aufgrund unerwünschter Ereignisse: Gesamtrate in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,868)					
<65 years	19/322 (5,9)	4/160 (2,5)	2,36 [0,82; 6,82]	2,45 [0,82; 7,31]	3,40 [-0,13; 6,93]
			0,115		
≥65 years	1/9 (11,1)	0/4 (0,0)	1,50 [0,07; 30,59]	1,59 [0,05; 47,52]	11,11 [-9,42; 31,64]
			1,000		
Age 2 (p-value of the interaction test: 0,584)					
<40 years	13/210 (6,2)	2/101 (2,0)	3,13 [0,72; 13,59]	3,27 [0,72; 14,76]	4,21 [-0,03; 8,45]
			0,156		
≥40 years	7/121 (5,8)	2/63 (3,2)	1,82 [0,39; 8,51]	1,87 [0,38; 9,29]	2,61 [-3,39; 8,61]
			0,721		
Sex (p-value of the interaction test: 0,206)					
Male	9/178 (5,1)	0/83 (0,0)	8,92 [0,53; >100]	9,36 [0,54; >100]	5,06 [1,84; 8,27]
			0,061		
Female	11/153 (7,2)	4/81 (4,9)	1,46 [0,48; 4,43]	1,49 [0,46; 4,84]	2,25 [-4,00; 8,50]
			0,586		
Race (p-value of the interaction test: 0,338)					
White	20/268 (7,5)	3/137 (2,2)	3,41 [1,03; 11,27]	3,60 [1,05; 12,34]	5,27 [1,28; 9,26]
			0,039		
Other	0/62 (0,0)	0/26 (0,0)	NB	NB	NB
			NB		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Geographic region 1 (p-value of the interaction test: 0,688)					
Europe	16/224 (7,1)	4/121 (3,3)	2,16 [0,74; 6,32]	2,25 [0,73; 6,89]	3,84 [-0,80; 8,48]
			0,226		
North America	0/31 (0,0)	0/13 (0,0)	NB	NB	NB
			NB		
Other	4/76 (5,3)	0/30 (0,0)	3,62 [0,20; 65,32]	3,79 [0,20; 72,50]	5,26 [0,24; 10,28]
			0,575		
Geographic region 2 (p-value of the interaction test: 0,817)					
Asia	3/58 (5,2)	0/23 (0,0)	2,85 [0,15; 53,06]	2,96 [0,15; 59,66]	5,17 [-0,53; 10,87]
			0,554		
Central America/South America	0/11 (0,0)	0/7 (0,0)	NB	NB	NB
			NB		
Europe and ROW	17/231 (7,4)	4/121 (3,3)	2,23 [0,77; 6,47]	2,32 [0,76; 7,07]	4,05 [-0,58; 8,69]
			0,158		
North America	0/31 (0,0)	0/13 (0,0)	NB	NB	NB
			NB		
Weight (p-value of the interaction test: 0,102)					
<100 kg	20/309 (6,5)	3/153 (2,0)	3,30 [1,00; 10,94]	3,46 [1,01; 11,83]	4,51 [1,00; 8,03]
			0,040		
≥100 kg	0/22 (0,0)	1/11 (9,1)	0,17 [0,01; 3,95]	0,16 [0,01; 4,15]	-9,09 [-26,08; 7,90]
			0,333		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
BMI (p-value of the interaction test: 0,083)					
Underweight ($<18.5 \text{ kg/m}^2$)	9/59 (15,3)	1/23 (4,3)	3,51 [0,47; 26,16]	3,96 [0,47; 33,19]	10,91 [-1,49; 23,30]
			0,269		
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	4/157 (2,5)	0/92 (0,0)	5,30 [0,29; 97,29]	5,42 [0,29; >100]	2,55 [0,08; 5,01]
			0,300		
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	6/68 (8,8)	0/28 (0,0)	5,46 [0,32; 93,85]	5,93 [0,32; >100]	8,82 [2,08; 15,57]
			0,176		
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	1/47 (2,1)	3/21 (14,3)	0,15 [0,02; 1,35]	0,13 [0,01; 1,34]	-12,16 [-27,68; 3,37]
			0,084		
Tobacco use (p-value of the interaction test: 0,714)					
Current	3/76 (3,9)	1/32 (3,1)	1,26 [0,14; 11,69]	1,27 [0,13; 12,73]	0,82 [-6,63; 8,27]
			1,000		
Former	5/46 (10,9)	1/29 (3,4)	3,15 [0,39; 25,64]	3,41 [0,38; 30,82]	7,42 [-3,76; 18,60]
			0,396		
Never	12/209 (5,7)	2/103 (1,9)	2,96 [0,67; 12,97]	3,08 [0,68; 14,01]	3,80 [-0,33; 7,93]
			0,155		
Prior biologic exposure (p-value of the interaction test: 0,903)					
Ever	2/36 (5,6)	0/12 (0,0)	1,76 [0,09; 34,24]	1,81 [0,08; 40,40]	5,56 [-1,93; 13,04]
			1,000		
Never	18/295 (6,1)	4/152 (2,6)	2,32 [0,80; 6,73]	2,40 [0,80; 7,23]	3,47 [-0,26; 7,20]
			0,164		

	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Subgruppe			p-Wert ^a		
Baseline corticosteroid use (p-value of the interaction test: 0,500)					
Yes	9/113 (8,0)	1/56 (1,8)	4,46 [0,58; 34,34]	4,76 [0,59; 38,55]	6,18 [0,10; 12,26]
			0,168		
No	11/218 (5,0)	3/108 (2,8)	1,82 [0,52; 6,38]	1,86 [0,51; 6,81]	2,27 [-1,98; 6,52]
			0,402		
Baseline immunomodulator use (p-value of the interaction test: 0,459)					
Yes	6/102 (5,9)	2/53 (3,8)	1,56 [0,33; 7,46]	1,59 [0,31; 8,18]	2,11 [-4,76; 8,98]
			0,716		
No	14/229 (6,1)	2/111 (1,8)	3,39 [0,78; 14,67]	3,55 [0,79; 15,90]	4,31 [0,34; 8,28]
			0,102		
Duration of CD (p-value of the interaction test: 0,707)					
<1 year	5/71 (7,0)	0/33 (0,0)	5,19 [0,30; 91,27]	5,54 [0,30; >100]	7,04 [1,09; 12,99]
			0,176		
≥1 to <5 years	5/132 (3,8)	1/71 (1,4)	2,69 [0,32; 22,58]	2,76 [0,32; 24,06]	2,38 [-1,88; 6,64]
			0,667		
≥5 years	10/127 (7,9)	3/60 (5,0)	1,57 [0,45; 5,51]	1,62 [0,43; 6,13]	2,87 [-4,36; 10,11]
			0,555		
Baseline disease location (p-value of the interaction test: 0,309)					
Colonic	8/135 (5,9)	4/73 (5,5)	1,08 [0,34; 3,47]	1,09 [0,32; 3,74]	0,45 [-6,12; 7,01]
			1,000		
Ileal	3/41 (7,3)	0/24 (0,0)	4,17 [0,22; 77,37]	4,45 [0,22; 90,03]	7,32 [-0,65; 15,29]
			0,290		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Ileal-Colonic	9/155 (5,8)	0/65 (0,0)	8,04 [0,47; >100]	8,49 [0,49; >100]	5,81 [2,12; 9,49]
0,061					
Baseline fecal calprotectin (p-value of the interaction test: 0,443)					
≤250	4/57 (7,0)	0/24 (0,0)	3,88 [0,22; 69,37]	4,12 [0,21; 79,58]	7,02 [0,39; 13,65]
0,313					
>250	7/203 (3,4)	3/103 (2,9)	1,18 [0,31; 4,48]	1,19 [0,30; 4,70]	0,54 [-3,57; 4,64]
1,000					
Baseline CRP (p-value of the interaction test: 0,873)					
≤10	15/217 (6,9)	3/108 (2,8)	2,49 [0,74; 8,41]	2,60 [0,74; 9,18]	4,13 [-0,45; 8,72]
0,196					
>10	5/114 (4,4)	1/56 (1,8)	2,46 [0,29; 20,53]	2,52 [0,29; 22,13]	2,60 [-2,51; 7,72]
0,665					
Baseline SES-CD total score (p-value of the interaction test: 0,586)					
<12	13/200 (6,5)	2/96 (2,1)	3,12 [0,72; 13,55]	3,27 [0,72; 14,78]	4,42 [-0,04; 8,87]
0,156					
≥12	7/131 (5,3)	2/66 (3,0)	1,76 [0,38; 8,25]	1,81 [0,36; 8,95]	2,31 [-3,34; 7,96]
0,720					
Baseline AP average (p-value of the interaction test: 0,344)					
<2	6/70 (8,6)	0/35 (0,0)	6,59 [0,38; >100]	7,16 [0,39; >100]	8,57 [2,01; 15,13]
0,175					
≥2	14/260 (5,4)	4/129 (3,1)	1,74 [0,58; 5,17]	1,78 [0,57; 5,52]	2,28 [-1,78; 6,34]
0,443					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline SF average (p-value of the interaction test: 0,608)					
<7	17/265 (6,4)	4/125 (3,2)	2,00 [0,69; 5,83]	2,07 [0,68; 6,30]	3,22 [-1,05; 7,48]
			0,235		
≥7	3/65 (4,6)	0/39 (0,0)	4,24 [0,22; 80,01]	4,42 [0,22; 87,96]	4,62 [-0,49; 9,72]
			0,290		
Baseline CDAI 1 (p-value of the interaction test: 0,385)					
<300	10/148 (6,8)	1/75 (1,3)	5,07 [0,66; 38,85]	5,36 [0,67; 42,71]	5,42 [0,62; 10,23]
			0,104		
≥300	10/182 (5,5)	3/89 (3,4)	1,63 [0,46; 5,78]	1,67 [0,45; 6,21]	2,12 [-2,88; 7,13]
			0,555		
Baseline CDAI 2 (p-value of the interaction test: 0,935)					
<150	1/5 (20,0)	0/6 (0,0)	3,50 [0,17; 70,94]	4,33 [0,14; >100]	20,00 [-15,06; 55,06]
			0,455		
≥150 and <220	2/27 (7,4)	0/18 (0,0)	3,39 [0,17; 66,79]	3,63 [0,16; 80,10]	7,41 [-2,47; 17,29]
			0,509		
≥220 and <450	16/275 (5,8)	4/125 (3,2)	1,82 [0,62; 5,33]	1,87 [0,61; 5,71]	2,62 [-1,53; 6,76]
			0,329		
≥450	1/23 (4,3)	0/15 (0,0)	2,00 [0,09; 46,09]	2,07 [0,08; 54,12]	4,35 [-3,99; 12,68]
			1,000		
OECD Country (p-value of the interaction test: 0,848)					
Yes	16/209 (7,7)	3/94 (3,2)	2,40 [0,72; 8,03]	2,51 [0,71; 8,85]	4,46 [-0,60; 9,53]
			0,200		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
No	4/122 (3,3)	1/70 (1,4)	2,30 [0,26; 20,13]	2,34 [0,26; 21,35]	1,85 [-2,36; 6,06]
0,654					

Datenschnitt: 23. August 2023; Conventional-failed Safety Population.

Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency.

Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt.

RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald.

Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm.

a: Exakter Test nach Fisher.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_aedst_sub_safa_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
20DEC2024 / 04:00

Subgruppen für Schwerwiegende unerwünschte Ereignisse: Gesamtrate in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,623)					
<65 years	21/322 (6,5)	14/160 (8,8)	0,75 [0,39; 1,43]	0,73 [0,36; 1,47]	-2,23 [-7,37; 2,91]
			0,456		
≥65 years	1/9 (11,1)	0/4 (0,0)	1,50 [0,07; 30,59]	1,59 [0,05; 47,52]	11,11 [-9,42; 31,64]
			1,000		
Age 2 (p-value of the interaction test: 0,361)					
<40 years	15/210 (7,1)	7/101 (6,9)	1,03 [0,43; 2,45]	1,03 [0,41; 2,62]	0,21 [-5,84; 6,27]
			1,000		
≥40 years	7/121 (5,8)	7/63 (11,1)	0,52 [0,19; 1,42]	0,49 [0,16; 1,47]	-5,33 [-14,13; 3,48]
			0,243		
Sex (p-value of the interaction test: 0,287)					
Male	11/178 (6,2)	4/83 (4,8)	1,28 [0,42; 3,91]	1,30 [0,40; 4,21]	1,36 [-4,45; 7,17]
			0,781		
Female	11/153 (7,2)	10/81 (12,3)	0,58 [0,26; 1,31]	0,55 [0,22; 1,36]	-5,16 [-13,41; 3,09]
			0,230		
Race (p-value of the interaction test: 0,113)					
White	19/268 (7,1)	9/137 (6,6)	1,08 [0,50; 2,32]	1,09 [0,48; 2,47]	0,52 [-4,64; 5,68]
			1,000		
Other	3/62 (4,8)	4/26 (15,4)	0,31 [0,08; 1,31]	0,28 [0,06; 1,35]	-10,55 [-25,41; 4,32]
			0,188		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,412)					
Europe	15/224 (6,7)	8/121 (6,6)	1,01 [0,44; 2,32]	1,01 [0,42; 2,46]	0,08 [-5,42; 5,59]
				1,000	
North America	1/31 (3,2)	2/13 (15,4)	0,21 [0,02; 2,12]	0,18 [0,02; 2,23]	-12,16 [-32,73; 8,42]
				0,204	
Other	6/76 (7,9)	4/30 (13,3)	0,59 [0,18; 1,95]	0,56 [0,15; 2,13]	-5,44 [-19,03; 8,15]
				0,464	
Geographic region 2 (p-value of the interaction test: 0,559)					
Asia	4/58 (6,9)	3/23 (13,0)	0,53 [0,13; 2,18]	0,49 [0,10; 2,40]	-6,15 [-21,38; 9,08]
				0,399	
Central America/South America	1/11 (9,1)	1/7 (14,3)	0,64 [0,05; 8,61]	0,60 [0,03; 11,47]	-5,19 [-36,19; 25,80]
				1,000	
Europe and ROW	16/231 (6,9)	8/121 (6,6)	1,05 [0,46; 2,38]	1,05 [0,44; 2,53]	0,31 [-5,19; 5,82]
				1,000	
North America	1/31 (3,2)	2/13 (15,4)	0,21 [0,02; 2,12]	0,18 [0,02; 2,23]	-12,16 [-32,73; 8,42]
				0,204	
Weight (p-value of the interaction test: 0,339)					
<100 kg	22/309 (7,1)	13/153 (8,5)	0,84 [0,43; 1,62]	0,83 [0,40; 1,69]	-1,38 [-6,64; 3,89]
				0,581	
≥100 kg	0/22 (0,0)	1/11 (9,1)	0,17 [0,01; 3,95]	0,16 [0,01; 4,15]	-9,09 [-26,08; 7,90]
				0,333	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
BMI (p-value of the interaction test: 0,581)					
Underweight ($<18.5 \text{ kg/m}^2$)	5/59 (8,5)	3/23 (13,0)	0,65 [0,17; 2,50]	0,62 [0,13; 2,82]	-4,57 [-20,06; 10,92]
			0,680		
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	12/157 (7,6)	8/92 (8,7)	0,88 [0,37; 2,07]	0,87 [0,34; 2,21]	-1,05 [-8,15; 6,05]
			0,811		
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	3/68 (4,4)	0/28 (0,0)	2,94 [0,16; 55,17]	3,05 [0,15; 60,91]	4,41 [-0,47; 9,29]
			0,554		
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	2/47 (4,3)	3/21 (14,3)	0,30 [0,05; 1,65]	0,27 [0,04; 1,73]	-10,03 [-26,07; 6,01]
			0,167		
Tobacco use (p-value of the interaction test: 0,232)					
Current	3/76 (3,9)	5/32 (15,6)	0,25 [0,06; 0,99]	0,22 [0,05; 0,99]	-11,68 [-25,00; 1,64]
			0,048		
Former	3/46 (6,5)	2/29 (6,9)	0,95 [0,17; 5,32]	0,94 [0,15; 6,01]	-0,37 [-12,04; 11,29]
			1,000		
Never	16/209 (7,7)	7/103 (6,8)	1,13 [0,48; 2,65]	1,14 [0,45; 2,86]	0,86 [-5,19; 6,91]
			1,000		
Prior biologic exposure (p-value of the interaction test: 0,507)					
Ever	1/36 (2,8)	1/12 (8,3)	0,33 [0,02; 4,93]	0,31 [0,02; 5,45]	-5,56 [-22,09; 10,98]
			0,441		
Never	21/295 (7,1)	13/152 (8,6)	0,83 [0,43; 1,62]	0,82 [0,40; 1,69]	-1,43 [-6,76; 3,89]
			0,578		

	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Subgruppe			p-Wert ^a		
Baseline corticosteroid use (p-value of the interaction test: 0,764)					
Yes	9/113 (8,0)	5/56 (8,9)	0,89 [0,31; 2,54]	0,88 [0,28; 2,77]	-0,96 [-9,95; 8,02]
			1,000		
No	13/218 (6,0)	9/108 (8,3)	0,72 [0,32; 1,62]	0,70 [0,29; 1,69]	-2,37 [-8,46; 3,72]
			0,483		
Baseline immunomodulator use (p-value of the interaction test: 0,824)					
Yes	5/102 (4,9)	4/53 (7,5)	0,65 [0,18; 2,32]	0,63 [0,16; 2,46]	-2,65 [-10,90; 5,61]
			0,493		
No	17/229 (7,4)	10/111 (9,0)	0,82 [0,39; 1,74]	0,81 [0,36; 1,83]	-1,59 [-7,90; 4,73]
			0,670		
Duration of CD (p-value of the interaction test: 0,502)					
<1 year	6/71 (8,5)	2/33 (6,1)	1,39 [0,30; 6,54]	1,43 [0,27; 7,50]	2,39 [-8,01; 12,79]
			1,000		
≥1 to <5 years	6/132 (4,5)	7/71 (9,9)	0,46 [0,16; 1,32]	0,44 [0,14; 1,35]	-5,31 [-13,11; 2,48]
			0,227		
≥5 years	10/127 (7,9)	5/60 (8,3)	0,94 [0,34; 2,64]	0,94 [0,31; 2,88]	-0,46 [-8,88; 7,96]
			1,000		
Baseline disease location (p-value of the interaction test: 0,841)					
Colonic	10/135 (7,4)	7/73 (9,6)	0,77 [0,31; 1,94]	0,75 [0,27; 2,07]	-2,18 [-10,25; 5,89]
			0,603		
Ileal	4/41 (9,8)	2/24 (8,3)	1,17 [0,23; 5,92]	1,19 [0,20; 7,03]	1,42 [-12,89; 15,73]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Ileal-Colonic	8/155 (5,2)	5/65 (7,7)	0,67 [0,23; 1,97]	0,65 [0,21; 2,08]	-2,53 [-9,89; 4,82]
0,533					
Baseline fecal calprotectin (p-value of the interaction test: 0,303)					
≤250	5/57 (8,8)	1/24 (4,2)	2,11 [0,26; 17,08]	2,21 [0,24; 20,01]	4,61 [-6,25; 15,46]
0,664					
>250	12/203 (5,9)	10/103 (9,7)	0,61 [0,27; 1,36]	0,58 [0,24; 1,40]	-3,80 [-10,37; 2,78]
0,246					
Baseline CRP (p-value of the interaction test: 0,954)					
≤10	9/217 (4,1)	6/108 (5,6)	0,75 [0,27; 2,04]	0,74 [0,25; 2,12]	-1,41 [-6,48; 3,66]
0,582					
>10	13/114 (11,4)	8/56 (14,3)	0,80 [0,35; 1,81]	0,77 [0,30; 1,99]	-2,88 [-13,75; 7,98]
0,624					
Baseline SES-CD total score (p-value of the interaction test: 0,826)					
<12	12/200 (6,0)	7/96 (7,3)	0,82 [0,33; 2,02]	0,81 [0,31; 2,13]	-1,29 [-7,45; 4,86]
0,800					
≥12	10/131 (7,6)	7/66 (10,6)	0,72 [0,29; 1,81]	0,70 [0,25; 1,92]	-2,97 [-11,68; 5,74]
0,592					
Baseline AP average (p-value of the interaction test: 0,609)					
<2	3/70 (4,3)	1/35 (2,9)	1,50 [0,16; 13,90]	1,52 [0,15; 15,19]	1,43 [-5,85; 8,71]
1,000					
≥2	19/260 (7,3)	13/129 (10,1)	0,73 [0,37; 1,42]	0,70 [0,34; 1,47]	-2,77 [-8,85; 3,31]
0,433					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline SF average (p-value of the interaction test: 0,235)					
<7	16/265 (6,0)	12/125 (9,6)	0,63 [0,31; 1,29]	0,61 [0,28; 1,32]	-3,56 [-9,47; 2,34]
			0,212		
≥7	6/65 (9,2)	2/39 (5,1)	1,80 [0,38; 8,48]	1,88 [0,36; 9,82]	4,10 [-5,77; 13,97]
			0,707		
Baseline CDAI 1 (p-value of the interaction test: 0,384)					
<300	9/148 (6,1)	4/75 (5,3)	1,14 [0,36; 3,58]	1,15 [0,34; 3,86]	0,75 [-5,63; 7,13]
			1,000		
≥300	13/182 (7,1)	10/89 (11,2)	0,64 [0,29; 1,39]	0,61 [0,26; 1,45]	-4,09 [-11,65; 3,46]
			0,256		
Baseline CDAI 2 (p-value of the interaction test: 0,593)					
<150	0/5 (0,0)	0/6 (0,0)	NB	NB	NB
			NB		
≥150 and <220	1/27 (3,7)	0/18 (0,0)	2,04 [0,09; 47,37]	2,09 [0,08; 54,30]	3,70 [-3,42; 10,83]
			1,000		
≥220 and <450	19/275 (6,9)	14/125 (11,2)	0,62 [0,32; 1,19]	0,59 [0,28; 1,22]	-4,29 [-10,58; 2,00]
			0,171		
≥450	2/23 (8,7)	0/15 (0,0)	3,33 [0,17; 64,96]	3,60 [0,16; 80,48]	8,70 [-2,82; 20,21]
			0,509		
OECD Country (p-value of the interaction test: 0,787)					
Yes	16/209 (7,7)	10/94 (10,6)	0,72 [0,34; 1,53]	0,70 [0,30; 1,60]	-2,98 [-10,18; 4,22]
			0,384		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
No	6/122 (4,9)	4/70 (5,7)	0,86 [0,25; 2,95]	0,85 [0,23; 3,13]	-0,80 [-7,45; 5,86]
			1,000		
Datenschnitt: 23. August 2023; Conventional-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_sae_sub_safa_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
20DEC2024 / 04:00

Anhang 4-G.3.6.3.2 Unerwünschte Ereignisse von speziellem Interesse (UESI)**Hepatische Ereignisse**

Subgruppen für Hepatic Safety: Gesamtrate in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,111)					
<65 years	23/322 (7,1)	4/160 (2,5)	2,86 [1,01; 8,12]	3,00 [1,02; 8,83]	4,64 [0,93; 8,35]
			0,037		
≥65 years	0/9 (0,0)	1/4 (25,0)	0,17 [0,01; 3,40]	0,12 [0,00; 3,78]	-25,00 [-67,43; 17,43]
			0,308		
Age 2 (p-value of the interaction test: 0,613)					
<40 years	13/210 (6,2)	2/101 (2,0)	3,13 [0,72; 13,59]	3,27 [0,72; 14,76]	4,21 [-0,03; 8,45]
			0,156		
≥40 years	10/121 (8,3)	3/63 (4,8)	1,74 [0,50; 6,08]	1,80 [0,48; 6,80]	3,50 [-3,69; 10,69]
			0,547		
Sex (p-value of the interaction test: 0,428)					
Male	14/178 (7,9)	4/83 (4,8)	1,63 [0,55; 4,81]	1,69 [0,54; 5,29]	3,05 [-3,03; 9,12]
			0,441		
Female	9/153 (5,9)	1/81 (1,2)	4,76 [0,61; 36,95]	5,00 [0,62; 40,18]	4,65 [0,21; 9,08]
			0,171		
Race (p-value of the interaction test: 0,942)					
White	17/268 (6,3)	4/137 (2,9)	2,17 [0,75; 6,33]	2,25 [0,74; 6,83]	3,42 [-0,63; 7,48]
			0,162		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Other	6/62 (9,7)	1/26 (3,8)	2,52 [0,32; 19,88]	2,68 [0,31; 23,43]	5,83 [-4,60; 16,26]
0,669					
Geographic region 1 (p-value of the interaction test: 0,839)					
Europe	13/224 (5,8)	4/121 (3,3)	1,76 [0,59; 5,27]	1,80 [0,57; 5,65]	2,50 [-1,92; 6,92]
0,436					
North America	4/31 (12,9)	0/13 (0,0)	3,94 [0,23; 68,31]	4,42 [0,22; 88,16]	12,90 [1,10; 24,70]
0,302					
Other	6/76 (7,9)	1/30 (3,3)	2,37 [0,30; 18,85]	2,49 [0,29; 21,57]	4,56 [-4,27; 13,39]
0,670					
Geographic region 2 (p-value of the interaction test: 0,908)					
Asia	6/58 (10,3)	1/23 (4,3)	2,38 [0,30; 18,69]	2,54 [0,29; 22,34]	6,00 [-5,44; 17,44]
0,667					
Central America/South America	0/11 (0,0)	0/7 (0,0)	NB	NB	NB
NB					
Europe and ROW	13/231 (5,6)	4/121 (3,3)	1,70 [0,57; 5,11]	1,74 [0,56; 5,47]	2,32 [-2,03; 6,68]
0,437					
North America	4/31 (12,9)	0/13 (0,0)	3,94 [0,23; 68,31]	4,42 [0,22; 88,16]	12,90 [1,10; 24,70]
0,302					
Weight (p-value of the interaction test: 0,210)					
<100 kg	22/309 (7,1)	4/153 (2,6)	2,72 [0,96; 7,76]	2,86 [0,97; 8,44]	4,51 [0,68; 8,33]
0,054					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
≥100 kg	1/22 (4,5)	1/11 (9,1)	0,50 [0,03; 7,26]	0,48 [0,03; 8,42]	-4,55 [-23,63; 14,54]
1,000					
BMI (p-value of the interaction test: 0,500)					
Underweight ($<18.5 \text{ kg/m}^2$)	4/59 (6,8)	0/23 (0,0)	3,60 [0,20; 64,33]	3,81 [0,20; 73,64]	6,78 [0,36; 13,19]
0,573					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	12/157 (7,6)	2/92 (2,2)	3,52 [0,80; 15,36]	3,72 [0,81; 17,03]	5,47 [0,36; 10,58]
0,089					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	4/68 (5,9)	1/28 (3,6)	1,65 [0,19; 14,09]	1,69 [0,18; 15,80]	2,31 [-6,55; 11,17]
1,000					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	3/47 (6,4)	2/21 (9,5)	0,67 [0,12; 3,72]	0,65 [0,10; 4,20]	-3,14 [-17,51; 11,23]
0,641					
Tobacco use (p-value of the interaction test: 0,570)					
Current	5/76 (6,6)	1/32 (3,1)	2,11 [0,26; 17,31]	2,18 [0,24; 19,47]	3,45 [-4,76; 11,66]
0,667					
Former	5/46 (10,9)	0/29 (0,0)	7,02 [0,40; >100]	7,82 [0,42; >100]	10,87 [1,87; 19,86]
0,150					
Never	13/209 (6,2)	4/103 (3,9)	1,60 [0,54; 4,79]	1,64 [0,52; 5,17]	2,34 [-2,63; 7,30]
0,596					
Prior biologic exposure (p-value of the interaction test: 0,666)					
Ever	4/36 (11,1)	0/12 (0,0)	3,16 [0,18; 54,81]	3,46 [0,17; 69,09]	11,11 [0,85; 21,38]
0,560					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Never	19/295 (6,4)	5/152 (3,3)	1,96 [0,75; 5,14]	2,02 [0,74; 5,53]	3,15 [-0,83; 7,14]
0,189					
Baseline corticosteroid use (p-value of the interaction test: 0,762)					
Yes	7/113 (6,2)	1/56 (1,8)	3,47 [0,44; 27,51]	3,63 [0,44; 30,27]	4,41 [-1,23; 10,05]
0,273					
No	16/218 (7,3)	4/108 (3,7)	1,98 [0,68; 5,78]	2,06 [0,67; 6,32]	3,64 [-1,33; 8,60]
0,230					
Baseline immunomodulator use (p-value of the interaction test: 0,658)					
Yes	7/102 (6,9)	1/53 (1,9)	3,64 [0,46; 28,79]	3,83 [0,46; 32,00]	4,98 [-1,15; 11,10]
0,265					
No	16/229 (7,0)	4/111 (3,6)	1,94 [0,66; 5,66]	2,01 [0,66; 6,16]	3,38 [-1,40; 8,17]
0,325					
Duration of CD (p-value of the interaction test: 0,756)					
<1 year	4/71 (5,6)	1/33 (3,0)	1,86 [0,22; 15,99]	1,91 [0,21; 17,79]	2,60 [-5,33; 10,54]
1,000					
≥1 to <5 years	12/132 (9,1)	2/71 (2,8)	3,23 [0,74; 14,02]	3,45 [0,75; 15,87]	6,27 [0,04; 12,51]
0,145					
≥5 years	7/127 (5,5)	2/60 (3,3)	1,65 [0,35; 7,72]	1,69 [0,34; 8,40]	2,18 [-3,85; 8,21]
0,721					
Baseline disease location (p-value of the interaction test: 0,582)					
Colonic	7/135 (5,2)	2/73 (2,7)	1,89 [0,40; 8,88]	1,94 [0,39; 9,60]	2,45 [-2,85; 7,74]
0,499					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Ileal	5/41 (12,2)	0/24 (0,0)	6,55 [0,38; >100]	7,38 [0,39; >100]	12,20 [2,18; 22,21]
			0,149		
Ileal-Colonic	11/155 (7,1)	3/65 (4,6)	1,54 [0,44; 5,33]	1,58 [0,43; 5,86]	2,48 [-4,03; 8,99]
			0,763		
Baseline fecal calprotectin (p-value of the interaction test: 0,284)					
≤250	7/57 (12,3)	3/24 (12,5)	0,98 [0,28; 3,48]	0,98 [0,23; 4,16]	-0,22 [-15,96; 15,52]
			1,000		
>250	13/203 (6,4)	2/103 (1,9)	3,30 [0,76; 14,34]	3,46 [0,76; 15,61]	4,46 [0,17; 8,76]
			0,100		
Baseline CRP (p-value of the interaction test: 0,906)					
≤10	17/217 (7,8)	4/108 (3,7)	2,12 [0,73; 6,13]	2,21 [0,72; 6,74]	4,13 [-0,92; 9,18]
			0,230		
>10	6/114 (5,3)	1/56 (1,8)	2,95 [0,36; 23,89]	3,06 [0,36; 26,02]	3,48 [-1,89; 8,85]
			0,428		
Baseline SES-CD total score (p-value of the interaction test: 0,289)					
<12	12/200 (6,0)	4/96 (4,2)	1,44 [0,48; 4,35]	1,47 [0,46; 4,68]	1,83 [-3,34; 7,01]
			0,595		
≥12	11/131 (8,4)	1/66 (1,5)	5,54 [0,73; 42,01]	5,96 [0,75; 47,18]	6,88 [1,29; 12,47]
			0,064		
Baseline AP average (p-value of the interaction test: 0,342)					
<2	6/70 (8,6)	0/35 (0,0)	6,59 [0,38; >100]	7,16 [0,39; >100]	8,57 [2,01; 15,13]
			0,175		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
≥2	17/260 (6,5)	5/129 (3,9)	1,69 [0,64; 4,47]	1,73 [0,63; 4,81]	2,66 [-1,82; 7,15]
0,356					
Baseline SF average (p-value of the interaction test: 0,999)					
<7	15/265 (5,7)	3/125 (2,4)	2,36 [0,70; 8,00]	2,44 [0,69; 8,59]	3,26 [-0,60; 7,13]
0,199					
≥7	8/65 (12,3)	2/39 (5,1)	2,40 [0,54; 10,73]	2,60 [0,52; 12,91]	7,18 [-3,39; 17,75]
0,314					
Baseline CDAI 1 (p-value of the interaction test: 0,221)					
<300	8/148 (5,4)	0/75 (0,0)	8,67 [0,51; >100]	9,14 [0,52; >100]	5,41 [1,76; 9,05]
0,054					
≥300	15/182 (8,2)	5/89 (5,6)	1,47 [0,55; 3,91]	1,51 [0,53; 4,29]	2,62 [-3,61; 8,86]
0,621					
Baseline CDAI 2 (p-value of the interaction test: 0,751)					
<150	0/5 (0,0)	0/6 (0,0)	NB	NB	NB
NB					
≥150 and <220	3/27 (11,1)	0/18 (0,0)	4,75 [0,26; 86,79]	5,29 [0,26; >100]	11,11 [-0,74; 22,97]
0,264					
≥220 and <450	17/275 (6,2)	5/125 (4,0)	1,55 [0,58; 4,10]	1,58 [0,57; 4,39]	2,18 [-2,28; 6,64]
0,481					
≥450	3/23 (13,0)	0/15 (0,0)	4,67 [0,26; 84,38]	5,29 [0,25; >100]	13,04 [-0,72; 26,81]
0,264					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
OECD Country (p-value of the interaction test: 0,730)					
Yes	13/209 (6,2)	2/94 (2,1)	2,92 [0,67; 12,70]	3,05 [0,67; 13,80]	4,09 [-0,29; 8,48]
			0,160		
No	10/122 (8,2)	3/70 (4,3)	1,91 [0,54; 6,72]	1,99 [0,53; 7,50]	3,91 [-2,89; 10,71]
			0,381		
Datenschnitt: 23. August 2023; Conventional-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; SMQ: Standardised MedDRA Queries. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher. The number and percentage of participants reporting hepatic events were assessed using the MedDRA PTs contained in 5 SMQs: broad and narrow terms in the Liver-related investigations, signs and symptoms SMQ (SMQ 20000008), broad and narrow terms in the Cholestasis and jaundice of hepatic origin SMQ (SMQ 20000009); broad and narrow terms in the Hepatitis non-infectious SMQ (SMQ 20000010); broad and narrow terms in the Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions SMQ (SMQ 20000013), and narrow terms in the Liver-related coagulation and bleeding disturbances SMQ (SMQ 20000015).					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_heaes_sub_safa_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
20DEC2024 / 04:00

Subgruppen für Hepatic Safety: Nicht schwer in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,111)					
<65 years	23/322 (7,1)	4/160 (2,5)	2,86 [1,01; 8,12]	3,00 [1,02; 8,83]	4,64 [0,93; 8,35]
			0,037		
≥65 years	0/9 (0,0)	1/4 (25,0)	0,17 [0,01; 3,40]	0,12 [0,00; 3,78]	-25,00 [-67,43; 17,43]
			0,308		
Age 2 (p-value of the interaction test: 0,613)					
<40 years	13/210 (6,2)	2/101 (2,0)	3,13 [0,72; 13,59]	3,27 [0,72; 14,76]	4,21 [-0,03; 8,45]
			0,156		
≥40 years	10/121 (8,3)	3/63 (4,8)	1,74 [0,50; 6,08]	1,80 [0,48; 6,80]	3,50 [-3,69; 10,69]
			0,547		
Sex (p-value of the interaction test: 0,428)					
Male	14/178 (7,9)	4/83 (4,8)	1,63 [0,55; 4,81]	1,69 [0,54; 5,29]	3,05 [-3,03; 9,12]
			0,441		
Female	9/153 (5,9)	1/81 (1,2)	4,76 [0,61; 36,95]	5,00 [0,62; 40,18]	4,65 [0,21; 9,08]
			0,171		
Race (p-value of the interaction test: 0,942)					
White	17/268 (6,3)	4/137 (2,9)	2,17 [0,75; 6,33]	2,25 [0,74; 6,83]	3,42 [-0,63; 7,48]
			0,162		
Other	6/62 (9,7)	1/26 (3,8)	2,52 [0,32; 19,88]	2,68 [0,31; 23,43]	5,83 [-4,60; 16,26]
			0,669		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Geographic region 1 (p-value of the interaction test: 0,839)					
Europe	13/224 (5,8)	4/121 (3,3)	1,76 [0,59; 5,27]	1,80 [0,57; 5,65]	2,50 [-1,92; 6,92]
			0,436		
North America	4/31 (12,9)	0/13 (0,0)	3,94 [0,23; 68,31]	4,42 [0,22; 88,16]	12,90 [1,10; 24,70]
			0,302		
Other	6/76 (7,9)	1/30 (3,3)	2,37 [0,30; 18,85]	2,49 [0,29; 21,57]	4,56 [-4,27; 13,39]
			0,670		
Geographic region 2 (p-value of the interaction test: 0,908)					
Asia	6/58 (10,3)	1/23 (4,3)	2,38 [0,30; 18,69]	2,54 [0,29; 22,34]	6,00 [-5,44; 17,44]
			0,667		
Central America/South America	0/11 (0,0)	0/7 (0,0)	NB	NB	NB
			NB		
Europe and ROW	13/231 (5,6)	4/121 (3,3)	1,70 [0,57; 5,11]	1,74 [0,56; 5,47]	2,32 [-2,03; 6,68]
			0,437		
North America	4/31 (12,9)	0/13 (0,0)	3,94 [0,23; 68,31]	4,42 [0,22; 88,16]	12,90 [1,10; 24,70]
			0,302		
Weight (p-value of the interaction test: 0,210)					
<100 kg	22/309 (7,1)	4/153 (2,6)	2,72 [0,96; 7,76]	2,86 [0,97; 8,44]	4,51 [0,68; 8,33]
			0,054		
≥100 kg	1/22 (4,5)	1/11 (9,1)	0,50 [0,03; 7,26]	0,48 [0,03; 8,42]	-4,55 [-23,63; 14,54]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
BMI (p-value of the interaction test: 0,500)					
Underweight ($<18.5 \text{ kg/m}^2$)	4/59 (6,8)	0/23 (0,0)	3,60 [0,20; 64,33]	3,81 [0,20; 73,64]	6,78 [0,36; 13,19]
			0,573		
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	12/157 (7,6)	2/92 (2,2)	3,52 [0,80; 15,36]	3,72 [0,81; 17,03]	5,47 [0,36; 10,58]
			0,089		
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	4/68 (5,9)	1/28 (3,6)	1,65 [0,19; 14,09]	1,69 [0,18; 15,80]	2,31 [-6,55; 11,17]
			1,000		
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	3/47 (6,4)	2/21 (9,5)	0,67 [0,12; 3,72]	0,65 [0,10; 4,20]	-3,14 [-17,51; 11,23]
			0,641		
Tobacco use (p-value of the interaction test: 0,570)					
Current	5/76 (6,6)	1/32 (3,1)	2,11 [0,26; 17,31]	2,18 [0,24; 19,47]	3,45 [-4,76; 11,66]
			0,667		
Former	5/46 (10,9)	0/29 (0,0)	7,02 [0,40; >100]	7,82 [0,42; >100]	10,87 [1,87; 19,86]
			0,150		
Never	13/209 (6,2)	4/103 (3,9)	1,60 [0,54; 4,79]	1,64 [0,52; 5,17]	2,34 [-2,63; 7,30]
			0,596		
Prior biologic exposure (p-value of the interaction test: 0,666)					
Ever	4/36 (11,1)	0/12 (0,0)	3,16 [0,18; 54,81]	3,46 [0,17; 69,09]	11,11 [0,85; 21,38]
			0,560		
Never	19/295 (6,4)	5/152 (3,3)	1,96 [0,75; 5,14]	2,02 [0,74; 5,53]	3,15 [-0,83; 7,14]
			0,189		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline corticosteroid use (p-value of the interaction test: 0,762)					
Yes	7/113 (6,2)	1/56 (1,8)	3,47 [0,44; 27,51]	3,63 [0,44; 30,27]	4,41 [-1,23; 10,05]
			0,273		
No	16/218 (7,3)	4/108 (3,7)	1,98 [0,68; 5,78]	2,06 [0,67; 6,32]	3,64 [-1,33; 8,60]
			0,230		
Baseline immunomodulator use (p-value of the interaction test: 0,658)					
Yes	7/102 (6,9)	1/53 (1,9)	3,64 [0,46; 28,79]	3,83 [0,46; 32,00]	4,98 [-1,15; 11,10]
			0,265		
No	16/229 (7,0)	4/111 (3,6)	1,94 [0,66; 5,66]	2,01 [0,66; 6,16]	3,38 [-1,40; 8,17]
			0,325		
Duration of CD (p-value of the interaction test: 0,756)					
<1 year	4/71 (5,6)	1/33 (3,0)	1,86 [0,22; 15,99]	1,91 [0,21; 17,79]	2,60 [-5,33; 10,54]
			1,000		
≥1 to <5 years	12/132 (9,1)	2/71 (2,8)	3,23 [0,74; 14,02]	3,45 [0,75; 15,87]	6,27 [0,04; 12,51]
			0,145		
≥5 years	7/127 (5,5)	2/60 (3,3)	1,65 [0,35; 7,72]	1,69 [0,34; 8,40]	2,18 [-3,85; 8,21]
			0,721		
Baseline disease location (p-value of the interaction test: 0,582)					
Colonic	7/135 (5,2)	2/73 (2,7)	1,89 [0,40; 8,88]	1,94 [0,39; 9,60]	2,45 [-2,85; 7,74]
			0,499		
Ileal	5/41 (12,2)	0/24 (0,0)	6,55 [0,38; >100]	7,38 [0,39; >100]	12,20 [2,18; 22,21]
			0,149		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Ileal-Colonic	11/155 (7,1)	3/65 (4,6)	1,54 [0,44; 5,33]	1,58 [0,43; 5,86]	2,48 [-4,03; 8,99]
0,763					
Baseline fecal calprotectin (p-value of the interaction test: 0,284)					
≤250	7/57 (12,3)	3/24 (12,5)	0,98 [0,28; 3,48]	0,98 [0,23; 4,16]	-0,22 [-15,96; 15,52]
1,000					
>250	13/203 (6,4)	2/103 (1,9)	3,30 [0,76; 14,34]	3,46 [0,76; 15,61]	4,46 [0,17; 8,76]
0,100					
Baseline CRP (p-value of the interaction test: 0,906)					
≤10	17/217 (7,8)	4/108 (3,7)	2,12 [0,73; 6,13]	2,21 [0,72; 6,74]	4,13 [-0,92; 9,18]
0,230					
>10	6/114 (5,3)	1/56 (1,8)	2,95 [0,36; 23,89]	3,06 [0,36; 26,02]	3,48 [-1,89; 8,85]
0,428					
Baseline SES-CD total score (p-value of the interaction test: 0,289)					
<12	12/200 (6,0)	4/96 (4,2)	1,44 [0,48; 4,35]	1,47 [0,46; 4,68]	1,83 [-3,34; 7,01]
0,595					
≥12	11/131 (8,4)	1/66 (1,5)	5,54 [0,73; 42,01]	5,96 [0,75; 47,18]	6,88 [1,29; 12,47]
0,064					
Baseline AP average (p-value of the interaction test: 0,342)					
<2	6/70 (8,6)	0/35 (0,0)	6,59 [0,38; >100]	7,16 [0,39; >100]	8,57 [2,01; 15,13]
0,175					
≥2	17/260 (6,5)	5/129 (3,9)	1,69 [0,64; 4,47]	1,73 [0,63; 4,81]	2,66 [-1,82; 7,15]
0,356					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline SF average (p-value of the interaction test: 0,999)					
<7	15/265 (5,7)	3/125 (2,4)	2,36 [0,70; 8,00]	2,44 [0,69; 8,59]	3,26 [-0,60; 7,13]
			0,199		
≥7	8/65 (12,3)	2/39 (5,1)	2,40 [0,54; 10,73]	2,60 [0,52; 12,91]	7,18 [-3,39; 17,75]
			0,314		
Baseline CDAI 1 (p-value of the interaction test: 0,221)					
<300	8/148 (5,4)	0/75 (0,0)	8,67 [0,51; >100]	9,14 [0,52; >100]	5,41 [1,76; 9,05]
			0,054		
≥300	15/182 (8,2)	5/89 (5,6)	1,47 [0,55; 3,91]	1,51 [0,53; 4,29]	2,62 [-3,61; 8,86]
			0,621		
Baseline CDAI 2 (p-value of the interaction test: 0,751)					
<150	0/5 (0,0)	0/6 (0,0)	NB	NB	NB
			NB		
≥150 and <220	3/27 (11,1)	0/18 (0,0)	4,75 [0,26; 86,79]	5,29 [0,26; >100]	11,11 [-0,74; 22,97]
			0,264		
≥220 and <450	17/275 (6,2)	5/125 (4,0)	1,55 [0,58; 4,10]	1,58 [0,57; 4,39]	2,18 [-2,28; 6,64]
			0,481		
≥450	3/23 (13,0)	0/15 (0,0)	4,67 [0,26; 84,38]	5,29 [0,25; >100]	13,04 [-0,72; 26,81]
			0,264		
OECD Country (p-value of the interaction test: 0,730)					
Yes	13/209 (6,2)	2/94 (2,1)	2,92 [0,67; 12,70]	3,05 [0,67; 13,80]	4,09 [-0,29; 8,48]
			0,160		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
No	10/122 (8,2)	3/70 (4,3)	1,91 [0,54; 6,72]	1,99 [0,53; 7,50]	3,91 [-2,89; 10,71]
			0,381		
Datenschnitt: 23. August 2023; Conventional-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; SMQ: Standardised MedDRA Queries. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher. The number and percentage of participants reporting hepatic events were assessed using the MedDRA PTs contained in 5 SMQs: broad and narrow terms in the Liver-related investigations, signs and symptoms SMQ (SMQ 20000008), broad and narrow terms in the Cholestasis and jaundice of hepatic origin SMQ (SMQ 20000009); broad and narrow terms in the Hepatitis non-infectious SMQ (SMQ 20000010); broad and narrow terms in the Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions SMQ (SMQ 20000013), and narrow terms in the Liver-related coagulation and bleeding disturbances SMQ (SMQ 20000015).					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_heaesins_sub_safa_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
20DEC2024 / 04:00

Infektionen, inklusive opportunistischer Infektionen und schwerwiegender Infektionen

Subgruppen für Infections, including Opportunistic Infections and Serious Infections:

Gesamtrate in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A

(Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,899)					
<65 years	128/322 (39,8)	50/160 (31,3)	1,27 [0,97; 1,66]	1,45 [0,97; 2,17]	8,50 [-0,45; 17,45]
			0,072		
≥65 years	3/9 (33,3)	1/4 (25,0)	1,33 [0,19; 9,21]	1,50 [0,11; 21,31]	8,33 [-44,10; 60,77]
			1,000		
Age 2 (p-value of the interaction test: 0,338)					
<40 years	81/210 (38,6)	34/101 (33,7)	1,15 [0,83; 1,58]	1,24 [0,75; 2,03]	4,91 [-6,42; 16,23]
			0,452		
≥40 years	50/121 (41,3)	17/63 (27,0)	1,53 [0,97; 2,42]	1,91 [0,98; 3,70]	14,34 [0,30; 28,38]
			0,075		
Sex (p-value of the interaction test: 0,073)					
Male	80/178 (44,9)	24/83 (28,9)	1,55 [1,07; 2,26]	2,01 [1,15; 3,51]	16,03 [3,84; 28,22]
			0,015		
Female	51/153 (33,3)	27/81 (33,3)	1,00 [0,68; 1,46]	1,00 [0,56; 1,77]	0,00 [-12,70; 12,70]
			1,000		
Race (p-value of the interaction test: 0,480)					
White	102/268 (38,1)	39/137 (28,5)	1,34 [0,98; 1,82]	1,54 [0,99; 2,41]	9,59 [0,06; 19,13]
			0,061		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Other	29/62 (46,8)	12/26 (46,2)	1,01 [0,62; 1,66]	1,03 [0,41; 2,57]	0,62 [-22,21; 23,46]
1,000					
Geographic region 1 (p-value of the interaction test: 0,282)					
Europe	84/224 (37,5)	32/121 (26,4)	1,42 [1,01; 2,00]	1,67 [1,03; 2,71]	11,05 [0,96; 21,15]
0,043					
North America	12/31 (38,7)	3/13 (23,1)	1,68 [0,57; 4,97]	2,11 [0,48; 9,24]	15,63 [-12,98; 44,24]
0,488					
Other	35/76 (46,1)	16/30 (53,3)	0,86 [0,57; 1,31]	0,75 [0,32; 1,74]	-7,28 [-28,36; 13,80]
0,525					
Geographic region 2 (p-value of the interaction test: 0,060)					
Asia	28/58 (48,3)	10/23 (43,5)	1,11 [0,65; 1,90]	1,21 [0,46; 3,21]	4,80 [-19,20; 28,79]
0,807					
Central America/South America	2/11 (18,2)	6/7 (85,7)	0,21 [0,06; 0,77]	0,04 [0,00; 0,51]	-67,53 [-100,00; -33,01]
0,013					
Europe and ROW	89/231 (38,5)	32/121 (26,4)	1,46 [1,04; 2,04]	1,74 [1,08; 2,83]	12,08 [2,02; 22,14]
0,025					
North America	12/31 (38,7)	3/13 (23,1)	1,68 [0,57; 4,97]	2,11 [0,48; 9,24]	15,63 [-12,98; 44,24]
0,488					
Weight (p-value of the interaction test: 0,792)					
<100 kg	122/309 (39,5)	47/153 (30,7)	1,29 [0,98; 1,69]	1,47 [0,97; 2,22]	8,76 [-0,35; 17,88]
0,081					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
≥100 kg	9/22 (40,9)	4/11 (36,4)	1,13 [0,44; 2,85]	1,21 [0,27; 5,40]	4,55 [-30,53; 39,62]
1,000					
BMI (p-value of the interaction test: 0,066)					
Underweight ($<18.5 \text{ kg/m}^2$)	22/59 (37,3)	9/23 (39,1)	0,95 [0,52; 1,75]	0,92 [0,34; 2,49]	-1,84 [-25,30; 21,61]
1,000					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	53/157 (33,8)	30/92 (32,6)	1,04 [0,72; 1,49]	1,05 [0,61; 1,82]	1,15 [-10,95; 13,25]
0,890					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	36/68 (52,9)	5/28 (17,9)	2,96 [1,30; 6,77]	5,18 [1,76; 15,21]	35,08 [16,59; 53,58]
0,002					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	20/47 (42,6)	7/21 (33,3)	1,28 [0,64; 2,55]	1,48 [0,51; 4,34]	9,22 [-15,40; 33,84]
0,594					
Tobacco use (p-value of the interaction test: 0,928)					
Current	33/76 (43,4)	12/32 (37,5)	1,16 [0,69; 1,94]	1,28 [0,55; 2,98]	5,92 [-14,22; 26,06]
0,671					
Former	26/46 (56,5)	13/29 (44,8)	1,26 [0,78; 2,03]	1,60 [0,63; 4,08]	11,69 [-11,39; 34,78]
0,352					
Never	72/209 (34,4)	26/103 (25,2)	1,36 [0,93; 2,00]	1,56 [0,92; 2,64]	9,21 [-1,37; 19,78]
0,120					
Prior biologic exposure (p-value of the interaction test: 0,994)					
Ever	18/36 (50,0)	5/12 (41,7)	1,20 [0,57; 2,53]	1,40 [0,37; 5,24]	8,33 [-23,99; 40,66]
0,743					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Never	113/295 (38,3)	46/152 (30,3)	1,27 [0,96; 1,68]	1,43 [0,94; 2,17]	8,04 [-1,13; 17,21]
0,096					
Baseline corticosteroid use (p-value of the interaction test: 0,387)					
Yes	41/113 (36,3)	13/56 (23,2)	1,56 [0,92; 2,67]	1,88 [0,91; 3,91]	13,07 [-1,10; 27,24]
0,114					
No	90/218 (41,3)	38/108 (35,2)	1,17 [0,87; 1,59]	1,30 [0,80; 2,09]	6,10 [-5,03; 17,23]
0,335					
Baseline immunomodulator use (p-value of the interaction test: 0,145)					
Yes	41/102 (40,2)	22/53 (41,5)	0,97 [0,65; 1,44]	0,95 [0,48; 1,86]	-1,31 [-17,64; 15,01]
1,000					
No	90/229 (39,3)	29/111 (26,1)	1,50 [1,06; 2,14]	1,83 [1,11; 3,02]	13,18 [2,84; 23,51]
0,021					
Baseline disease location (p-value of the interaction test: 0,837)					
Colonic	49/135 (36,3)	22/73 (30,1)	1,20 [0,80; 1,82]	1,32 [0,72; 2,43]	6,16 [-7,13; 19,45]
0,444					
Ileal	15/41 (36,6)	8/24 (33,3)	1,10 [0,55; 2,20]	1,15 [0,40; 3,33]	3,25 [-20,69; 27,19]
1,000					
Ileal-Colonic	67/155 (43,2)	21/65 (32,3)	1,34 [0,90; 1,99]	1,60 [0,87; 2,93]	10,92 [-2,87; 24,70]
0,174					
Baseline fecal calprotectin (p-value of the interaction test: 0,992)					
≤250	21/57 (36,8)	7/24 (29,2)	1,26 [0,62; 2,57]	1,42 [0,50; 3,97]	7,68 [-14,40; 29,75]
0,613					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
>250	77/203 (37,9)	31/103 (30,1)	1,26 [0,89; 1,78]	1,42 [0,85; 2,36]	7,83 [-3,26; 18,93]
0,206					
Baseline CRP (p-value of the interaction test: 0,436)					
≤10	88/217 (40,6)	37/108 (34,3)	1,18 [0,87; 1,61]	1,31 [0,81; 2,12]	6,29 [-4,79; 17,37]
0,279					
>10	43/114 (37,7)	14/56 (25,0)	1,51 [0,90; 2,52]	1,82 [0,89; 3,71]	12,72 [-1,70; 27,13]
0,120					
Baseline SES-CD total score (p-value of the interaction test: 0,760)					
<12	81/200 (40,5)	30/96 (31,3)	1,30 [0,92; 1,82]	1,50 [0,89; 2,51]	9,25 [-2,25; 20,75]
0,158					
≥12	50/131 (38,2)	21/66 (31,8)	1,20 [0,79; 1,82]	1,32 [0,71; 2,48]	6,35 [-7,63; 20,33]
0,433					
Baseline AP average (p-value of the interaction test: 0,230)					
<2	40/70 (57,1)	13/35 (37,1)	1,54 [0,96; 2,48]	2,26 [0,98; 5,19]	20,00 [0,24; 39,76]
0,064					
≥2	90/260 (34,6)	38/129 (29,5)	1,18 [0,86; 1,61]	1,27 [0,80; 2,00]	5,16 [-4,61; 14,92]
0,359					
Baseline SF average (p-value of the interaction test: 0,449)					
<7	107/265 (40,4)	38/125 (30,4)	1,33 [0,98; 1,80]	1,55 [0,99; 2,44]	9,98 [-0,02; 19,97]
0,072					
≥7	23/65 (35,4)	13/39 (33,3)	1,06 [0,61; 1,84]	1,10 [0,47; 2,53]	2,05 [-16,76; 20,87]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline CDAI 1 (p-value of the interaction test: 0,507)					
<300	69/148 (46,6)	26/75 (34,7)	1,34 [0,94; 1,92]	1,65 [0,93; 2,92]	11,95 [-1,48; 25,39]
				0,115	
≥300	61/182 (33,5)	25/89 (28,1)	1,19 [0,81; 1,76]	1,29 [0,74; 2,25]	5,43 [-6,16; 17,01]
				0,406	
Baseline CDAI 2 (p-value of the interaction test: 0,235)					
<150	3/5 (60,0)	2/6 (33,3)	1,80 [0,47; 6,87]	3,00 [0,25; 35,33]	26,67 [-30,49; 83,82]
				0,567	
≥150 and <220	15/27 (55,6)	8/18 (44,4)	1,25 [0,67; 2,32]	1,56 [0,47; 5,19]	11,11 [-18,52; 40,75]
				0,550	
≥220 and <450	108/275 (39,3)	35/125 (28,0)	1,40 [1,02; 1,93]	1,66 [1,05; 2,63]	11,27 [1,51; 21,03]
				0,033	
≥450	4/23 (17,4)	6/15 (40,0)	0,43 [0,15; 1,29]	0,32 [0,07; 1,41]	-22,61 [-51,84; 6,62]
				0,150	
OECD Country (p-value of the interaction test: 0,970)					
Yes	91/209 (43,5)	33/94 (35,1)	1,24 [0,90; 1,70]	1,43 [0,86; 2,36]	8,43 [-3,33; 20,19]
				0,207	
No	40/122 (32,8)	18/70 (25,7)	1,28 [0,80; 2,04]	1,41 [0,73; 2,72]	7,07 [-6,13; 20,27]
				0,331	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Datenschnitt: 23. August 2023; Conventional-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. a: Exakter Test nach Fisher. Infections were defined using the PTs from the MedDRA Infections and Infestations SOC. The MedDRA terms used to identify infections considered to be opportunistic infections in participants with immune mediated inflammatory conditions treated with immunomodulatory drugs were based on Winthrop et al. (2015).					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_inaesi_sub_safa_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
20DEC2024 / 04:00

Subgruppen für Infections, including Opportunistic Infections and Serious Infections: Nicht schwer in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,910)					
<65 years	121/322 (37,6)	49/160 (30,6)	1,23 [0,93; 1,61]	1,36 [0,91; 2,04]	6,95 [-1,94; 15,84]
			0,156		
≥65 years	3/9 (33,3)	1/4 (25,0)	1,33 [0,19; 9,21]	1,50 [0,11; 21,31]	8,33 [-44,10; 60,77]
			1,000		
Age 2 (p-value of the interaction test: 0,236)					
<40 years	76/210 (36,2)	34/101 (33,7)	1,08 [0,77; 1,49]	1,12 [0,68; 1,84]	2,53 [-8,75; 13,80]
			0,705		
≥40 years	48/121 (39,7)	16/63 (25,4)	1,56 [0,97; 2,52]	1,93 [0,98; 3,79]	14,27 [0,43; 28,11]
			0,072		
Sex (p-value of the interaction test: 0,075)					
Male	77/178 (43,3)	24/83 (28,9)	1,50 [1,03; 2,18]	1,87 [1,07; 3,28]	14,34 [2,17; 26,51]
			0,029		
Female	47/153 (30,7)	26/81 (32,1)	0,96 [0,64; 1,42]	0,94 [0,53; 1,67]	-1,38 [-13,90; 11,14]
			0,882		
Race (p-value of the interaction test: 0,596)					
White	95/268 (35,4)	38/137 (27,7)	1,28 [0,93; 1,75]	1,43 [0,91; 2,24]	7,71 [-1,72; 17,14]
			0,146		
Other	29/62 (46,8)	12/26 (46,2)	1,01 [0,62; 1,66]	1,03 [0,41; 2,57]	0,62 [-22,21; 23,46]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,359)					
Europe	77/224 (34,4)	31/121 (25,6)	1,34 [0,94; 1,91]	1,52 [0,93; 2,49]	8,76 [-1,20; 18,71]
				0,114	
North America	12/31 (38,7)	3/13 (23,1)	1,68 [0,57; 4,97]	2,11 [0,48; 9,24]	15,63 [-12,98; 44,24]
				0,488	
Other	35/76 (46,1)	16/30 (53,3)	0,86 [0,57; 1,31]	0,75 [0,32; 1,74]	-7,28 [-28,36; 13,80]
				0,525	
Geographic region 2 (p-value of the interaction test: 0,070)					
Asia	28/58 (48,3)	10/23 (43,5)	1,11 [0,65; 1,90]	1,21 [0,46; 3,21]	4,80 [-19,20; 28,79]
				0,807	
Central America/South America	2/11 (18,2)	6/7 (85,7)	0,21 [0,06; 0,77]	0,04 [0,00; 0,51]	-67,53 [-100,00; -33,01]
				0,013	
Europe and ROW	82/231 (35,5)	31/121 (25,6)	1,39 [0,98; 1,97]	1,60 [0,98; 2,61]	9,88 [-0,05; 19,81]
				0,071	
North America	12/31 (38,7)	3/13 (23,1)	1,68 [0,57; 4,97]	2,11 [0,48; 9,24]	15,63 [-12,98; 44,24]
				0,488	
Weight (p-value of the interaction test: 0,751)					
<100 kg	115/309 (37,2)	47/153 (30,7)	1,21 [0,92; 1,60]	1,34 [0,88; 2,02]	6,50 [-2,58; 15,58]
				0,179	
≥100 kg	9/22 (40,9)	3/11 (27,3)	1,50 [0,51; 4,45]	1,85 [0,38; 8,93]	13,64 [-19,75; 47,02]
				0,703	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
BMI (p-value of the interaction test: 0,066)					
Underweight (<18.5 kg/m ²)	21/59 (35,6)	9/23 (39,1)	0,91 [0,49; 1,68]	0,86 [0,32; 2,32]	-3,54 [-26,93; 19,85]
				0,802	
Normal (≥18.5 and <25 kg/m ²)	50/157 (31,8)	30/92 (32,6)	0,98 [0,67; 1,42]	0,97 [0,56; 1,67]	-0,76 [-12,80; 11,27]
				1,000	
Overweight (≥25 and <30 kg/m ²)	34/68 (50,0)	5/28 (17,9)	2,80 [1,22; 6,42]	4,60 [1,57; 13,51]	32,14 [13,64; 50,65]
				0,006	
Obese and Extreme obese (≥30 kg/m ²)	19/47 (40,4)	6/21 (28,6)	1,41 [0,66; 3,03]	1,70 [0,56; 5,16]	11,85 [-12,02; 35,73]
				0,422	
Tobacco use (p-value of the interaction test: 0,991)					
Current	33/76 (43,4)	11/32 (34,4)	1,26 [0,73; 2,17]	1,47 [0,62; 3,46]	9,05 [-10,83; 28,92]
				0,402	
Former	24/46 (52,2)	13/29 (44,8)	1,16 [0,71; 1,90]	1,34 [0,53; 3,41]	7,35 [-15,81; 30,50]
				0,637	
Never	67/209 (32,1)	26/103 (25,2)	1,27 [0,86; 1,87]	1,40 [0,82; 2,38]	6,81 [-3,69; 17,32]
				0,238	
Prior biologic exposure (p-value of the interaction test: 0,813)					
Ever	16/36 (44,4)	5/12 (41,7)	1,07 [0,50; 2,29]	1,12 [0,30; 4,20]	2,78 [-29,50; 35,05]
				1,000	
Never	108/295 (36,6)	45/152 (29,6)	1,24 [0,93; 1,65]	1,37 [0,90; 2,09]	7,00 [-2,10; 16,11]
				0,143	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline corticosteroid use (p-value of the interaction test: 0,497)					
Yes	38/113 (33,6)	13/56 (23,2)	1,45 [0,84; 2,49]	1,68 [0,81; 3,49]	10,41 [-3,66; 24,49]
				0,213	
No	86/218 (39,4)	37/108 (34,3)	1,15 [0,85; 1,57]	1,25 [0,77; 2,02]	5,19 [-5,86; 16,24]
				0,397	
Baseline immunomodulator use (p-value of the interaction test: 0,266)					
Yes	40/102 (39,2)	21/53 (39,6)	0,99 [0,66; 1,49]	0,98 [0,50; 1,94]	-0,41 [-16,63; 15,82]
				1,000	
No	84/229 (36,7)	29/111 (26,1)	1,40 [0,98; 2,00]	1,64 [0,99; 2,70]	10,56 [0,27; 20,84]
				0,065	
Baseline disease location (p-value of the interaction test: 0,839)					
Colonic	46/135 (34,1)	21/73 (28,8)	1,18 [0,77; 1,82]	1,28 [0,69; 2,38]	5,31 [-7,80; 18,41]
				0,534	
Ileal	14/41 (34,1)	8/24 (33,3)	1,02 [0,50; 2,08]	1,04 [0,36; 3,01]	0,81 [-22,99; 24,61]
				1,000	
Ileal-Colonic	64/155 (41,3)	21/65 (32,3)	1,28 [0,86; 1,90]	1,47 [0,80; 2,71]	8,98 [-4,78; 22,74]
				0,228	
Baseline fecal calprotectin (p-value of the interaction test: 0,894)					
≤250	19/57 (33,3)	7/24 (29,2)	1,14 [0,55; 2,36]	1,21 [0,43; 3,43]	4,17 [-17,75; 26,09]
				0,798	
>250	74/203 (36,5)	31/103 (30,1)	1,21 [0,86; 1,71]	1,33 [0,80; 2,22]	6,36 [-4,70; 17,42]
				0,309	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline CRP (p-value of the interaction test: 0,748)					
≤10	86/217 (39,6)	36/108 (33,3)	1,19 [0,87; 1,63]	1,31 [0,81; 2,13]	6,30 [-4,72; 17,32]
			0,277		
>10	38/114 (33,3)	14/56 (25,0)	1,33 [0,79; 2,25]	1,50 [0,73; 3,08]	8,33 [-5,93; 22,60]
			0,293		
Baseline SES-CD total score (p-value of the interaction test: 0,764)					
<12	78/200 (39,0)	30/96 (31,3)	1,25 [0,89; 1,76]	1,41 [0,84; 2,36]	7,75 [-3,72; 19,22]
			0,201		
≥12	46/131 (35,1)	20/66 (30,3)	1,16 [0,75; 1,79]	1,24 [0,66; 2,35]	4,81 [-8,96; 18,59]
			0,527		
Baseline AP average (p-value of the interaction test: 0,286)					
<2	38/70 (54,3)	13/35 (37,1)	1,46 [0,90; 2,37]	2,01 [0,88; 4,62]	17,14 [-2,67; 36,95]
			0,147		
≥2	85/260 (32,7)	37/129 (28,7)	1,14 [0,83; 1,57]	1,21 [0,76; 1,92]	4,01 [-5,66; 13,68]
			0,486		
Baseline SF average (p-value of the interaction test: 0,439)					
<7	101/265 (38,1)	37/125 (29,6)	1,29 [0,94; 1,76]	1,46 [0,93; 2,31]	8,51 [-1,40; 18,42]
			0,113		
≥7	22/65 (33,8)	13/39 (33,3)	1,02 [0,58; 1,78]	1,02 [0,44; 2,37]	0,51 [-18,23; 19,25]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline CDAI 1 (p-value of the interaction test: 0,587)					
<300	66/148 (44,6)	26/75 (34,7)	1,29 [0,90; 1,84]	1,52 [0,85; 2,70]	9,93 [-3,49; 23,35]
				0,195	
≥300	57/182 (31,3)	24/89 (27,0)	1,16 [0,78; 1,74]	1,24 [0,70; 2,17]	4,35 [-7,07; 15,77]
				0,484	
Baseline CDAI 2 (p-value of the interaction test: 0,228)					
<150	3/5 (60,0)	2/6 (33,3)	1,80 [0,47; 6,87]	3,00 [0,25; 35,33]	26,67 [-30,49; 83,82]
				0,567	
≥150 and <220	13/27 (48,1)	8/18 (44,4)	1,08 [0,57; 2,07]	1,16 [0,35; 3,84]	3,70 [-26,00; 33,40]
				1,000	
≥220 and <450	103/275 (37,5)	34/125 (27,2)	1,38 [0,99; 1,91]	1,60 [1,01; 2,55]	10,25 [0,58; 19,93]
				0,053	
≥450	4/23 (17,4)	6/15 (40,0)	0,43 [0,15; 1,29]	0,32 [0,07; 1,41]	-22,61 [-51,84; 6,62]
				0,150	
OECD Country (p-value of the interaction test: 0,877)					
Yes	87/209 (41,6)	32/94 (34,0)	1,22 [0,88; 1,69]	1,38 [0,83; 2,30]	7,58 [-4,10; 19,26]
				0,253	
No	37/122 (30,3)	18/70 (25,7)	1,18 [0,73; 1,91]	1,26 [0,65; 2,43]	4,61 [-8,48; 17,70]
				0,513	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Datenschnitt: 23. August 2023; Conventional-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. a: Exakter Test nach Fisher. Infections were defined using the PTs from the MedDRA Infections and Infestations SOC. The MedDRA terms used to identify infections considered to be opportunistic infections in participants with immune mediated inflammatory conditions treated with immunomodulatory drugs were based on Winthrop et al. (2015).					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_inaesins_sub_safa_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
20DEC2024 / 04:00

Überempfindlichkeitsreaktionen, inklusive Anaphylaxie

Subgruppen für Hypersensitivity Reactions: Gesamtrate in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,599)					
<65 years	35/322 (10,9)	10/160 (6,3)	1,74 [0,88; 3,42]	1,83 [0,88; 3,80]	4,62 [-0,44; 9,68]
			0,134		
≥65 years	0/9 (0,0)	0/4 (0,0)	NB	NB	NB
			NB		
Age 2 (p-value of the interaction test: 0,344)					
<40 years	29/210 (13,8)	7/101 (6,9)	1,99 [0,90; 4,39]	2,15 [0,91; 5,10]	6,88 [0,07; 13,68]
			0,089		
≥40 years	6/121 (5,0)	3/63 (4,8)	1,04 [0,27; 4,03]	1,04 [0,25; 4,32]	0,20 [-6,33; 6,72]
			1,000		
Sex (p-value of the interaction test: 0,500)					
Male	16/178 (9,0)	3/83 (3,6)	2,49 [0,75; 8,30]	2,63 [0,75; 9,30]	5,37 [-0,44; 11,19]
			0,134		
Female	19/153 (12,4)	7/81 (8,6)	1,44 [0,63; 3,27]	1,50 [0,60; 3,73]	3,78 [-4,27; 11,82]
			0,513		
Race (p-value of the interaction test: 0,404)					
White	21/268 (7,8)	8/137 (5,8)	1,34 [0,61; 2,95]	1,37 [0,59; 3,18]	2,00 [-3,08; 7,07]
			0,545		
Other	13/62 (21,0)	2/26 (7,7)	2,73 [0,66; 11,24]	3,18 [0,66; 15,25]	13,28 [-1,13; 27,68]
			0,213		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,990)					
Europe	18/224 (8,0)	6/121 (5,0)	1,62 [0,66; 3,97]	1,67 [0,65; 4,34]	3,08 [-2,18; 8,33]
				0,376	
North America	4/31 (12,9)	1/13 (7,7)	1,68 [0,21; 13,61]	1,78 [0,18; 17,63]	5,21 [-13,47; 23,89]
				1,000	
Other	13/76 (17,1)	3/30 (10,0)	1,71 [0,52; 5,58]	1,86 [0,49; 7,05]	7,11 [-6,57; 20,78]
				0,548	
Geographic region 2 (p-value of the interaction test: 0,994)					
Asia	11/58 (19,0)	3/23 (13,0)	1,45 [0,45; 4,74]	1,56 [0,39; 6,20]	5,92 [-11,14; 22,99]
				0,747	
Central America/South America	1/11 (9,1)	0/7 (0,0)	2,00 [0,09; 43,22]	2,14 [0,08; 60,17]	9,09 [-7,90; 26,08]
				1,000	
Europe and ROW	19/231 (8,2)	6/121 (5,0)	1,66 [0,68; 4,04]	1,72 [0,67; 4,42]	3,27 [-1,98; 8,51]
				0,285	
North America	4/31 (12,9)	1/13 (7,7)	1,68 [0,21; 13,61]	1,78 [0,18; 17,63]	5,21 [-13,47; 23,89]
				1,000	
Weight (p-value of the interaction test: 0,990)					
<100 kg	34/309 (11,0)	10/153 (6,5)	1,68 [0,85; 3,32]	1,77 [0,85; 3,68]	4,47 [-0,78; 9,71]
				0,133	
≥100 kg	1/22 (4,5)	0/11 (0,0)	1,57 [0,07; 35,57]	1,60 [0,06; 42,63]	4,55 [-4,16; 13,25]
				1,000	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
BMI (p-value of the interaction test: 0,617)					
Underweight ($<18.5 \text{ kg/m}^2$)	10/59 (16,9)	2/23 (8,7)	1,95 [0,46; 8,22]	2,14 [0,43; 10,63]	8,25 [-6,72; 23,23]
			0,494		
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	15/157 (9,6)	6/92 (6,5)	1,46 [0,59; 3,64]	1,51 [0,57; 4,05]	3,03 [-3,79; 9,86]
			0,484		
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	4/68 (5,9)	2/28 (7,1)	0,82 [0,16; 4,24]	0,81 [0,14; 4,71]	-1,26 [-12,32; 9,80]
			1,000		
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	6/47 (12,8)	0/21 (0,0)	5,96 [0,35; >100]	6,73 [0,36; >100]	12,77 [3,23; 22,31]
			0,166		
Tobacco use (p-value of the interaction test: 0,545)					
Current	10/76 (13,2)	2/32 (6,3)	2,11 [0,49; 9,07]	2,27 [0,47; 11,02]	6,91 [-4,41; 18,23]
			0,503		
Former	2/46 (4,3)	2/29 (6,9)	0,63 [0,09; 4,23]	0,61 [0,08; 4,62]	-2,55 [-13,49; 8,40]
			0,638		
Never	23/209 (11,0)	6/103 (5,8)	1,89 [0,79; 4,50]	2,00 [0,79; 5,07]	5,18 [-1,02; 11,38]
			0,153		
Prior biologic exposure (p-value of the interaction test: 0,771)					
Ever	5/36 (13,9)	1/12 (8,3)	1,67 [0,22; 12,88]	1,77 [0,19; 16,91]	5,56 [-13,74; 24,85]
			1,000		
Never	30/295 (10,2)	9/152 (5,9)	1,72 [0,84; 3,52]	1,80 [0,83; 3,89]	4,25 [-0,85; 9,34]
			0,158		

	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Subgruppe			p-Wert ^a		
Baseline corticosteroid use (p-value of the interaction test: 0,119)					
Yes	6/113 (5,3)	4/56 (7,1)	0,74 [0,22; 2,53]	0,73 [0,20; 2,70]	-1,83 [-9,74; 6,08]
			0,732		
No	29/218 (13,3)	6/108 (5,6)	2,39 [1,03; 5,59]	2,61 [1,05; 6,49]	7,75 [1,50; 13,99]
			0,037		
Baseline immunomodulator use (p-value of the interaction test: 0,634)					
Yes	13/102 (12,7)	3/53 (5,7)	2,25 [0,67; 7,56]	2,43 [0,66; 8,95]	7,08 [-1,89; 16,06]
			0,265		
No	22/229 (9,6)	7/111 (6,3)	1,52 [0,67; 3,46]	1,58 [0,65; 3,82]	3,30 [-2,62; 9,22]
			0,408		
Duration of CD (p-value of the interaction test: 0,218)					
<1 year	8/71 (11,3)	5/33 (15,2)	0,74 [0,26; 2,10]	0,71 [0,21; 2,37]	-3,88 [-18,16; 10,39]
			0,751		
≥1 to <5 years	13/132 (9,8)	3/71 (4,2)	2,33 [0,69; 7,91]	2,48 [0,68; 9,00]	5,62 [-1,29; 12,53]
			0,183		
≥5 years	14/127 (11,0)	2/60 (3,3)	3,31 [0,78; 14,09]	3,59 [0,79; 16,35]	7,69 [0,60; 14,78]
			0,097		
Baseline disease location (p-value of the interaction test: 0,110)					
Colonic	14/135 (10,4)	2/73 (2,7)	3,79 [0,88; 16,20]	4,11 [0,91; 18,60]	7,63 [1,27; 13,99]
			0,058		
Ileal	3/41 (7,3)	4/24 (16,7)	0,44 [0,11; 1,80]	0,39 [0,08; 1,94]	-9,35 [-26,26; 7,56]
			0,408		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Ileal-Colonic	18/155 (11,6)	4/65 (6,2)	1,89 [0,66; 5,36]	2,00 [0,65; 6,17]	5,46 [-2,26; 13,18]
0,324					
Baseline fecal calprotectin (p-value of the interaction test: 0,399)					
≤250	6/57 (10,5)	0/24 (0,0)	5,60 [0,33; 95,71]	6,18 [0,33; >100]	10,53 [2,56; 18,49]
0,172					
>250	17/203 (8,4)	5/103 (4,9)	1,73 [0,65; 4,54]	1,79 [0,64; 5,00]	3,52 [-2,11; 9,15]
0,351					
Baseline CRP (p-value of the interaction test: 0,982)					
≤10	21/217 (9,7)	6/108 (5,6)	1,74 [0,72; 4,19]	1,82 [0,71; 4,65]	4,12 [-1,72; 9,96]
0,286					
>10	14/114 (12,3)	4/56 (7,1)	1,72 [0,59; 4,98]	1,82 [0,57; 5,81]	5,14 [-3,91; 14,18]
0,428					
Baseline AP average (p-value of the interaction test: 0,970)					
<2	10/70 (14,3)	3/35 (8,6)	1,67 [0,49; 5,67]	1,78 [0,46; 6,92]	5,71 [-6,66; 18,09]
0,537					
≥2	24/260 (9,2)	7/129 (5,4)	1,70 [0,75; 3,84]	1,77 [0,74; 4,23]	3,80 [-1,46; 9,06]
0,235					
Baseline SF average (p-value of the interaction test: 0,226)					
<7	28/265 (10,6)	10/125 (8,0)	1,32 [0,66; 2,63]	1,36 [0,64; 2,89]	2,57 [-3,46; 8,59]
0,470					
≥7	6/65 (9,2)	0/39 (0,0)	7,88 [0,46; >100]	8,63 [0,47; >100]	9,23 [2,19; 16,27]
0,081					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline CDAI 1 (p-value of the interaction test: 0,663)					
<300	20/148 (13,5)	7/75 (9,3)	1,45 [0,64; 3,27]	1,52 [0,61; 3,77]	4,18 [-4,40; 12,76]
			0,515		
≥300	14/182 (7,7)	3/89 (3,4)	2,28 [0,67; 7,74]	2,39 [0,67; 8,54]	4,32 [-1,07; 9,71]
			0,194		
Baseline CDAI 2 (p-value of the interaction test: 0,890)					
<150	1/5 (20,0)	0/6 (0,0)	3,50 [0,17; 70,94]	4,33 [0,14; >100]	20,00 [-15,06; 55,06]
			0,455		
≥150 and <220	3/27 (11,1)	2/18 (11,1)	1,00 [0,19; 5,40]	1,00 [0,15; 6,67]	0,00 [-18,74; 18,74]
			1,000		
≥220 and <450	29/275 (10,5)	8/125 (6,4)	1,65 [0,78; 3,50]	1,72 [0,76; 3,89]	4,15 [-1,47; 9,77]
			0,263		
≥450	1/23 (4,3)	0/15 (0,0)	2,00 [0,09; 46,09]	2,07 [0,08; 54,12]	4,35 [-3,99; 12,68]
			1,000		
OECD Country (p-value of the interaction test: 0,353)					
Yes	24/209 (11,5)	8/94 (8,5)	1,35 [0,63; 2,89]	1,39 [0,60; 3,23]	2,97 [-4,13; 10,08]
			0,546		
No	11/122 (9,0)	2/70 (2,9)	3,16 [0,72; 13,83]	3,37 [0,72; 15,66]	6,16 [-0,25; 12,57]
			0,138		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Datenschnitt: 23. August 2023; Conventional-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SF: Stool Frequency. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher. The TEAEs were summarized using all narrow or algorithm terms in the Anaphylatic reaction, Angioedema, or Hypersensitivity SMQs.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_hyaesi_sub_safa_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba

20DEC2024 / 04:00

Subgruppen für Hypersensitivity Reactions: Nicht schwer in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,618)					
<65 years	33/322 (10,2)	10/160 (6,3)	1,64 [0,83; 3,24]	1,71 [0,82; 3,57]	4,00 [-1,01; 9,00]
			0,176		
≥65 years	0/9 (0,0)	0/4 (0,0)	NB	NB	NB
			NB		
Age 2 (p-value of the interaction test: 0,397)					
<40 years	27/210 (12,9)	7/101 (6,9)	1,86 [0,84; 4,11]	1,98 [0,83; 4,72]	5,93 [-0,78; 12,64]
			0,126		
≥40 years	6/121 (5,0)	3/63 (4,8)	1,04 [0,27; 4,03]	1,04 [0,25; 4,32]	0,20 [-6,33; 6,72]
			1,000		
Sex (p-value of the interaction test: 0,402)					
Male	16/178 (9,0)	3/83 (3,6)	2,49 [0,75; 8,30]	2,63 [0,75; 9,30]	5,37 [-0,44; 11,19]
			0,134		
Female	17/153 (11,1)	7/81 (8,6)	1,29 [0,56; 2,97]	1,32 [0,52; 3,33]	2,47 [-5,42; 10,36]
			0,654		
Race (p-value of the interaction test: 0,335)					
White	19/268 (7,1)	8/137 (5,8)	1,21 [0,55; 2,70]	1,23 [0,52; 2,89]	1,25 [-3,74; 6,24]
			0,834		
Other	13/62 (21,0)	2/26 (7,7)	2,73 [0,66; 11,24]	3,18 [0,66; 15,25]	13,28 [-1,13; 27,68]
			0,213		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,974)					
Europe	16/224 (7,1)	6/121 (5,0)	1,44 [0,58; 3,59]	1,47 [0,56; 3,87]	2,18 [-2,95; 7,32]
				0,496	
North America	4/31 (12,9)	1/13 (7,7)	1,68 [0,21; 13,61]	1,78 [0,18; 17,63]	5,21 [-13,47; 23,89]
				1,000	
Other	13/76 (17,1)	3/30 (10,0)	1,71 [0,52; 5,58]	1,86 [0,49; 7,05]	7,11 [-6,57; 20,78]
				0,548	
Geographic region 2 (p-value of the interaction test: 0,997)					
Asia	11/58 (19,0)	3/23 (13,0)	1,45 [0,45; 4,74]	1,56 [0,39; 6,20]	5,92 [-11,14; 22,99]
				0,747	
Central America/South America	1/11 (9,1)	0/7 (0,0)	2,00 [0,09; 43,22]	2,14 [0,08; 60,17]	9,09 [-7,90; 26,08]
				1,000	
Europe and ROW	17/231 (7,4)	6/121 (5,0)	1,48 [0,60; 3,67]	1,52 [0,58; 3,97]	2,40 [-2,73; 7,53]
				0,498	
North America	4/31 (12,9)	1/13 (7,7)	1,68 [0,21; 13,61]	1,78 [0,18; 17,63]	5,21 [-13,47; 23,89]
				1,000	
Weight (p-value of the interaction test: 0,979)					
<100 kg	32/309 (10,4)	10/153 (6,5)	1,58 [0,80; 3,14]	1,65 [0,79; 3,46]	3,82 [-1,36; 9,00]
				0,229	
≥100 kg	1/22 (4,5)	0/11 (0,0)	1,57 [0,07; 35,57]	1,60 [0,06; 42,63]	4,55 [-4,16; 13,25]
				1,000	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
BMI (p-value of the interaction test: 0,631)					
Underweight ($<18.5 \text{ kg/m}^2$)	9/59 (15,3)	2/23 (8,7)	1,75 [0,41; 7,51]	1,89 [0,38; 9,50]	6,56 [-8,16; 21,28]
			0,720		
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	14/157 (8,9)	6/92 (6,5)	1,37 [0,54; 3,43]	1,40 [0,52; 3,79]	2,40 [-4,34; 9,13]
			0,632		
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	4/68 (5,9)	2/28 (7,1)	0,82 [0,16; 4,24]	0,81 [0,14; 4,71]	-1,26 [-12,32; 9,80]
			1,000		
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	6/47 (12,8)	0/21 (0,0)	5,96 [0,35; >100]	6,73 [0,36; >100]	12,77 [3,23; 22,31]
			0,166		
Tobacco use (p-value of the interaction test: 0,581)					
Current	10/76 (13,2)	2/32 (6,3)	2,11 [0,49; 9,07]	2,27 [0,47; 11,02]	6,91 [-4,41; 18,23]
			0,503		
Former	2/46 (4,3)	2/29 (6,9)	0,63 [0,09; 4,23]	0,61 [0,08; 4,62]	-2,55 [-13,49; 8,40]
			0,638		
Never	21/209 (10,0)	6/103 (5,8)	1,72 [0,72; 4,14]	1,81 [0,71; 4,62]	4,22 [-1,87; 10,31]
			0,285		
Prior biologic exposure (p-value of the interaction test: 0,640)					
Ever	4/36 (11,1)	1/12 (8,3)	1,33 [0,16; 10,80]	1,38 [0,14; 13,66]	2,78 [-15,93; 21,48]
			1,000		
Never	29/295 (9,8)	9/152 (5,9)	1,66 [0,81; 3,42]	1,73 [0,80; 3,76]	3,91 [-1,15; 8,97]
			0,210		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline corticosteroid use (p-value of the interaction test: 0,090)					
Yes	5/113 (4,4)	4/56 (7,1)	0,62 [0,17; 2,22]	0,60 [0,16; 2,34]	-2,72 [-10,46; 5,02]
				0,481	
No	28/218 (12,8)	6/108 (5,6)	2,31 [0,99; 5,41]	2,51 [1,00; 6,25]	7,29 [1,09; 13,48]
				0,053	
Baseline immunomodulator use (p-value of the interaction test: 0,546)					
Yes	13/102 (12,7)	3/53 (5,7)	2,25 [0,67; 7,56]	2,43 [0,66; 8,95]	7,08 [-1,89; 16,06]
				0,265	
No	20/229 (8,7)	7/111 (6,3)	1,38 [0,60; 3,18]	1,42 [0,58; 3,47]	2,43 [-3,39; 8,24]
				0,525	
Duration of CD (p-value of the interaction test: 0,267)					
<1 year	8/71 (11,3)	5/33 (15,2)	0,74 [0,26; 2,10]	0,71 [0,21; 2,37]	-3,88 [-18,16; 10,39]
				0,751	
≥1 to <5 years	13/132 (9,8)	3/71 (4,2)	2,33 [0,69; 7,91]	2,48 [0,68; 9,00]	5,62 [-1,29; 12,53]
				0,183	
≥5 years	12/127 (9,4)	2/60 (3,3)	2,83 [0,65; 12,27]	3,03 [0,66; 13,97]	6,12 [-0,70; 12,94]
				0,232	
Baseline disease location (p-value of the interaction test: 0,130)					
Colonic	13/135 (9,6)	2/73 (2,7)	3,51 [0,82; 15,15]	3,78 [0,83; 17,25]	6,89 [0,66; 13,12]
				0,091	
Ileal	3/41 (7,3)	4/24 (16,7)	0,44 [0,11; 1,80]	0,39 [0,08; 1,94]	-9,35 [-26,26; 7,56]
				0,408	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Ileal-Colonic	17/155 (11,0)	4/65 (6,2)	1,78 [0,62; 5,09]	1,88 [0,61; 5,82]	4,81 [-2,82; 12,45]
0,324					
Baseline fecal calprotectin (p-value of the interaction test: 0,375)					
≤250	6/57 (10,5)	0/24 (0,0)	5,60 [0,33; 95,71]	6,18 [0,33; >100]	10,53 [2,56; 18,49]
0,172					
>250	16/203 (7,9)	5/103 (4,9)	1,62 [0,61; 4,31]	1,68 [0,60; 4,71]	3,03 [-2,54; 8,59]
0,473					
Baseline CRP (p-value of the interaction test: 0,987)					
≤10	20/217 (9,2)	6/108 (5,6)	1,66 [0,69; 4,01]	1,73 [0,67; 4,43]	3,66 [-2,12; 9,45]
0,286					
>10	13/114 (11,4)	4/56 (7,1)	1,60 [0,55; 4,67]	1,67 [0,52; 5,39]	4,26 [-4,66; 13,18]
0,587					
Baseline AP average (p-value of the interaction test: 0,901)					
<2	9/70 (12,9)	3/35 (8,6)	1,50 [0,43; 5,19]	1,57 [0,40; 6,22]	4,29 [-7,86; 16,43]
0,747					
≥2	23/260 (8,8)	7/129 (5,4)	1,63 [0,72; 3,70]	1,69 [0,71; 4,05]	3,42 [-1,80; 8,63]
0,313					
Baseline SF average (p-value of the interaction test: 0,208)					
<7	26/265 (9,8)	10/125 (8,0)	1,23 [0,61; 2,46]	1,25 [0,58; 2,68]	1,81 [-4,14; 7,76]
0,708					
≥7	6/65 (9,2)	0/39 (0,0)	7,88 [0,46; >100]	8,63 [0,47; >100]	9,23 [2,19; 16,27]
0,081					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Baseline CDAI 1 (p-value of the interaction test: 0,682)					
<300	19/148 (12,8)	7/75 (9,3)	1,38 [0,61; 3,13]	1,43 [0,57; 3,57]	3,50 [-5,00; 12,01]
				0,513	
≥300	13/182 (7,1)	3/89 (3,4)	2,12 [0,62; 7,25]	2,21 [0,61; 7,95]	3,77 [-1,52; 9,07]
				0,279	
Baseline CDAI 2 (p-value of the interaction test: 0,895)					
<150	1/5 (20,0)	0/6 (0,0)	3,50 [0,17; 70,94]	4,33 [0,14; >100]	20,00 [-15,06; 55,06]
				0,455	
≥150 and <220	3/27 (11,1)	2/18 (11,1)	1,00 [0,19; 5,40]	1,00 [0,15; 6,67]	0,00 [-18,74; 18,74]
				1,000	
≥220 and <450	27/275 (9,8)	8/125 (6,4)	1,53 [0,72; 3,28]	1,59 [0,70; 3,61]	3,42 [-2,13; 8,97]
				0,340	
≥450	1/23 (4,3)	0/15 (0,0)	2,00 [0,09; 46,09]	2,07 [0,08; 54,12]	4,35 [-3,99; 12,68]
				1,000	
OECD Country (p-value of the interaction test: 0,298)					
Yes	22/209 (10,5)	8/94 (8,5)	1,24 [0,57; 2,68]	1,26 [0,54; 2,95]	2,02 [-4,99; 9,03]
				0,681	
No	11/122 (9,0)	2/70 (2,9)	3,16 [0,72; 13,83]	3,37 [0,72; 15,66]	6,16 [-0,25; 12,57]
				0,138	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Datenschnitt: 23. August 2023; Conventional-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SF: Stool Frequency. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher. The TEAEs were summarized using all narrow or algorithm terms in the Anaphylatic reaction, Angioedema, or Hypersensitivity SMQs.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_hyaesins_sub_safa_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
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Reaktionen an der Injektions-/Infusionsstelle

Subgruppen für Infusion and Injection Site Reactions: Gesamtrate in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,619)					
<65 years	26/322 (8,1)	10/160 (6,3)	1,29 [0,64; 2,61]	1,32 [0,62; 2,80]	1,82 [-2,96; 6,61]
			0,582		
≥65 years	3/9 (33,3)	0/4 (0,0)	3,50 [0,22; 55,40]	4,85 [0,20; >100]	33,33 [2,54; 64,13]
			0,497		
Age 2 (p-value of the interaction test: 0,087)					
<40 years	16/210 (7,6)	3/101 (3,0)	2,57 [0,76; 8,60]	2,69 [0,77; 9,47]	4,65 [-0,23; 9,53]
			0,133		
≥40 years	13/121 (10,7)	7/63 (11,1)	0,97 [0,41; 2,30]	0,96 [0,36; 2,55]	-0,37 [-9,89; 9,15]
			1,000		
Sex (p-value of the interaction test: 0,430)					
Male	17/178 (9,6)	4/83 (4,8)	1,98 [0,69; 5,71]	2,09 [0,68; 6,40]	4,73 [-1,58; 11,05]
			0,229		
Female	12/153 (7,8)	6/81 (7,4)	1,06 [0,41; 2,72]	1,06 [0,38; 2,95]	0,44 [-6,68; 7,55]
			1,000		
Race (p-value of the interaction test: 0,853)					
White	23/268 (8,6)	8/137 (5,8)	1,47 [0,68; 3,20]	1,51 [0,66; 3,48]	2,74 [-2,42; 7,91]
			0,430		
Other	6/62 (9,7)	2/26 (7,7)	1,26 [0,27; 5,83]	1,29 [0,24; 6,83]	1,99 [-10,63; 14,60]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,826)					
Europe	14/224 (6,3)	6/121 (5,0)	1,26 [0,50; 3,20]	1,28 [0,48; 3,41]	1,29 [-3,71; 6,29]
				0,810	
North America	5/31 (16,1)	2/13 (15,4)	1,05 [0,23; 4,73]	1,06 [0,18; 6,30]	0,74 [-22,76; 24,25]
				1,000	
Other	10/76 (13,2)	2/30 (6,7)	1,97 [0,46; 8,48]	2,12 [0,44; 10,31]	6,49 [-5,23; 18,21]
				0,502	
Geographic region 2 (p-value of the interaction test: 0,519)					
Asia	6/58 (10,3)	1/23 (4,3)	2,38 [0,30; 18,69]	2,54 [0,29; 22,34]	6,00 [-5,44; 17,44]
				0,667	
Central America/South America	0/11 (0,0)	1/7 (14,3)	0,22 [0,01; 4,80]	0,19 [0,01; 5,33]	-14,29 [-40,21; 11,64]
				0,389	
Europe and ROW	18/231 (7,8)	6/121 (5,0)	1,57 [0,64; 3,85]	1,62 [0,63; 4,19]	2,83 [-2,35; 8,02]
				0,379	
North America	5/31 (16,1)	2/13 (15,4)	1,05 [0,23; 4,73]	1,06 [0,18; 6,30]	0,74 [-22,76; 24,25]
				1,000	
Weight (p-value of the interaction test: 0,683)					
<100 kg	27/309 (8,7)	10/153 (6,5)	1,34 [0,66; 2,69]	1,37 [0,64; 2,91]	2,20 [-2,82; 7,23]
				0,470	
≥100 kg	2/22 (9,1)	0/11 (0,0)	2,61 [0,14; 50,09]	2,80 [0,12; 63,59]	9,09 [-2,92; 21,10]
				0,542	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
BMI (p-value of the interaction test: 0,655)					
Underweight ($<18.5 \text{ kg/m}^2$)	5/59 (8,5)	0/23 (0,0)	4,40 [0,25; 76,53]	4,74 [0,25; 89,29]	8,47 [1,37; 15,58]
			0,315		
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	11/157 (7,0)	5/92 (5,4)	1,29 [0,46; 3,59]	1,31 [0,44; 3,90]	1,57 [-4,54; 7,69]
			0,791		
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	7/68 (10,3)	4/28 (14,3)	0,72 [0,23; 2,27]	0,69 [0,18; 2,57]	-3,99 [-18,83; 10,85]
			0,725		
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	6/47 (12,8)	1/21 (4,8)	2,68 [0,34; 20,90]	2,93 [0,33; 25,98]	8,00 [-5,19; 21,19]
			0,423		
Tobacco use (p-value of the interaction test: 0,845)					
Current	8/76 (10,5)	1/32 (3,1)	3,37 [0,44; 25,84]	3,65 [0,44; 30,44]	7,40 [-1,76; 16,56]
			0,276		
Former	7/46 (15,2)	3/29 (10,3)	1,47 [0,41; 5,24]	1,56 [0,37; 6,57]	4,87 [-10,31; 20,06]
			0,732		
Never	14/209 (6,7)	6/103 (5,8)	1,15 [0,46; 2,91]	1,16 [0,43; 3,11]	0,87 [-4,78; 6,53]
			1,000		
Prior biologic exposure (p-value of the interaction test: 0,153)					
Ever	3/36 (8,3)	2/12 (16,7)	0,50 [0,09; 2,64]	0,45 [0,07; 3,11]	-8,33 [-31,27; 14,60]
			0,587		
Never	26/295 (8,8)	8/152 (5,3)	1,67 [0,78; 3,61]	1,74 [0,77; 3,94]	3,55 [-1,25; 8,35]
			0,194		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline corticosteroid use (p-value of the interaction test: 0,202)					
Yes	7/113 (6,2)	0/56 (0,0)	7,50 [0,44; >100]	7,96 [0,45; >100]	6,19 [1,75; 10,64]
			0,097		
No	22/218 (10,1)	10/108 (9,3)	1,09 [0,54; 2,22]	1,10 [0,50; 2,41]	0,83 [-5,94; 7,61]
			1,000		
Baseline immunomodulator use (p-value of the interaction test: 0,589)					
Yes	10/102 (9,8)	4/53 (7,5)	1,30 [0,43; 3,95]	1,33 [0,40; 4,47]	2,26 [-6,90; 11,42]
			0,773		
No	19/229 (8,3)	6/111 (5,4)	1,53 [0,63; 3,74]	1,58 [0,61; 4,08]	2,89 [-2,63; 8,41]
			0,385		
Duration of CD (p-value of the interaction test: 0,404)					
<1 year	7/71 (9,9)	0/33 (0,0)	7,08 [0,42; >100]	7,79 [0,43; >100]	9,86 [2,92; 16,79]
			0,094		
≥1 to <5 years	9/132 (6,8)	3/71 (4,2)	1,61 [0,45; 5,77]	1,66 [0,43; 6,33]	2,59 [-3,76; 8,95]
			0,547		
≥5 years	13/127 (10,2)	7/60 (11,7)	0,88 [0,37; 2,09]	0,86 [0,33; 2,29]	-1,43 [-11,11; 8,25]
			0,802		
Baseline disease location (p-value of the interaction test: 0,797)					
Colonic	9/135 (6,7)	4/73 (5,5)	1,22 [0,39; 3,82]	1,23 [0,37; 4,15]	1,19 [-5,52; 7,89]
			1,000		
Ileal	6/41 (14,6)	2/24 (8,3)	1,76 [0,38; 8,02]	1,89 [0,35; 10,19]	6,30 [-9,17; 21,77]
			0,699		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Ileal-Colonic	14/155 (9,0)	3/65 (4,6)	1,96 [0,58; 6,58]	2,05 [0,57; 7,40]	4,42 [-2,39; 11,23]
0,407					
Baseline fecal calprotectin (p-value of the interaction test: 0,703)					
≤250	2/57 (3,5)	0/24 (0,0)	2,16 [0,11; 43,28]	2,21 [0,10; 47,71]	3,51 [-1,27; 8,29]
1,000					
>250	14/203 (6,9)	7/103 (6,8)	1,01 [0,42; 2,44]	1,02 [0,40; 2,60]	0,10 [-5,88; 6,08]
1,000					
Baseline CRP (p-value of the interaction test: 0,797)					
≤10	23/217 (10,6)	8/108 (7,4)	1,43 [0,66; 3,09]	1,48 [0,64; 3,43]	3,19 [-3,22; 9,61]
0,426					
>10	6/114 (5,3)	2/56 (3,6)	1,47 [0,31; 7,07]	1,50 [0,29; 7,68]	1,69 [-4,67; 8,05]
1,000					
Baseline SES-CD total score (p-value of the interaction test: 0,421)					
<12	23/200 (11,5)	6/96 (6,3)	1,84 [0,77; 4,37]	1,95 [0,77; 4,96]	5,25 [-1,31; 11,81]
0,210					
≥12	6/131 (4,6)	3/66 (4,5)	1,01 [0,26; 3,90]	1,01 [0,24; 4,16]	0,03 [-6,14; 6,20]
1,000					
Baseline AP average (p-value of the interaction test: 0,882)					
<2	6/70 (8,6)	2/35 (5,7)	1,50 [0,32; 7,05]	1,55 [0,30; 8,09]	2,86 [-7,25; 12,96]
0,716					
≥2	23/260 (8,8)	8/129 (6,2)	1,43 [0,66; 3,10]	1,47 [0,64; 3,38]	2,64 [-2,76; 8,05]
0,430					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline SF average (p-value of the interaction test: 0,669)					
<7	27/265 (10,2)	8/125 (6,4)	1,59 [0,74; 3,40]	1,66 [0,73; 3,76]	3,79 [-1,84; 9,42]
			0,259		
≥7	2/65 (3,1)	2/39 (5,1)	0,60 [0,09; 4,09]	0,59 [0,08; 4,35]	-2,05 [-10,15; 6,04]
			0,630		
Baseline CDAI 1 (p-value of the interaction test: 0,457)					
<300	17/148 (11,5)	4/75 (5,3)	2,15 [0,75; 6,17]	2,30 [0,75; 7,11]	6,15 [-1,08; 13,38]
			0,154		
≥300	12/182 (6,6)	6/89 (6,7)	0,98 [0,38; 2,52]	0,98 [0,35; 2,69]	-0,15 [-6,48; 6,19]
			1,000		
OECD Country (p-value of the interaction test: 0,164)					
Yes	24/209 (11,5)	6/94 (6,4)	1,80 [0,76; 4,26]	1,90 [0,75; 4,82]	5,10 [-1,46; 11,67]
			0,214		
No	5/122 (4,1)	4/70 (5,7)	0,72 [0,20; 2,58]	0,71 [0,18; 2,72]	-1,62 [-8,09; 4,86]
			0,726		
Datenschnitt: 23. August 2023; Conventional-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher. The TEAEs were summarized using the MedDRA HLT Injection site reactions excluding certain PTs (e.g., those PTs related to joint) and the MedDRA HLT Infusion site reactions.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_iiatesi_sub_safa_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba

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Subgruppen für Infusion and Injection Site Reactions: Nicht schwer in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,597)					
<65 years	24/322 (7,5)	10/160 (6,3)	1,19 [0,58; 2,43]	1,21 [0,56; 2,59]	1,20 [-3,52; 5,93]
			0,708		
≥65 years	3/9 (33,3)	0/4 (0,0)	3,50 [0,22; 55,40]	4,85 [0,20; >100]	33,33 [2,54; 64,13]
			0,497		
Age 2 (p-value of the interaction test: 0,121)					
<40 years	14/210 (6,7)	3/101 (3,0)	2,24 [0,66; 7,63]	2,33 [0,66; 8,31]	3,70 [-1,03; 8,42]
			0,286		
≥40 years	13/121 (10,7)	7/63 (11,1)	0,97 [0,41; 2,30]	0,96 [0,36; 2,55]	-0,37 [-9,89; 9,15]
			1,000		
Sex (p-value of the interaction test: 0,296)					
Male	17/178 (9,6)	4/83 (4,8)	1,98 [0,69; 5,71]	2,09 [0,68; 6,40]	4,73 [-1,58; 11,05]
			0,229		
Female	10/153 (6,5)	6/81 (7,4)	0,88 [0,33; 2,34]	0,87 [0,31; 2,50]	-0,87 [-7,79; 6,05]
			0,791		
Race (p-value of the interaction test: 0,957)					
White	21/268 (7,8)	8/137 (5,8)	1,34 [0,61; 2,95]	1,37 [0,59; 3,18]	2,00 [-3,08; 7,07]
			0,545		
Other	6/62 (9,7)	2/26 (7,7)	1,26 [0,27; 5,83]	1,29 [0,24; 6,83]	1,99 [-10,63; 14,60]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Geographic region 1 (p-value of the interaction test: 0,806)					
Europe	12/224 (5,4)	6/121 (5,0)	1,08 [0,42; 2,81]	1,08 [0,40; 2,97]	0,40 [-4,47; 5,26]
			1,000		
North America	5/31 (16,1)	2/13 (15,4)	1,05 [0,23; 4,73]	1,06 [0,18; 6,30]	0,74 [-22,76; 24,25]
			1,000		
Other	10/76 (13,2)	2/30 (6,7)	1,97 [0,46; 8,48]	2,12 [0,44; 10,31]	6,49 [-5,23; 18,21]
			0,502		
Geographic region 2 (p-value of the interaction test: 0,542)					
Asia	6/58 (10,3)	1/23 (4,3)	2,38 [0,30; 18,69]	2,54 [0,29; 22,34]	6,00 [-5,44; 17,44]
			0,667		
Central America/South America	0/11 (0,0)	1/7 (14,3)	0,22 [0,01; 4,80]	0,19 [0,01; 5,33]	-14,29 [-40,21; 11,64]
			0,389		
Europe and ROW	16/231 (6,9)	6/121 (5,0)	1,40 [0,56; 3,48]	1,43 [0,54; 3,74]	1,97 [-3,10; 7,04]
			0,644		
North America	5/31 (16,1)	2/13 (15,4)	1,05 [0,23; 4,73]	1,06 [0,18; 6,30]	0,74 [-22,76; 24,25]
			1,000		
Weight (p-value of the interaction test: 0,645)					
<100 kg	25/309 (8,1)	10/153 (6,5)	1,24 [0,61; 2,51]	1,26 [0,59; 2,69]	1,55 [-3,40; 6,51]
			0,709		
≥100 kg	2/22 (9,1)	0/11 (0,0)	2,61 [0,14; 50,09]	2,80 [0,12; 63,59]	9,09 [-2,92; 21,10]
			0,542		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
BMI (p-value of the interaction test: 0,595)					
Underweight ($<18.5 \text{ kg/m}^2$)	5/59 (8,5)	0/23 (0,0)	4,40 [0,25; 76,53]	4,74 [0,25; 89,29]	8,47 [1,37; 15,58]
			0,315		
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	10/157 (6,4)	5/92 (5,4)	1,17 [0,41; 3,32]	1,18 [0,39; 3,58]	0,93 [-5,07; 6,94]
			1,000		
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	6/68 (8,8)	4/28 (14,3)	0,62 [0,19; 2,02]	0,58 [0,15; 2,24]	-5,46 [-20,07; 9,15]
			0,471		
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	6/47 (12,8)	1/21 (4,8)	2,68 [0,34; 20,90]	2,93 [0,33; 25,98]	8,00 [-5,19; 21,19]
			0,423		
Tobacco use (p-value of the interaction test: 0,890)					
Current	7/76 (9,2)	1/32 (3,1)	2,95 [0,38; 22,99]	3,14 [0,37; 26,67]	6,09 [-2,78; 14,95]
			0,432		
Former	7/46 (15,2)	3/29 (10,3)	1,47 [0,41; 5,24]	1,56 [0,37; 6,57]	4,87 [-10,31; 20,06]
			0,732		
Never	13/209 (6,2)	6/103 (5,8)	1,07 [0,42; 2,73]	1,07 [0,40; 2,91]	0,39 [-5,19; 5,98]
			1,000		
Prior biologic exposure (p-value of the interaction test: 0,179)					
Ever	3/36 (8,3)	2/12 (16,7)	0,50 [0,09; 2,64]	0,45 [0,07; 3,11]	-8,33 [-31,27; 14,60]
			0,587		
Never	24/295 (8,1)	8/152 (5,3)	1,55 [0,71; 3,36]	1,59 [0,70; 3,64]	2,87 [-1,85; 7,60]
			0,334		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline corticosteroid use (p-value of the interaction test: 0,228)					
Yes	6/113 (5,3)	0/56 (0,0)	6,50 [0,37; >100]	6,83 [0,38; >100]	5,31 [1,18; 9,44]
			0,180		
No	21/218 (9,6)	10/108 (9,3)	1,04 [0,51; 2,13]	1,04 [0,47; 2,30]	0,37 [-6,35; 7,10]
			1,000		
Baseline immunomodulator use (p-value of the interaction test: 0,540)					
Yes	9/102 (8,8)	4/53 (7,5)	1,17 [0,38; 3,62]	1,19 [0,35; 4,05]	1,28 [-7,72; 10,27]
			1,000		
No	18/229 (7,9)	6/111 (5,4)	1,45 [0,59; 3,56]	1,49 [0,58; 3,87]	2,45 [-3,01; 7,92]
			0,502		
Duration of CD (p-value of the interaction test: 0,407)					
<1 year	7/71 (9,9)	0/33 (0,0)	7,08 [0,42; >100]	7,79 [0,43; >100]	9,86 [2,92; 16,79]
			0,094		
≥1 to <5 years	7/132 (5,3)	3/71 (4,2)	1,26 [0,33; 4,70]	1,27 [0,32; 5,07]	1,08 [-4,96; 7,12]
			1,000		
≥5 years	13/127 (10,2)	7/60 (11,7)	0,88 [0,37; 2,09]	0,86 [0,33; 2,29]	-1,43 [-11,11; 8,25]
			0,802		
Baseline disease location (p-value of the interaction test: 0,756)					
Colonic	8/135 (5,9)	4/73 (5,5)	1,08 [0,34; 3,47]	1,09 [0,32; 3,74]	0,45 [-6,12; 7,01]
			1,000		
Ileal	6/41 (14,6)	2/24 (8,3)	1,76 [0,38; 8,02]	1,89 [0,35; 10,19]	6,30 [-9,17; 21,77]
			0,699		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Ileal-Colonic	13/155 (8,4)	3/65 (4,6)	1,82 [0,54; 6,16]	1,89 [0,52; 6,88]	3,77 [-2,94; 10,48]
0,405					
Baseline fecal calprotectin (p-value of the interaction test: 0,962)					
≤250	1/57 (1,8)	0/24 (0,0)	1,29 [0,05; 30,66]	1,30 [0,05; 33,07]	1,75 [-1,65; 5,16]
1,000					
>250	14/203 (6,9)	7/103 (6,8)	1,01 [0,42; 2,44]	1,02 [0,40; 2,60]	0,10 [-5,88; 6,08]
1,000					
Baseline CRP (p-value of the interaction test: 0,692)					
≤10	22/217 (10,1)	8/108 (7,4)	1,37 [0,63; 2,97]	1,41 [0,61; 3,28]	2,73 [-3,63; 9,10]
0,543					
>10	5/114 (4,4)	2/56 (3,6)	1,23 [0,25; 6,13]	1,24 [0,23; 6,59]	0,81 [-5,33; 6,96]
1,000					
Baseline SES-CD total score (p-value of the interaction test: 0,348)					
<12	22/200 (11,0)	6/96 (6,3)	1,76 [0,74; 4,20]	1,85 [0,73; 4,73]	4,75 [-1,75; 11,25]
0,211					
≥12	5/131 (3,8)	3/66 (4,5)	0,84 [0,21; 3,41]	0,83 [0,19; 3,60]	-0,73 [-6,73; 5,27]
1,000					
Baseline AP average (p-value of the interaction test: 0,972)					
<2	6/70 (8,6)	2/35 (5,7)	1,50 [0,32; 7,05]	1,55 [0,30; 8,09]	2,86 [-7,25; 12,96]
0,716					
≥2	21/260 (8,1)	8/129 (6,2)	1,30 [0,59; 2,86]	1,33 [0,57; 3,09]	1,88 [-3,44; 7,19]
0,682					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline SF average (p-value of the interaction test: 0,437)					
<7	26/265 (9,8)	8/125 (6,4)	1,53 [0,71; 3,29]	1,59 [0,70; 3,62]	3,41 [-2,18; 9,00]
				0,337	
≥7	1/65 (1,5)	2/39 (5,1)	0,30 [0,03; 3,20]	0,29 [0,03; 3,30]	-3,59 [-11,13; 3,95]
				0,555	
Baseline CDAI 1 (p-value of the interaction test: 0,451)					
<300	16/148 (10,8)	4/75 (5,3)	2,03 [0,70; 5,85]	2,15 [0,69; 6,68]	5,48 [-1,66; 12,61]
				0,220	
≥300	11/182 (6,0)	6/89 (6,7)	0,90 [0,34; 2,35]	0,89 [0,32; 2,49]	-0,70 [-6,95; 5,56]
				0,795	
Baseline CDAI 2 (p-value of the interaction test: 0,661)					
<150	3/5 (60,0)	1/6 (16,7)	3,60 [0,52; 24,73]	7,50 [0,46; >100]	43,33 [-8,95; 95,61]
				0,242	
≥150 and <220	1/27 (3,7)	0/18 (0,0)	2,04 [0,09; 47,37]	2,09 [0,08; 54,30]	3,70 [-3,42; 10,83]
				1,000	
≥220 and <450	23/275 (8,4)	9/125 (7,2)	1,16 [0,55; 2,44]	1,18 [0,53; 2,62]	1,16 [-4,43; 6,75]
				0,843	
≥450	0/23 (0,0)	0/15 (0,0)	NB	NB	NB
				NB	
OECD Country (p-value of the interaction test: 0,202)					
Yes	22/209 (10,5)	6/94 (6,4)	1,65 [0,69; 3,93]	1,73 [0,68; 4,41]	4,14 [-2,32; 10,60]
				0,290	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
No	5/122 (4,1)	4/70 (5,7)	0,72 [0,20; 2,58]	0,71 [0,18; 2,72]	-1,62 [-8,09; 4,86]
			0,726		
Datenschnitt: 23. August 2023; Conventional-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher. The TEAEs were summarized using the MedDRA HLT Injection site reactions excluding certain PTs (e.g. those PTs related to joint) and the MedDRA HLT Infusion site reactions.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_iiasesins_sub_safa_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba

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Anhang 4-G.3.6.3.3 Unerwünschte Ereignisse (UE) nach SOC/PT

Subgruppen für TEAE (PT): Musculoskeletal and connective tissue disorders/Arthralgia - in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,232)					
<65 years	18/322 (5,6)	1/160 (0,6)	8,94 [1,20; 66,40]	9,41 [1,25; 71,17]	4,97 [2,17; 7,76]
			0,006		
≥65 years	0/9 (0,0)	0/4 (0,0)	NB	NB	NB
			NB		
Age 2 (p-value of the interaction test: 0,601)					
<40 years	8/210 (3,8)	0/101 (0,0)	8,22 [0,48; >100]	8,52 [0,49; >100]	3,81 [1,22; 6,40]
			0,057		
≥40 years	10/121 (8,3)	1/63 (1,6)	5,21 [0,68; 39,76]	5,59 [0,70; 44,66]	6,68 [0,88; 12,47]
			0,101		
Sex (p-value of the interaction test: 0,929)					
Male	5/178 (2,8)	0/83 (0,0)	5,16 [0,29; 92,27]	5,29 [0,29; 96,87]	2,81 [0,38; 5,24]
			0,182		
Female	13/153 (8,5)	1/81 (1,2)	6,88 [0,92; 51,68]	7,43 [0,95; 57,84]	7,26 [2,23; 12,29]
			0,038		
Race (p-value of the interaction test: 0,641)					
White	16/268 (6,0)	1/137 (0,7)	8,18 [1,10; 61,03]	8,63 [1,13; 65,81]	5,24 [2,07; 8,41]
			0,015		
Other	2/62 (3,2)	0/26 (0,0)	2,14 [0,11; 43,16]	2,19 [0,10; 47,20]	3,23 [-1,17; 7,62]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Geographic region 1 (p-value of the interaction test: 0,983)					
Europe	10/224 (4,5)	1/121 (0,8)	5,40 [0,70; 41,70]	5,61 [0,71; 44,34]	3,64 [0,49; 6,79]
			0,105		
North America	3/31 (9,7)	0/13 (0,0)	3,06 [0,17; 55,43]	3,32 [0,16; 68,84]	9,68 [-0,73; 20,08]
			0,544		
Other	5/76 (6,6)	0/30 (0,0)	4,43 [0,25; 77,71]	4,69 [0,25; 87,52]	6,58 [1,01; 12,15]
			0,318		
Geographic region 2 (p-value of the interaction test: 0,812)					
Asia	2/58 (3,4)	0/23 (0,0)	2,03 [0,10; 40,81]	2,08 [0,10; 44,99]	3,45 [-1,25; 8,14]
			1,000		
Central America/South America	0/11 (0,0)	0/7 (0,0)	NB	NB	NB
			NB		
Europe and ROW	13/231 (5,6)	1/121 (0,8)	6,81 [0,90; 51,44]	7,16 [0,92; 55,37]	4,80 [1,42; 8,18]
			0,040		
North America	3/31 (9,7)	0/13 (0,0)	3,06 [0,17; 55,43]	3,32 [0,16; 68,84]	9,68 [-0,73; 20,08]
			0,544		
Weight (p-value of the interaction test: 0,101)					
<100 kg	16/309 (5,2)	0/153 (0,0)	16,39 [0,99; >100]	17,26 [1,03; >100]	5,18 [2,71; 7,65]
			0,002		
≥100 kg	2/22 (9,1)	1/11 (9,1)	1,00 [0,10; 9,86]	1,00 [0,08; 12,40]	0,00 [-20,81; 20,81]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
BMI (p-value of the interaction test: 0,616)					
Underweight ($<18.5 \text{ kg/m}^2$)	2/59 (3,4)	0/23 (0,0)	2,00 [0,10; 40,14]	2,04 [0,09; 44,20]	3,39 [-1,23; 8,01]
			1,000		
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	10/157 (6,4)	0/92 (0,0)	12,36 [0,73; >100]	13,17 [0,76; >100]	6,37 [2,55; 10,19]
			0,015		
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	2/68 (2,9)	0/28 (0,0)	2,10 [0,10; 42,43]	2,14 [0,10; 46,06]	2,94 [-1,07; 6,96]
			1,000		
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	4/47 (8,5)	1/21 (4,8)	1,79 [0,21; 15,04]	1,86 [0,20; 17,73]	3,75 [-8,36; 15,86]
			1,000		
Tobacco use (p-value of the interaction test: 0,961)					
Current	4/76 (5,3)	0/32 (0,0)	3,86 [0,21; 69,62]	4,03 [0,21; 77,15]	5,26 [0,24; 10,28]
			0,316		
Former	4/46 (8,7)	0/29 (0,0)	5,74 [0,32; >100]	6,25 [0,32; >100]	8,70 [0,55; 16,84]
			0,154		
Never	10/209 (4,8)	1/103 (1,0)	4,93 [0,64; 37,98]	5,13 [0,65; 40,60]	3,81 [0,36; 7,27]
			0,109		
Prior biologic exposure (p-value of the interaction test: 0,348)					
Ever	1/36 (2,8)	0/12 (0,0)	1,05 [0,05; 24,29]	1,06 [0,04; 27,65]	2,78 [-2,59; 8,15]
			1,000		
Never	17/295 (5,8)	1/152 (0,7)	8,76 [1,18; 65,20]	9,23 [1,22; 70,06]	5,10 [2,15; 8,06]
			0,009		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline corticosteroid use (p-value of the interaction test: 0,975)					
Yes	4/113 (3,5)	0/56 (0,0)	4,50 [0,25; 82,14]	4,64 [0,25; 87,78]	3,54 [0,13; 6,95]
			0,303		
No	14/218 (6,4)	1/108 (0,9)	6,94 [0,92; 52,05]	7,34 [0,95; 56,60]	5,50 [1,77; 9,22]
			0,025		
Baseline immunomodulator use (p-value of the interaction test: 0,305)					
Yes	6/102 (5,9)	1/53 (1,9)	3,12 [0,39; 25,23]	3,25 [0,38; 27,73]	4,00 [-1,86; 9,85]
			0,423		
No	12/229 (5,2)	0/111 (0,0)	12,17 [0,73; >100]	12,82 [0,75; >100]	5,24 [2,35; 8,13]
			0,011		
Duration of CD (p-value of the interaction test: 0,957)					
<1 year	4/71 (5,6)	0/33 (0,0)	4,25 [0,24; 76,71]	4,47 [0,23; 85,42]	5,63 [0,27; 11,00]
			0,304		
≥1 to <5 years	2/132 (1,5)	0/71 (0,0)	2,71 [0,13; 55,62]	2,74 [0,13; 57,85]	1,52 [-0,57; 3,60]
			0,543		
≥5 years	12/127 (9,4)	1/60 (1,7)	5,67 [0,75; 42,60]	6,16 [0,78; 48,50]	7,78 [1,75; 13,81]
			0,065		
Baseline disease location (p-value of the interaction test: 0,824)					
Colonic	7/135 (5,2)	0/73 (0,0)	8,16 [0,47; >100]	8,58 [0,48; >100]	5,19 [1,44; 8,93]
			0,099		
Ileal	2/41 (4,9)	0/24 (0,0)	2,98 [0,15; 59,52]	3,10 [0,14; 67,34]	4,88 [-1,72; 11,47]
			0,527		

	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Subgruppe			p-Wert ^a		
Ileal-Colonic	9/155 (5,8)	1/65 (1,5)	3,77 [0,49; 29,19]	3,95 [0,49; 31,79]	4,27 [-0,48; 9,01]
			0,288		
Baseline CRP (p-value of the interaction test: 0,797)					
≤10	12/217 (5,5)	1/108 (0,9)	5,97 [0,79; 45,33]	6,26 [0,80; 48,82]	4,60 [1,07; 8,14]
			0,068		
>10	6/114 (5,3)	0/56 (0,0)	6,44 [0,37; >100]	6,77 [0,37; >100]	5,26 [1,16; 9,36]
			0,179		
Baseline SES-CD total score (p-value of the interaction test: 0,888)					
<12	13/200 (6,5)	1/96 (1,0)	6,24 [0,83; 47,01]	6,60 [0,85; 51,24]	5,46 [1,48; 9,43]
			0,041		
≥12	5/131 (3,8)	0/66 (0,0)	5,58 [0,31; 99,47]	5,78 [0,31; >100]	3,82 [0,54; 7,10]
			0,171		
Baseline AP average (p-value of the interaction test: 0,394)					
<2	7/70 (10,0)	1/35 (2,9)	3,50 [0,45; 27,34]	3,78 [0,45; 31,99]	7,14 [-1,79; 16,08]
			0,264		
≥2	11/260 (4,2)	0/129 (0,0)	11,46 [0,68; >100]	11,94 [0,70; >100]	4,23 [1,78; 6,68]
			0,019		
Baseline SF average (p-value of the interaction test: 0,911)					
<7	15/265 (5,7)	1/125 (0,8)	7,08 [0,95; 52,97]	7,44 [0,97; 56,97]	4,86 [1,67; 8,05]
			0,026		
≥7	3/65 (4,6)	0/39 (0,0)	4,24 [0,22; 80,01]	4,42 [0,22; 87,96]	4,62 [-0,49; 9,72]
			0,290		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline CDAI 1 (p-value of the interaction test: 0,812)					
<300	12/148 (8,1)	1/75 (1,3)	6,08 [0,81; 45,89]	6,53 [0,83; 51,21]	6,77 [1,67; 11,88]
			0,065		
≥300	6/182 (3,3)	0/89 (0,0)	6,39 [0,36; >100]	6,59 [0,37; >100]	3,30 [0,70; 5,89]
			0,182		
Baseline CDAI 2 (p-value of the interaction test: 0,717)					
<150	2/5 (40,0)	0/6 (0,0)	5,83 [0,34; 99,23]	9,29 [0,34; >100]	40,00 [-2,94; 82,94]
			0,182		
≥150 and <220	4/27 (14,8)	1/18 (5,6)	2,67 [0,32; 21,96]	2,96 [0,30; 28,88]	9,26 [-7,81; 26,33]
			0,634		
≥220 and <450	11/275 (4,0)	0/125 (0,0)	10,50 [0,62; >100]	10,91 [0,64; >100]	4,00 [1,68; 6,32]
			0,020		
≥450	1/23 (4,3)	0/15 (0,0)	2,00 [0,09; 46,09]	2,07 [0,08; 54,12]	4,35 [-3,99; 12,68]
			1,000		
OECD Country (p-value of the interaction test: 0,927)					
Yes	14/209 (6,7)	1/94 (1,1)	6,30 [0,84; 47,19]	6,68 [0,86; 51,54]	5,63 [1,66; 9,61]
			0,043		
No	4/122 (3,3)	0/70 (0,0)	5,20 [0,28; 95,09]	5,35 [0,28; >100]	3,28 [0,12; 6,44]
			0,298		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Datenschnitt: 23. August 2023; Conventional-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_aespt_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_aeppn004_sub_safa_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
19DEC2024 / 16:53

Subgruppen für TEAE (PT): Vascular disorders/Hypertension - in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,974)					
<65 years	12/322 (3,7)	1/160 (0,6)	5,96 [0,78; 45,45]	6,15 [0,79; 47,76]	3,10 [0,70; 5,50]
			0,069		
≥65 years	2/9 (22,2)	0/4 (0,0)	2,50 [0,15; 42,80]	3,00 [0,12; 77,64]	22,22 [-4,94; 49,38]
			1,000		
Age 2 (p-value of the interaction test: 0,839)					
<40 years	5/210 (2,4)	0/101 (0,0)	5,32 [0,30; 95,24]	5,43 [0,30; 99,22]	2,38 [0,32; 4,44]
			0,178		
≥40 years	9/121 (7,4)	1/63 (1,6)	4,69 [0,61; 36,16]	4,98 [0,62; 40,25]	5,85 [0,25; 11,45]
			0,168		
Sex (p-value of the interaction test: 0,196)					
Male	11/178 (6,2)	0/83 (0,0)	10,79 [0,64; >100]	11,47 [0,67; >100]	6,18 [2,64; 9,72]
			0,019		
Female	3/153 (2,0)	1/81 (1,2)	1,59 [0,17; 15,02]	1,60 [0,16; 15,63]	0,73 [-2,53; 3,98]
			1,000		
Race (p-value of the interaction test: 0,459)					
White	13/268 (4,9)	1/137 (0,7)	6,65 [0,88; 50,27]	6,93 [0,90; 53,57]	4,12 [1,18; 7,06]
			0,041		
Other	1/62 (1,6)	0/26 (0,0)	1,29 [0,05; 30,57]	1,29 [0,05; 32,77]	1,61 [-1,52; 4,75]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Geographic region 1 (p-value of the interaction test: 0,771)					
Europe	11/224 (4,9)	1/121 (0,8)	5,94 [0,78; 45,48]	6,20 [0,79; 48,59]	4,08 [0,83; 7,34]
			0,063		
North America	2/31 (6,5)	0/13 (0,0)	2,19 [0,11; 42,67]	2,29 [0,10; 50,99]	6,45 [-2,20; 15,10]
			1,000		
Other	1/76 (1,3)	0/30 (0,0)	1,21 [0,05; 28,85]	1,21 [0,05; 30,58]	1,32 [-1,25; 3,88]
			1,000		
Geographic region 2 (p-value of the interaction test: 0,818)					
Asia	1/58 (1,7)	0/23 (0,0)	1,22 [0,05; 28,92]	1,23 [0,05; 31,19]	1,72 [-1,63; 5,07]
			1,000		
Central America/South America	0/11 (0,0)	0/7 (0,0)	NB	NB	NB
			NB		
Europe and ROW	11/231 (4,8)	1/121 (0,8)	5,76 [0,75; 44,10]	6,00 [0,77; 47,04]	3,94 [0,75; 7,12]
			0,065		
North America	2/31 (6,5)	0/13 (0,0)	2,19 [0,11; 42,67]	2,29 [0,10; 50,99]	6,45 [-2,20; 15,10]
			1,000		
Weight (p-value of the interaction test: 0,851)					
<100 kg	12/309 (3,9)	1/153 (0,7)	5,94 [0,78; 45,28]	6,14 [0,79; 47,67]	3,23 [0,73; 5,73]
			0,069		
≥100 kg	2/22 (9,1)	0/11 (0,0)	2,61 [0,14; 50,09]	2,80 [0,12; 63,59]	9,09 [-2,92; 21,10]
			0,542		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Prior biologic exposure (p-value of the interaction test: 0,743)					
Ever	3/36 (8,3)	0/12 (0,0)	2,46 [0,14; 44,48]	2,61 [0,13; 54,25]	8,33 [-0,70; 17,36]
			0,563		
Never	11/295 (3,7)	1/152 (0,7)	5,67 [0,74; 43,49]	5,85 [0,75; 45,73]	3,07 [0,56; 5,59]
			0,067		
Baseline immunomodulator use (p-value of the interaction test: 0,860)					
Yes	4/102 (3,9)	0/53 (0,0)	4,72 [0,26; 86,02]	4,89 [0,26; 92,53]	3,92 [0,15; 7,69]
			0,300		
No	10/229 (4,4)	1/111 (0,9)	4,85 [0,63; 37,39]	5,02 [0,63; 39,74]	3,47 [0,29; 6,64]
			0,111		
Baseline CRP (p-value of the interaction test: 0,707)					
≤10	9/217 (4,1)	1/108 (0,9)	4,48 [0,57; 34,90]	4,63 [0,58; 37,03]	3,22 [0,01; 6,43]
			0,174		
>10	5/114 (4,4)	0/56 (0,0)	5,45 [0,31; 96,89]	5,68 [0,31; >100]	4,39 [0,63; 8,15]
			0,173		
Baseline AP average (p-value of the interaction test: 0,714)					
<2	5/70 (7,1)	0/35 (0,0)	5,58 [0,32; 98,09]	5,96 [0,32; >100]	7,14 [1,11; 13,18]
			0,167		
≥2	9/260 (3,5)	1/129 (0,8)	4,47 [0,57; 34,87]	4,59 [0,58; 36,62]	2,69 [-0,00; 5,37]
			0,175		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline SF average (p-value of the interaction test: 0,624)					
<7	13/265 (4,9)	1/125 (0,8)	6,13 [0,81; 46,36]	6,40 [0,83; 49,46]	4,11 [1,07; 7,14]
			0,044		
≥7	1/65 (1,5)	0/39 (0,0)	1,82 [0,08; 43,57]	1,84 [0,07; 46,21]	1,54 [-1,45; 4,53]
			1,000		
Baseline CDAI 2 (p-value of the interaction test: 0,848)					
<150	0/5 (0,0)	0/6 (0,0)	NB	NB	NB
			NB		
≥150 and <220	1/27 (3,7)	0/18 (0,0)	2,04 [0,09; 47,37]	2,09 [0,08; 54,30]	3,70 [-3,42; 10,83]
			1,000		
≥220 and <450	13/275 (4,7)	1/125 (0,8)	5,91 [0,78; 44,68]	6,15 [0,80; 47,56]	3,93 [0,97; 6,88]
			0,074		
≥450	0/23 (0,0)	0/15 (0,0)	NB	NB	NB
			NB		
OECD Country (p-value of the interaction test: 0,633)					
Yes	13/209 (6,2)	1/94 (1,1)	5,85 [0,78; 44,05]	6,17 [0,79; 47,86]	5,16 [1,28; 9,03]
			0,072		
No	1/122 (0,8)	0/70 (0,0)	1,73 [0,07; 41,94]	1,74 [0,07; 43,31]	0,82 [-0,78; 2,42]
			1,000		

	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Subgruppe			p-Wert ^a		
Datenschnitt: 23. August 2023; Conventional-failed Safety Population. Abkürzungen: AP: Abdominal Pain; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SF: Stool Frequency. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_aespt_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_aeppn010_sub_safa_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
19DEC2024 / 16:53

Subgruppen für TEAE (PT): Gastrointestinal disorders/Vomiting - in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,234)					
<65 years	10/322 (3,1)	0/160 (0,0)	10,47 [0,62; >100]	10,79 [0,63; >100]	3,11 [1,21; 5,00]
			0,035		
≥65 years	0/9 (0,0)	0/4 (0,0)	NB	NB	NB
			NB		
Weight (p-value of the interaction test: 0,216)					
<100 kg	10/309 (3,2)	0/153 (0,0)	10,43 [0,62; >100]	10,76 [0,63; >100]	3,24 [1,26; 5,21]
			0,035		
≥100 kg	0/22 (0,0)	0/11 (0,0)	NB	NB	NB
			NB		
Datenschnitt: 23. August 2023; Conventional-failed Safety Population. Abkürzungen: kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OR: Odds Ratio; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; RR: relatives Risiko. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_aespt_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_aeppn014_sub_safa_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba

19DEC2024 / 16:53

Subgruppen für TEAE (SOC): Renal and urinary disorders - in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation A (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,929)					
<65 years	7/322 (2,2)	10/160 (6,3)	0,35 [0,13; 0,90]	0,33 [0,12; 0,89]	-4,08 [-8,15; -0,00]
			0,033		
≥65 years	0/9 (0,0)	0/4 (0,0)	NB	NB	NB
			NB		
Age 2 (p-value of the interaction test: 0,917)					
<40 years	3/210 (1,4)	4/101 (4,0)	0,36 [0,08; 1,58]	0,35 [0,08; 1,60]	-2,53 [-6,66; 1,60]
			0,220		
≥40 years	4/121 (3,3)	6/63 (9,5)	0,35 [0,10; 1,19]	0,32 [0,09; 1,20]	-6,22 [-14,14; 1,70]
			0,094		
Sex (p-value of the interaction test: 0,942)					
Male	2/178 (1,1)	3/83 (3,6)	0,31 [0,05; 1,83]	0,30 [0,05; 1,85]	-2,49 [-6,79; 1,81]
			0,331		
Female	5/153 (3,3)	7/81 (8,6)	0,38 [0,12; 1,15]	0,36 [0,11; 1,16]	-5,37 [-12,11; 1,36]
			0,116		
Race (p-value of the interaction test: 0,560)					
White	7/268 (2,6)	9/137 (6,6)	0,40 [0,15; 1,04]	0,38 [0,14; 1,05]	-3,96 [-8,52; 0,61]
			0,062		
Other	0/62 (0,0)	1/26 (3,8)	0,14 [0,01; 3,40]	0,14 [0,01; 3,45]	-3,85 [-11,24; 3,55]
			0,295		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,810)					
Europe	6/224 (2,7)	8/121 (6,6)	0,41 [0,14; 1,14]	0,39 [0,13; 1,15]	-3,93 [-8,84; 0,97]
				0,090	
North America	1/31 (3,2)	1/13 (7,7)	0,42 [0,03; 6,21]	0,40 [0,02; 6,93]	-4,47 [-20,23; 11,30]
				0,508	
Other	0/76 (0,0)	1/30 (3,3)	0,13 [0,01; 3,21]	0,13 [0,01; 3,25]	-3,33 [-9,76; 3,09]
				0,283	
Geographic region 2 (p-value of the interaction test: 0,928)					
Asia	0/58 (0,0)	1/23 (4,3)	0,14 [0,01; 3,21]	0,13 [0,01; 3,26]	-4,35 [-12,68; 3,99]
				0,284	
Central America/South America	0/11 (0,0)	0/7 (0,0)	NB	NB	NB
				NB	
Europe and ROW	6/231 (2,6)	8/121 (6,6)	0,39 [0,14; 1,11]	0,38 [0,13; 1,11]	-4,01 [-8,89; 0,87]
				0,085	
North America	1/31 (3,2)	1/13 (7,7)	0,42 [0,03; 6,21]	0,40 [0,02; 6,93]	-4,47 [-20,23; 11,30]
				0,508	
Weight (p-value of the interaction test: 0,340)					
<100 kg	7/309 (2,3)	8/153 (5,2)	0,43 [0,16; 1,17]	0,42 [0,15; 1,18]	-2,96 [-6,86; 0,93]
				0,101	
≥100 kg	0/22 (0,0)	2/11 (18,2)	0,10 [0,01; 2,00]	0,08 [0,00; 1,93]	-18,18 [-40,97; 4,61]
				0,104	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Prior biologic exposure (p-value of the interaction test: 0,977)					
Ever	0/36 (0,0)	0/12 (0,0)	NB	NB NB	NB
Never	7/295 (2,4)	10/152 (6,6)	0,36 [0,14; 0,93]	0,35 [0,13; 0,93]	-4,21 [-8,51; 0,10]
			0,036		
Baseline corticosteroid use (p-value of the interaction test: 0,273)					
Yes	4/113 (3,5)	3/56 (5,4)	0,66 [0,15; 2,85]	0,65 [0,14; 3,00]	-1,82 [-8,63; 4,99]
			0,686		
No	3/218 (1,4)	7/108 (6,5)	0,21 [0,06; 0,80]	0,20 [0,05; 0,79]	-5,11 [-10,00; -0,21]
			0,017		
Baseline immunomodulator use (p-value of the interaction test: 0,449)					
Yes	2/102 (2,0)	5/53 (9,4)	0,21 [0,04; 1,04]	0,19 [0,04; 1,03]	-7,47 [-15,79; 0,84]
			0,046		
No	5/229 (2,2)	5/111 (4,5)	0,48 [0,14; 1,64]	0,47 [0,13; 1,67]	-2,32 [-6,62; 1,98]
			0,305		
Baseline CRP (p-value of the interaction test: 0,944)					
≤10	4/217 (1,8)	6/108 (5,6)	0,33 [0,10; 1,15]	0,32 [0,09; 1,16]	-3,71 [-8,39; 0,96]
			0,089		
>10	3/114 (2,6)	4/56 (7,1)	0,37 [0,09; 1,59]	0,35 [0,08; 1,63]	-4,51 [-11,87; 2,85]
			0,220		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline SES-CD total score (p-value of the interaction test: 0,700)					
<12	5/200 (2,5)	6/96 (6,3)	0,40 [0,13; 1,28]	0,38 [0,11; 1,29]	-3,75 [-9,05; 1,55]
			0,185		
≥12	2/131 (1,5)	4/66 (6,1)	0,25 [0,05; 1,34]	0,24 [0,04; 1,35]	-4,53 [-10,66; 1,59]
			0,098		
Baseline AP average (p-value of the interaction test: 0,216)					
<2	0/70 (0,0)	3/35 (8,6)	0,07 [0,00; 1,36]	0,07 [0,00; 1,31]	-8,57 [-17,85; 0,70]
			0,035		
≥2	7/260 (2,7)	7/129 (5,4)	0,50 [0,18; 1,38]	0,48 [0,17; 1,41]	-2,73 [-7,11; 1,64]
			0,245		
Baseline SF average (p-value of the interaction test: 0,990)					
<7	6/265 (2,3)	8/125 (6,4)	0,35 [0,13; 1,00]	0,34 [0,11; 1,00]	-4,14 [-8,79; 0,51]
			0,075		
≥7	1/65 (1,5)	2/39 (5,1)	0,30 [0,03; 3,20]	0,29 [0,03; 3,30]	-3,59 [-11,13; 3,95]
			0,555		
Baseline CDAI 2 (p-value of the interaction test: 0,940)					
<150	0/5 (0,0)	1/6 (16,7)	0,39 [0,02; 7,88]	0,33 [0,01; 10,11]	-16,67 [-46,49; 13,15]
			1,000		
≥150 and <220	2/27 (7,4)	2/18 (11,1)	0,67 [0,10; 4,31]	0,64 [0,08; 5,01]	-3,70 [-21,26; 13,86]
			1,000		
≥220 and <450	5/275 (1,8)	6/125 (4,8)	0,38 [0,12; 1,22]	0,37 [0,11; 1,23]	-2,98 [-7,05; 1,08]
			0,105		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
≥450	0/23 (0,0)	1/15 (6,7)	0,22 [0,01; 5,12]	0,21 [0,01; 5,39]	-6,67 [-19,29; 5,96]
0,395					
OECD Country (p-value of the interaction test: 0,253)					
Yes	6/209 (2,9)	10/94 (10,6)	0,27 [0,10; 0,72]	0,25 [0,09; 0,70]	-7,77 [-14,40; -1,14]
0,010					
No	1/122 (0,8)	0/70 (0,0)	1,73 [0,07; 41,94]	1,74 [0,07; 43,31]	0,82 [-0,78; 2,42]
1,000					
Datenschnitt: 23. August 2023; Conventional-failed Safety Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; SOC: System Organ Class. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_aespt_sub.sas
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Anhang 4-G.4 Teilpopulation B**Anhang 4-G.4.1 Charakterisierung der Studienpopulation in RCT VIVID-1 in Teilpopulation B**

Demografische und Krankheitscharakteristika in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Merkmal	Mirikizumab (N=300)	Ustekinumab (N=145)
Demografie		
Alter (Jahre)		
MW (SD)	36,25 (13,32)	36,34 (12,36)
Alter, n (%)		
<65	287 (95,7)	141 (97,2)
≥65	13 (4,3)	4 (2,8)
Geschlecht, n (%)		
Männlich	179 (59,7)	65 (44,8)
Weiblich	121 (40,3)	80 (55,2)
Abstammung, n (%)		
Asiatisch	100 (33,3)	56 (38,6)
Schwarz oder Afroamerikanisch	11 (3,7)	6 (4,1)
Weiß/kaukasisch	180 (60,0)	82 (56,6)
Multiple	2 (0,7)	1 (0,7)
Region, n (%)		
Asien	105 (35,0)	56 (38,6)
Nordamerika	54 (18,0)	26 (17,9)
Zentral- oder Südamerika	24 (8,0)	13 (9,0)
Europa und restliche Welt	117 (39,0)	50 (34,5)
Gewicht (kg)		
MW (SD)	66,74 (18,06)	66,01 (17,01)
BMI (kg/m ²)		
MW (SD)	22,92 (5,24)	23,33 (5,15)
Krankheitsspezifische Charakterisierung		
Zeit seit Diagnose (Jahre)		
MW (SD)	9,33 (9,08)	9,28 (8,47)
Alter bei Diagnose		
MW (SD)	27,41 (11,26)	27,52 (11,25)

Merkmal	Mirikizumab (N=300)	Ustekinumab (N=145)
Disease location, n (%)		
Colonic	120 (40,0)	59 (40,7)
Ileal	32 (10,7)	6 (4,1)
Ileal-Colonic	148 (49,3)	80 (55,2)
History of surgical bowel resection, n (%)		
Ja	65 (21,7)	22 (15,2)
Nein	235 (78,3)	123 (84,8)
Number of surgical bowel resection, n (%)		
0	235 (78,3)	123 (84,8)
1	49 (16,3)	17 (11,7)
2	12 (4,0)	5 (3,4)
3	3 (1,0)	0
4	1 (0,3)	0
Baseline C-reactive Protein (CRP) (mg/L)		
MW (SD)	21,16 (25,27)	24,86 (35,56)
Baseline Fecal calprotectin (ug/g)		
MW (SD)	2.548,76 (4.081,48)	2.750,82 (3.470,39)
Baseline SES-CD total score		
MW (SD)	13,83 (6,87)	14,53 (6,78)
Baseline CDAI total score		
MW (SD)	327,81 (88,90)	326,65 (95,79)
Baseline abdominal pain		
MW (SD)	2,12 (0,58)	2,02 (0,70)
Baseline stool frequency		
MW (SD)	5,97 (3,41)	5,95 (3,20)
Baseline IBDQ total score		
MW (SD)	127,45 (32,70)	126,51 (34,90)
Baseline IBDQ bowel symptoms subscore		
MW (SD)	37,80 (9,54)	37,26 (9,87)
Baseline IBDQ systemic symptoms subscore		
MW (SD)	17,58 (5,60)	17,74 (5,84)
Baseline IBDQ emotional function subscore		
MW (SD)	51,30 (14,32)	51,05 (15,25)

Merkmal	Mirikizumab (N=300)	Ustekinumab (N=145)
Baseline IBDQ social function subscore		
MW (SD)	20,77 (7,34)	20,46 (7,42)
Baseline Urgency NRS		
MW (SD)	6,71 (2,15)	6,54 (2,16)
Baseline Fistulae, n (%)		
Ja	25 (8,3)	14 (9,7)
Nein	275 (91,7)	131 (90,3)
Baseline Facit-Fatigue		
MW (SD)	31,48 (11,92)	31,94 (12,02)
Baseline SF-36 MCS		
MW (SD)	44,41 (10,69)	44,98 (10,52)
Baseline SF-36 PCS		
MW (SD)	39,15 (7,95)	38,75 (7,85)
Baseline WPAI-CD score		
MW (SD)	57,05 (24,19)	51,89 (29,53)
Baseline QIDS-SR16 score		
MW (SD)	7,16 (4,84)	6,66 (4,62)
Baseline EQ-5D-5L index score		
MW (SD)	0,63 (0,23)	0,66 (0,22)
Baseline EQ-5D-5L VAS		
MW (SD)	53,60 (20,23)	53,99 (21,04)
Baseline DSI-CD total score		
MW (SD)	37,75 (11,80)	39,88 (11,09)
Baseline IBD-DI total score		
MW (SD)	38,26 (17,70)	37,83 (16,41)
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; DSI: Disease Severity Index; EQ-5D: Fragebogen der EuroQol-Gruppe zur Lebensqualität auf 5 Dimensionen; IBD-DI: Inflammatory Bowel Disease Questionnaire Disability Index; IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; kg: Kilogramm; MCS: Mental Health Component Summary Score; MW: Mittelwert; n: Anzahl der Patienten; N: Anzahl der Patienten in der Analyse; NRS: Numeric Rating Scale; PCS: Physical Health Component Summary Score; QIDS-SR16: Quick Inventory of Depressive Symptomatology - Self Report (16 items); RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SES: Simple Endoscopy Score; SF-36: 36-Item Short Form Health Survey; VAS: Visuelle Analogskala; WPAI: Work Productivity and Activity Impairment Questionnaire.		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_demo.sas

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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba

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Abdominal Pain at Baseline in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Merkmal	Mirikizumab (N=300)	Ustekinumab (N=145)
Demografie		
Abdominal Pain at Baseline, n (%)		
<1	7 (2,3)	6 (4,1)
≥1 und <2	65 (21,7)	42 (29,0)
≥2 und <3	191 (63,7)	82 (56,6)
=3	35 (11,7)	15 (10,3)
Missing	2 (0,7)	0
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; n: Anzahl der Patienten; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie.		

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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba

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Anhang 4-G.4.2 Begleitmedikation in RCT VIVID-1 in Teilpopulation B

Begleitmedikation nach absteigender Häufigkeit in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
Patients with ≥ 1 concomitant medication	296 (98,7)	144 (99,3)
OSMOTICALLY ACTING LAXATIVES	194 (64,7)	90 (62,1)
MACROGOL 4000;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE	61 (20,3)	31 (21,4)
ASCORBIC ACID;MACROGOL 3350;POTASSIUM;SODIUM CHLORIDE;SODIUM SULFATE	33 (11,0)	14 (9,7)
MACROGOL	20 (6,7)	10 (6,9)
ASCORBIC ACID;MACROGOL 4000;POTASSIUM;SODIUM CHLORIDE;SODIUM SULFATE	11 (3,7)	6 (4,1)
MANNITOL	12 (4,0)	4 (2,8)
CITRIC ACID;MACROGOL 4000;POTASSIUM;SIMETICONE;SODIUM CHLORIDE;SODIUM CITRATE;SODIUM SULFATE	8 (2,7)	6 (4,1)
MACROGOL 3350	9 (3,0)	5 (3,4)
MAGNESIUM SULFATE;POTASSIUM SULFATE;SODIUM SULFATE	10 (3,3)	3 (2,1)
ASCORBIC ACID;MACROGOL;POTASSIUM;SODIUM CHLORIDE;SODIUM SULFATE	7 (2,3)	3 (2,1)
LACTULOSE	4 (1,3)	5 (3,4)
MAGNESIUM SULFATE;POTASSIUM SULFATE;SIMETICONE;SODIUM SULFATE	8 (2,7)	0
MACROGOL 3350;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE	5 (1,7)	2 (1,4)
MACROGOL;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE	5 (1,7)	1 (0,7)
MAGNESIUM CITRATE	4 (1,3)	2 (1,4)
OSMOTICALLY ACTING LAXATIVES	6 (2,0)	0
SODIUM PHOSPHATE	4 (1,3)	2 (1,4)
MACROGOL 4000;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE	2 (0,7)	3 (2,1)
MACROGOL;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE	4 (1,3)	1 (0,7)
MAGNESIUM SULFATE;POTASSIUM;SODIUM SULFATE	3 (1,0)	2 (1,4)
MACROGOL 4000	3 (1,0)	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE	2 (0,7)	1 (0,7)
ELECTROLYTES NOS;MACROGOL 3350	1 (0,3)	1 (0,7)
MACROGOL 3350;POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE	1 (0,3)	1 (0,7)
MAGNESIUM OXIDE	0	2 (1,4)
MAGNESIUM CARBONATE	1 (0,3)	0
MAGNESIUM SULFATE	1 (0,3)	0
PHOSPHORIC ACID	1 (0,3)	0
SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	1 (0,3)	0
OTHER GENERAL ANESTHETICS	150 (50,0)	72 (49,7)
PROPOFOL	150 (50,0)	72 (49,7)
ETOMIDATE	18 (6,0)	9 (6,2)
KETAMINE	13 (4,3)	4 (2,8)
CIPROFOL	1 (0,3)	0
BENZODIAZEPINE DERIVATIVES	116 (38,7)	42 (29,0)
MIDAZOLAM	104 (34,7)	39 (26,9)
FLUNITRAZEPAM	2 (0,7)	2 (1,4)
ALPRAZOLAM	3 (1,0)	0
CLONAZEPAM	3 (1,0)	0
BROMAZEPAM	2 (0,7)	0
BROTIZOLAM	2 (0,7)	0
DIAZEPAM	1 (0,3)	1 (0,7)
LORAZEPAM	2 (0,7)	0
REMIMAZOLAM	2 (0,7)	0
ETIZOLAM	1 (0,3)	0
OXAZEPAM	1 (0,3)	0
GLUCOCORTICOIDS	84 (28,0)	45 (31,0)
PREDNISONE	60 (20,0)	34 (23,4)
METHYLPREDNISOLONE	13 (4,3)	7 (4,8)
DEXAMETHASONE	8 (2,7)	4 (2,8)
PREDNISOLONE	5 (1,7)	1 (0,7)
BUDESONIDE	1 (0,3)	2 (1,4)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
HYDROCORTISONE	2 (0,7)	1 (0,7)
TRIAMCINOLONE	1 (0,3)	1 (0,7)
BECLOMETASONE	0	1 (0,7)
BETAMETHASONE	1 (0,3)	0
LIDOCAINE;TRIAMCINOLONE	1 (0,3)	0
MOMETASONE	1 (0,3)	0
CONTACT LAXATIVES	84 (28,0)	41 (28,3)
CITRIC ACID;MAGNESIUM OXIDE;SODIUM PICOSULFATE	53 (17,7)	23 (15,9)
BISACODYL	13 (4,3)	11 (7,6)
SODIUM PICOSULFATE	11 (3,7)	8 (5,5)
SENNOSIDE A+B	5 (1,7)	2 (1,4)
BISACODYL;SENNOSIDE B	2 (0,7)	1 (0,7)
BISACODYL;DOCUSATE	1 (0,3)	1 (0,7)
BISACODYL;MACROGOL	1 (0,3)	0
DOCUSATE;SENNOSIDE A+B	1 (0,3)	0
SENNA SPP.	0	1 (0,7)
SENNOSIDE A	1 (0,3)	0
AMINOSALICYLIC ACID AND SIMILAR AGENTS	73 (24,3)	44 (30,3)
MESALAZINE	69 (23,0)	42 (29,0)
SULFASALAZINE	6 (2,0)	2 (1,4)
ANILIDES	78 (26,0)	38 (26,2)
PARACETAMOL	64 (21,3)	32 (22,1)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	3 (1,0)	1 (0,7)
AMANTADINE;CAFFEINE;CHLORPHENAMINE;COW BEZOAR;PARACETAMOL	1 (0,3)	1 (0,7)
CAFFEINE;CHLORPHENAMINE;PARACETAMOL	2 (0,7)	0
CAFFEINE;MEPYRAMINE;PARACETAMOL	2 (0,7)	0
CAFFEINE;PARACETAMOL;PROMETHAZINE;SALICYLAMIDE	0	2 (1,4)
CHLORPHENAMINE;PARACETAMOL	1 (0,3)	1 (0,7)
DEXTROMETHORPHAN;DOXYLAMINE;PARACETAMOL	1 (0,3)	1 (0,7)
DEXTROMETHORPHAN;PARACETAMOL;PHENYLEPHRINE	1 (0,3)	1 (0,7)
PARACETAMOL;PSEUDOEPHEDRINE	1 (0,3)	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
ARCTIUM LAPPA;FORSYTHIA SUSPENSIA;GLYCINE MAX;GLYCYRRHIZA SPP.;LONICERA JAPONICA;LOPHATHERUM GRACILE;MENTHOL;NEPETA TENUIFOLIA;PARACETAMOL;PLATYCODON GRANDIFLORUS	0	1 (0,7)
BROMHEXINE;BROMPHENIRAMINE;CAFFEINE;PARACETAMOL; PHENYLEPHRINE	1 (0,3)	0
BUTALBITAL;CAFFEINE;PARACETAMOL	0	1 (0,7)
CAFFEINE;CHLORPHENAMINE;COW BEZOAR;PARACETAMOL	0	1 (0,7)
CAFFEINE;CHLORPHENAMINE;GUAIFENESIN;METHYLEPHEDRI NE;PARACETAMOL;TIPEPIDINE	1 (0,3)	0
CHLORPHENAMINE;DEXTROMETHORPHAN;PARACETAMOL;PH ENYLPROPANOLAMINE	1 (0,3)	0
CHLORPHENAMINE;DEXTROMETHORPHAN;PARACETAMOL;PS EUOEPHEDRINE	1 (0,3)	0
CHLORPHENAMINE;PARACETAMOL;PSEUDOEPHEDRINE	0	1 (0,7)
DEXTROMETHORPHAN;GUAIFENESIN;PARACETAMOL;PSEUDO EPHEDRINE	1 (0,3)	0
METAMIZOLE;PARACETAMOL	1 (0,3)	0
PROPACETAMOL	1 (0,3)	0
OPIOID ANESTHETICS	78 (26,0)	34 (23,4)
FENTANYL	69 (23,0)	29 (20,0)
SUFENTANIL	7 (2,3)	9 (6,2)
ALFENTANIL	7 (2,3)	0
REMIFENTANIL	3 (1,0)	1 (0,7)
OTHER VIRAL VACCINES	70 (23,3)	38 (26,2)
COVID-19 VACCINE	69 (23,0)	38 (26,2)
OTHER VIRAL VACCINES	3 (1,0)	0
PROTON PUMP INHIBITORS	75 (25,0)	32 (22,1)
PANTOPRAZOLE	31 (10,3)	10 (6,9)
OMEPRazole	25 (8,3)	8 (5,5)
ESOMEPRazole	13 (4,3)	8 (5,5)
RABEPRazole	8 (2,7)	5 (3,4)
LANSOPRAZOLE	6 (2,0)	1 (0,7)
DEXLANSOPRAZOLE	1 (0,3)	0
DOMPERIDONE;PANTOPRAZOLE	0	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
ILAPRAZOLE	1 (0,3)	0
OMEPRazole;SODIUM BICARBONATE	1 (0,3)	0
PROTON PUMP INHIBITORS	0	1 (0,7)
VONOPRAZAN	0	1 (0,7)
OTHER IMMUNOSUPPRESSANTS	62 (20,7)	40 (27,6)
AZATHIOPRINE	58 (19,3)	36 (24,8)
METHOTREXATE	3 (1,0)	4 (2,8)
HYDROXYCHLOROQUINE	1 (0,3)	0
OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	68 (22,7)	28 (19,3)
SIMETICONE	41 (13,7)	16 (11,0)
DIMETICONE	20 (6,7)	12 (8,3)
PHLOROGLUCINOL	7 (2,3)	1 (0,7)
ATRACTYLODES MACROCEPHALA;GLYCYRRHIZA SPP.;LEVOGLUTAMIDE;PANAX GINSENG;PORIA COCOS	3 (1,0)	1 (0,7)
BUTYRIC ACID	1 (0,3)	1 (0,7)
PINAVERIUM	1 (0,3)	1 (0,7)
SILICON DIOXIDE	1 (0,3)	1 (0,7)
DIMETICONE;GUAIAZULENE	1 (0,3)	0
VITAMIN D AND ANALOGUES	43 (14,3)	25 (17,2)
COLECALCIFEROL	20 (6,7)	10 (6,9)
VITAMIN D NOS	16 (5,3)	13 (9,0)
CALCITRIOL	2 (0,7)	2 (1,4)
ERGOCALCIFEROL	2 (0,7)	1 (0,7)
COLECALCIFEROL-CHOLESTERIN	2 (0,7)	0
CALCIFEDIOL	1 (0,3)	0
BELLADONNA ALKALOIDS, SEMISYNTHETIC, QUATERNARY AMMONIUM COMPOUNDS	42 (14,0)	20 (13,8)
HYOSCINE	26 (8,7)	19 (13,1)
CIMETROPIUM	15 (5,0)	1 (0,7)
BUTYLSCOPOLAMINE	2 (0,7)	0
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	31 (10,3)	24 (16,6)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	6 (2,0)	13 (9,0)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
BIDENS BITERNATA;CAFFEINE;CHLORPHENAMINE;CHRYSANthemUM INDICUM;ILEX ASPRELLA;MELICOPE PTELEIFOLIA;MENTHA CANADENSIS;PARACETAMOL	5 (1,7)	2 (1,4)
BAICALIN;BUFFALO HORN;CHOLIC ACID;CONCHA MARGARITIFERA;GARDENIA JASMINOIDES;HYODEOXYCHOLIC ACID;ISATIS TINCTORIA;LONICERA JAPONICA	2 (0,7)	1 (0,7)
ANGELICA DAHURICA;ATRACTYLODES SPP.;BUPLEURUM SPP.;CAMELLIA SINENSIS;CITRUS AURANTIUM;CITRUS SPP.;CRATAEGUS PINNATIFIDA;FORSYTHIA SUSPENSIA;GLYCYRRHIZA SPP.;HANSENIA FORBESII;HORDEUM VULGARE;	1 (0,3)	1 (0,7)
CORYDALIS BUNGEANA;ISATIS TINCTORIA;SCUTELLARIA BAICALENSIS;TARAXACUM MONGOLICUM	2 (0,7)	0
LONICERA JAPONICA;SCUTELLARIA BAICALENSIS	1 (0,3)	1 (0,7)
PANAX GINSENG;ZANTHOXYLUM PIPERITUM;ZINGIBER OFFICINALE	1 (0,3)	1 (0,7)
UNSPECIFIED HERBAL	1 (0,3)	1 (0,7)
ACTAEA SPP.;ANGELICA SINENSIS;ASTRAGALUS MONGHOLICUS;ATRACTYLODES MACROCEPHALA;BUPLEURUM SPP.;CITRUS AURANTIUM;CODONOPSIS SPP.;GLYCYRRHIZA SPP.;ZINGIBER OFFICINALE;ZIZIPHUS JUJUBA	0	1 (0,7)
AGRIMONIA PILOSA;ANGELICA SINENSIS;ASINI CORII COLLA;ASTRAGALUS MONGHOLICUS;ATRACTYLODES MACROCEPHALA;CODONOPSIS SPP.;CULLEN CORYLIFOLIUM;CUSCUTA SPP.;DEER VELVET;ECLIPTA PROSTRATA;EPIMEDIUM SPP.;	1 (0,3)	0
ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE;CARTHAMUS TINCTORIUS;CHICKEN'S GIZZARD- MEMBRANE;CICADA SLOUGH;CURCUMA SPP.;FRITILLARIA THUNBERGII;ISATIS TINCTORIA;LASIOSPHAERA FENZLII;LONICERA JAPONICA;	1 (0,3)	0
ALUMINIUMHYDROXIDE;ATROPA BELLA-DONNA;VITAMIN U	1 (0,3)	0
ALUMINIUM SILICATE;AMOMUM SPP.;ANGELICA SINENSIS;ASTRAGALUS MONGHOLICUS;ATRACTYLODES MACROCEPHALA;CINNAMOMUM CASSIA;CODONOPSIS PILOSULA;CORYDALIS YANHUSUO;CULLEN CORYLIFOLIUM;DOLOMIAEA COSTUS;	0	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
ANEMARRHENA ASPHODELOIDES;CALCIUM SULFATE;COPTIS SPP.;FORSYTHIA SUSPENSAS;GARDENIA JASMINOIDES;GLYCYRRHIZA SPP.;PAEONIA SPP.;PAEONIA X SUFFRUTICOSA;PHELLODENDRON CHINENSE;PLATYCODON GRANDIFLORUS;	1 (0,3)	0
ANEMARRHENA ASPHODELOIDES;CALCIUM SULFATE;ISATIS TINCTORIA;PRUNUS SPP.;REHMANNIA GLUTINOSA;SCROPHULARIA NINGPOENSIS;TROLLIUS CHINENSIS	0	1 (0,7)
ANGELICA DAHURICA VAR. FORMOSANA;ASTRAGALUS MONGHOLICUS;ATRACTYLODES MACROCEPHALA;MAGNOLIA BIONDII;MENTHA CANADENSIS;SAPOSHNIKOVIA DIVARICATA;XANTHIUM STRUMARIUM SUBSP. STRUMARIUM	1 (0,3)	0
ANGELICA DAHURICA;ARECA CATECHU;ATRACTYLODES MACROCEPHALA;CITRUS AURANTIUM;GLYCYRRHIZA SPP.;MAGNOLIA OFFICINALIS;PERILLA FRUTESCENS;PINELLIA TERNATA;PLATYCODON GRANDIFLORUS;POGOSTEMON CABLIN;	1 (0,3)	0
ANGELICA DAHURICA;ATRACTYLODES LANCEA;CHRYSANthemum SPP.;CITRUS MAXIMA;COIX LACRYMA-JOBI VAR. MA-YUEN;DOLOMIAEA COSTUS;HERBAL NOS;MAGNOLIA OFFICINALIS;MENTHA CANADENSIS;ORYZA SATIVA;POGOSTEMON SPP.;	1 (0,3)	0
ANTELOPE HORN	0	1 (0,7)
ARECA CATECHU;CHICKEN'S GIZZARD-MEMBRANE;CITRUS AURANTIUM;CITRUS MEDICA;CITRUS SPP.;CYPERUS ROTUNDUS;PERILLA FRUTESCENS	1 (0,3)	0
ARTEMISIA ARGYI	1 (0,3)	0
ASTRAGALUS MONGHOLICUS;ATRACTYLODES MACROCEPHALA;SAPOSHNIKOVIA DIVARICATA	1 (0,3)	0
BUPLEURUM SPP.	0	1 (0,7)
CALCIUM SULFATE;DRYOPTERIS CRASSIRHIZOMA;EPHEDRA SPP.;FORSYTHIA SUSPENSAS;GLYCYRRHIZA SPP.;HOULTTUYNIA CORDATA;ISATIS TINCTORIA;LONICERA JAPONICA;MENTHOL;POGOSTEMON CABLIN;PRUNUS SPP.;RHEUM SPP.;	0	1 (0,7)
CALLICARPA NUDIFLORA	1 (0,3)	0
CANNABIS SATIVA	1 (0,3)	0
CHRYSANthemum INDICUM;MORUS ALBA;PRUNELLA VULGARIS	0	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
CINNAMOMUM CASSIA;EPHEDRA SPP.;GLYCYRRHIZA SPP.;PAEONIA LACTIFLORA;PUERARIA MONTANA VAR. LOBATA;ZINGIBER OFFICINALE;ZIZIPHUS JUJUBA	1 (0,3)	0
CINNAMOMUM SPP.	1 (0,3)	0
COCOS NUCIFERA	1 (0,3)	0
CURCUMA LONGA;PIPER NIGRUM	0	1 (0,7)
DIGITALIS SPP.	0	1 (0,7)
FRITILLARIA SPP.	1 (0,3)	0
GINKGO BILOBA	0	1 (0,7)
GINSENG NOS	1 (0,3)	0
GLYCYRRHIZA GLABRA	1 (0,3)	0
HIBISCUS SPP.;PROPOLIS	0	1 (0,7)
HOULTTUYNIA CORDATA	1 (0,3)	0
ILEX ROTUNDA;JASMINUM ELONGATUM;PERSICARIA CHINENSIS;PLANTAGO ASIATICA;PUNICA GRANATUM	1 (0,3)	0
INDIGOFERA TINCTORIA	1 (0,3)	0
ISATIS TINCTORIA	0	1 (0,7)
JUGLANS NIGRA	1 (0,3)	0
MELISSA OFFICINALIS;PASSIFLORA INCARNATA;PETASITES HYBRIDUS;VALERIANA OFFICINALIS	1 (0,3)	0
PAEONIA LACTIFLORA	1 (0,3)	0
PANAX PSEUDOGINSENG	1 (0,3)	0
QUERCUS SPP.	1 (0,3)	0
SALVIA MILTIORRHIZA	1 (0,3)	0
SANGUISORBA OFFICINALIS	1 (0,3)	0
SILYBUM MARIANUM	0	1 (0,7)
VITIS VINIFERA	1 (0,3)	0
WIKSTROEMIA INDICA	0	1 (0,7)
AMIDES	33 (11,0)	20 (13,8)
LIDOCAINE	30 (10,0)	18 (12,4)
ARTICAINE	2 (0,7)	0
CETRIMONIUM;LIDOCAINE	0	1 (0,7)
CHLORHEXIDINE;LIDOCAINE	0	1 (0,7)
ROPIVACAINE	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
FLUOROQUINOLONES	22 (7,3)	21 (14,5)
CIPROFLOXACIN	9 (3,0)	13 (9,0)
LEVOFLOXACIN	5 (1,7)	6 (4,1)
MOXIFLOXACIN	4 (1,3)	0
OFLOXACIN	2 (0,7)	2 (1,4)
NORFLOXACIN	2 (0,7)	0
ANTOFLOXACIN	0	1 (0,7)
LASCUFLOXACIN	1 (0,3)	0
IRON BIVALENT, ORAL PREPARATIONS	28 (9,3)	15 (10,3)
IRON	22 (7,3)	15 (10,3)
IRON POLYSACCHARIDE COMPLEX	4 (1,3)	1 (0,7)
ASCORBIC ACID;IRON	2 (0,7)	0
PROPIONIC ACID DERIVATIVES	26 (8,7)	17 (11,7)
IBUPROFEN	17 (5,7)	6 (4,1)
LOXOPROFEN	3 (1,0)	4 (2,8)
NAPROXEN	4 (1,3)	1 (0,7)
DEXKETOPROFEN	1 (0,3)	2 (1,4)
FLURBIPROFEN	1 (0,3)	2 (1,4)
DEXIBUPROFEN	1 (0,3)	1 (0,7)
APRONAL;CAFFEINE;IBUPROFEN	0	1 (0,7)
ELECTROLYTE SOLUTIONS	24 (8,0)	17 (11,7)
SODIUM CHLORIDE	13 (4,3)	13 (9,0)
POTASSIUM	6 (2,0)	3 (2,1)
MAGNESIUM SULFATE	2 (0,7)	2 (1,4)
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE;SODIUM CITRATE	2 (0,7)	1 (0,7)
CALCIUM GLUCONATE	2 (0,7)	1 (0,7)
CALCIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE	1 (0,3)	1 (0,7)
AMINO ACIDS NOS;ELECTROLYTES NOS;GLUCOSE	1 (0,3)	0
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM ACETATE;SODIUM CHLORIDE	0	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE;SORBITOL	0	1 (0,7)
CALCIUM CHLORIDE;POTASSIUM	1 (0,3)	0
CHROMIUM;COPPER;MANGANESE;ZINC	1 (0,3)	0
POTASSIUM PHOSPHATE MONOBASIC	1 (0,3)	0
POTASSIUM;SODIUM CHLORIDE	1 (0,3)	0
SODIUM CHLORIDE;SORBITOL	1 (0,3)	0
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	29 (9,7)	12 (8,3)
CALCIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	7 (2,3)	4 (2,8)
CALCIUM GLUCONATE;GLUCOSE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM ACETATE;SODIUM CHLORIDE;SODIUM CITRATE	10 (3,3)	1 (0,7)
SODIUM CHLORIDE	5 (1,7)	2 (1,4)
CALCIUM CHLORIDE;POTASSIUM;SODIUM LACTATE	5 (1,7)	0
GLUCOSE;SODIUM CHLORIDE	2 (0,7)	1 (0,7)
POTASSIUM	2 (0,7)	0
SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE	1 (0,3)	1 (0,7)
CALCIUM CHLORIDE;DEXTRAN;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	0	1 (0,7)
CALCIUM CHLORIDE;GLUCOSE;POTASSIUM;SODIUM ACETATE;SODIUM CHLORIDE	0	1 (0,7)
CALCIUM CHLORIDE;MALTOSE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	0	1 (0,7)
CALCIUM CHLORIDE;POTASSIUM;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE	0	1 (0,7)
CALCIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE	1 (0,3)	0
ELECTROLYTES WITH CARBOHYDRATES	0	1 (0,7)
FRUCTOSE;GLUCOSE;MAGNESIUM CHLORIDE;POTASSIUM;SODIUM BISULFITE;SODIUM CHLORIDE;SODIUM LACTATE;SODIUM PHOSPHATE	1 (0,3)	0
GLUCOSE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	0	1 (0,7)
POTASSIUM PHOSPHATE DIBASIC;POTASSIUM PHOSPHATE MONOBASIC	1 (0,3)	0
SODIUM BICARBONATE	0	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
SODIUM LACTATE	0	1 (0,7)
ANTIDIARRHEAL MICROORGANISMS	26 (8,7)	14 (9,7)
BACILLUS MESENTERICUS;CLOSTRIDIUM BUTYRICUM;ENTEROCOCCUS FAECALIS	2 (0,7)	3 (2,1)
SACCHAROMYCES BOULARDII	4 (1,3)	0
BACILLUS LICHENFORMIS	3 (1,0)	0
BACILLUS SUBTILIS;ENTEROCOCCUS FAECIUM	1 (0,3)	2 (1,4)
BIFIDOBACTERIUM NOS	1 (0,3)	2 (1,4)
LACTOBACILLUS NOS	3 (1,0)	0
PROBIOTICS NOS	3 (1,0)	0
BACILLUS SUBTILIS;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS	1 (0,3)	1 (0,7)
BIFIDOBACTERIUM INFANTIS	0	2 (1,4)
BIFIDOBACTERIUM LONGUM;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS	1 (0,3)	1 (0,7)
LACTOBACILLUS HELVETICUS;LACTOBACILLUS RHAMNOSUS	1 (0,3)	1 (0,7)
ANTIDIARRHEAL MICROORGANISMS	1 (0,3)	0
BACILLUS CEREUS;BIFIDOBACTERIUM INFANTIS;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS	0	1 (0,7)
BACILLUS SUBTILIS	0	1 (0,7)
BIFIDOBACTERIUM ANIMALIS;ENTEROCOCCUS FAECIUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS LACTIS;LACTOBACILLUS SALIVARIUS;STREPTOCOCCUS LACTIS	1 (0,3)	0
BIFIDOBACTERIUM BIFIDUM;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS	1 (0,3)	0
BIFIDOBACTERIUM INFANTIS;CLOSTRIDIUM BUTYRICUM	1 (0,3)	0
BIFIDOBACTERIUM INFANTIS;ENTEROCOCCUS FAECALIS;LACTOBACILLUS ACIDOPHILUS	0	1 (0,7)
BIFIDOBACTERIUM LACTIS	0	1 (0,7)
BIFIDOBACTERIUM LONGUM;LACTOBACILLUS BULGARICUS;STREPTOCOCCUS THERMOPHILUS	1 (0,3)	0
ENTEROCOCCUS FAECIUM;LACTOBACILLUS RHAMNOSUS	1 (0,3)	0
LACTOBACILLUS ACIDOPHILUS	1 (0,3)	0
LACTOBACILLUS RHAMNOSUS	0	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	32 (10,7)	8 (5,5)
LORATADINE	10 (3,3)	2 (1,4)
FEXOFENADINE	6 (2,0)	4 (2,8)
DESLORATADINE	8 (2,7)	0
BILASTINE	3 (1,0)	1 (0,7)
BEPOTASTINE	3 (1,0)	0
DIMENHYDRINATE;PYRIDOXINE	2 (0,7)	1 (0,7)
KETOTIFEN	3 (1,0)	0
CYPROHEPTADINE	1 (0,3)	0
RUPATADINE	0	1 (0,7)
OTHER OPIOIDS	26 (8,7)	10 (6,9)
TRAMADOL	15 (5,0)	5 (3,4)
DEZOCINE	11 (3,7)	4 (2,8)
SODIUM CHLORIDE;TRAMADOL	0	1 (0,7)
TAPENTADOL	1 (0,3)	0
VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES)	25 (8,3)	11 (7,6)
VITAMIN B12 NOS	12 (4,0)	6 (4,1)
CYANOCOBALAMIN	8 (2,7)	3 (2,1)
MECOBALAMIN	4 (1,3)	1 (0,7)
COBAMAMIDE	0	1 (0,7)
FOLIC ACID;VITAMIN B12 NOS	0	1 (0,7)
HYDROXOCOBALAMIN	1 (0,3)	0
PHENYLPIPERIDINE DERIVATIVES	27 (9,0)	6 (4,1)
PETHIDINE	19 (6,3)	5 (3,4)
FENTANYL	7 (2,3)	1 (0,7)
LEVALLORPHAN;PETHIDINE	1 (0,3)	0
ANTIPROPULSIVES	20 (6,7)	12 (8,3)
LOPERAMIDE	18 (6,0)	11 (7,6)
ATROPINE;DIPHENOXYLATE	1 (0,3)	1 (0,7)
PAPAVER SOMNIFERUM	1 (0,3)	0
PYRAZOLONES	20 (6,7)	12 (8,3)
METAMIZOLE	18 (6,0)	11 (7,6)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
AMINOPHENAZONE;BARBITAL	2 (0,7)	0
CAFFEINE;METAMIZOLE	0	1 (0,7)
CORTICOSTEROIDS ACTING LOCALLY	21 (7,0)	10 (6,9)
BUDESONIDE	21 (7,0)	10 (6,9)
BECLOMETASONE	1 (0,3)	0
SEROTONIN (5HT3) ANTAGONISTS	23 (7,7)	8 (5,5)
ONDANSETRON	23 (7,7)	8 (5,5)
GRANISETRON	1 (0,3)	0
BETA BLOCKING AGENTS, SELECTIVE	19 (6,3)	11 (7,6)
METOPROLOL	10 (3,3)	4 (2,8)
BISOPROLOL	6 (2,0)	6 (4,1)
ATENOLOL	2 (0,7)	1 (0,7)
NEBIVOLOL	1 (0,3)	0
FAT/CARBOHYDRATES/PROTEINS/MINERALS/VITAMINS, COMBINATIONS	18 (6,0)	12 (8,3)
CASEIN;FATS NOS;FIBRE, DIETARY;MALTODEXTRIN;MINERALS NOS;VITAMINS NOS	9 (3,0)	4 (2,8)
CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	3 (1,0)	5 (3,4)
ASCORBIC ACID;BIOTIN;CALCIUM;CAROTENOIDS NOS;CHLORINE;CHOLINE;CHROMIUM;COPPER;FATS NOS;FLUORINE;FOLIC ACID;IODINE;IRON;MAGNESIUM;MALTODEXTRIN;MANGANESE ;MOLYBDENUM;NICOTINIC ACID;PANTOTHENIC ACID;	1 (0,3)	1 (0,7)
CARBOHYDRATES NOS;FATTY ACIDS NOS;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	1 (0,3)	1 (0,7)
CASEIN;HERBAL OIL NOS;MALTODEXTRIN;MINERALS NOS;TRACE ELEMENTS NOS;VITAMINS NOS	1 (0,3)	1 (0,7)
NUTRIENTS NOS	1 (0,3)	1 (0,7)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CARBOHYDRATES NOS;CHOLINE;COLECALCIFEROL;FATS NOS;FIBRE, DIETARY;FOLIC ACID;MINERALS NOS;NICOTINIC ACID;PANTOTHENIC ACID;PHYTOMENADIONE;PROTEINS NOS;PYRIDOXINE;	1 (0,3)	0
CARBOHYDRATES NOS;ELECTROLYTES NOS;LIPIDS NOS;PROTEINS NOS;VITAMINS NOS	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
CASEIN;FIBRE, DIETARY;HERBAL OIL NOS;MALTODEXTRIN;MINERALS NOS;VITAMINS NOS	1 (0,3)	0
FAT/CARBOHYDRATES/PROTEINS/MINERALS/VITAMINS, COMBINATIONS	1 (0,3)	0
THIRD-GENERATION CEPHALOSPORINS	19 (6,3)	10 (6,9)
CEFDINIR	3 (1,0)	5 (3,4)
CEFTRIAZONE	5 (1,7)	2 (1,4)
CEFPODOXIME	4 (1,3)	1 (0,7)
CEFIXIME	3 (1,0)	0
CEFTAZIDIME	2 (0,7)	1 (0,7)
CEFTIZOXIME	3 (1,0)	0
CEFOPERAZONE;SULBACTAM	1 (0,3)	1 (0,7)
LATAMOXEF	2 (0,7)	0
CEFDITOREN	0	1 (0,7)
IRON, PARENTERAL PREPARATIONS	17 (5,7)	11 (7,6)
IRON	17 (5,7)	11 (7,6)
FERRIC DERISOMALTOSE	1 (0,3)	0
IRON, PARENTERAL PREPARATIONS	1 (0,3)	0
FOLIC ACID AND DERIVATIVES	20 (6,7)	7 (4,8)
FOLIC ACID	20 (6,7)	7 (4,8)
INFLUENZA VACCINES	20 (6,7)	7 (4,8)
INFLUENZA VACCINE	19 (6,3)	7 (4,8)
INFLUENZA A(H1N1)PDM09 VACCINE	1 (0,3)	0
PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS	13 (4,3)	13 (9,0)
DROSPIRENONE;ETHINYLESTRADIOL	3 (1,0)	4 (2,8)
ETHINYLESTRADIOL;LEVONORGESTREL	3 (1,0)	3 (2,1)
ETHINYLESTRADIOL;GESTODENE	2 (0,7)	1 (0,7)
ETHINYLESTRADIOL;NORETHISTERONE	1 (0,3)	2 (1,4)
DESOGESTREL;ETHINYLESTRADIOL	1 (0,3)	1 (0,7)
DIENOGEST;ETHINYLESTRADIOL	1 (0,3)	1 (0,7)
ETHINYLESTRADIOL;NORGESTIMATE	1 (0,3)	1 (0,7)
ESTRADIOL;NORETHISTERONE	1 (0,3)	0
ETHINYLESTRADIOL;NORELGESTROMIN	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
IMIDAZOLE DERIVATIVES	17 (5,7)	6 (4,1)
METRONIDAZOLE	14 (4,7)	4 (2,8)
CLOTTRIMAZOLE	2 (0,7)	0
ORNIDAZOLE	1 (0,3)	1 (0,7)
TINIDAZOLE	1 (0,3)	1 (0,7)
MORINIDAZOLE	1 (0,3)	0
PROPULSIVES	16 (5,3)	7 (4,8)
METOCLOPRAMIDE	10 (3,3)	5 (3,4)
MOSAPRIDE	5 (1,7)	1 (0,7)
DOMPERIDONE	3 (1,0)	0
ALIZAPRIDE	1 (0,3)	1 (0,7)
POTASSIUM	18 (6,0)	4 (2,8)
POTASSIUM	15 (5,0)	3 (2,1)
POTASSIUM CITRATE	3 (1,0)	0
CITRIC ACID;POTASSIUM BICARBONATE;POTASSIUM CITRATE	1 (0,3)	0
POTASSIUM ASPARTATE	0	1 (0,7)
ANTIDOTES	15 (5,0)	5 (3,4)
FLUMAZENIL	13 (4,3)	2 (1,4)
ANISODAMINE	0	2 (1,4)
PENEHYCLIDINE	1 (0,3)	1 (0,7)
ASCORBIC ACID	1 (0,3)	0
NALOXONE	0	1 (0,7)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	10 (3,3)	10 (6,9)
CALCIUM CARBONATE;COLECALCIFEROL	5 (1,7)	7 (4,8)
CALCIUM;COLECALCIFEROL	5 (1,7)	1 (0,7)
BORON;CALCIUM;COLECALCIFEROL;FOLIC ACID;IPRIFLAVONE;MAGNESIUM;MANGANESE;MENADIONE;MOLYBDENUM;ZINC	0	1 (0,7)
CALCIUM;VITAMIN D NOS	0	1 (0,7)
COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS	12 (4,0)	8 (5,5)
AMOXICILLIN;CLAVULANIC ACID	8 (2,7)	6 (4,1)
PIPERACILLIN;TAZOBACTAM	4 (1,3)	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
AMPICILLIN;SULBACTAM	1 (0,3)	1 (0,7)
SECOND-GENERATION CEPHALOSPORINS	13 (4,3)	7 (4,8)
CEFUROXIME	6 (2,0)	4 (2,8)
CEFACLOR	3 (1,0)	0
CEFOXITIN	2 (0,7)	1 (0,7)
CEFPROZIL	3 (1,0)	0
CEFAMANDOLE	0	1 (0,7)
CEFMETAZOLE	0	1 (0,7)
CEFOTETAN	0	1 (0,7)
MULTIVITAMINS, PLAIN	13 (4,3)	6 (4,1)
MULTIVITAMINS, PLAIN	7 (2,3)	6 (4,1)
VITAMINS NOS	7 (2,3)	0
OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS	18 (6,0)	1 (0,7)
PARACETAMOL;TRAMADOL	7 (2,3)	1 (0,7)
HYDROCODONE;PARACETAMOL	6 (2,0)	0
CAFFEINE;CODEINE;PARACETAMOL	2 (0,7)	0
CODEINE;PARACETAMOL	2 (0,7)	0
OXYCODONE;PARACETAMOL	2 (0,7)	0
SELECTIVE SEROTONIN REUPTAKE INHIBITORS	16 (5,3)	3 (2,1)
SERTRALINE	6 (2,0)	1 (0,7)
ESCITALOPRAM	4 (1,3)	2 (1,4)
FLUOXETINE	2 (0,7)	1 (0,7)
CITALOPRAM	2 (0,7)	0
FLUVOXAMINE	1 (0,3)	0
PAROXETINE	1 (0,3)	0
HMG COA REDUCTASE INHIBITORS	10 (3,3)	8 (5,5)
ATORVASTATIN	6 (2,0)	5 (3,4)
ROSUVASTATIN	3 (1,0)	0
SIMVASTATIN	0	3 (2,1)
LOVASTATIN	1 (0,3)	0
MACROLIDES	13 (4,3)	5 (3,4)
AZITHROMYCIN	6 (2,0)	5 (3,4)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
CLARITHROMYCIN	5 (1,7)	0
ERYTHROMYCIN	1 (0,3)	1 (0,7)
ROXITHROMYCIN	1 (0,3)	0
OTHER ANALGESICS AND ANTIPYRETICS	14 (4,7)	4 (2,8)
AMITRIPTYLINE	5 (1,7)	0
GABAPENTIN	5 (1,7)	0
PREGABALIN	3 (1,0)	2 (1,4)
VIMINOL	1 (0,3)	1 (0,7)
NEFOPAM	0	1 (0,7)
ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES	11 (3,7)	6 (4,1)
DICLOFENAC	7 (2,3)	4 (2,8)
KETOROLAC	3 (1,0)	3 (2,1)
CHLORPHENAMINE;COW BEZOAR;DICLOFENAC	0	1 (0,7)
DICLOFENAC;LIDOCAINE	1 (0,3)	0
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), PLAIN	12 (4,0)	5 (3,4)
LOSARTAN	6 (2,0)	2 (1,4)
CANDESARTAN	2 (0,7)	1 (0,7)
TELMISARTAN	2 (0,7)	1 (0,7)
VALSARTAN	2 (0,7)	1 (0,7)
H2-RECEPTOR ANTAGONISTS	12 (4,0)	5 (3,4)
FAMOTIDINE	9 (3,0)	2 (1,4)
ROXATIDINE	1 (0,3)	2 (1,4)
RANITIDINE	1 (0,3)	1 (0,7)
LAFUTIDINE	1 (0,3)	0
IRON TRIVALENT, ORAL PREPARATIONS	11 (3,7)	5 (3,4)
IRON	10 (3,3)	5 (3,4)
FERRIC HYDROXIDE	1 (0,3)	0
OTHER ANTIDEPRESSANTS	11 (3,7)	5 (3,4)
TRAZODONE	4 (1,3)	4 (2,8)
BUPROPION	4 (1,3)	2 (1,4)
MIRTAZAPINE	3 (1,0)	0
VENLAFAXINE	2 (0,7)	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
DULOXETINE	1 (0,3)	1 (0,7)
LAMOTRIGINE	1 (0,3)	1 (0,7)
AGOMELATINE	0	1 (0,7)
OTHER ANXIOLYTICS	11 (3,7)	5 (3,4)
ESCITALOPRAM	3 (1,0)	3 (2,1)
FLUOXETINE	4 (1,3)	1 (0,7)
DULOXETINE	1 (0,3)	1 (0,7)
SERTRALINE	2 (0,7)	0
PAROXETINE	1 (0,3)	0
VENLAFAXINE	1 (0,3)	0
PIPERAZINE DERIVATIVES	11 (3,7)	5 (3,4)
CETIRIZINE	6 (2,0)	4 (2,8)
LEVOCETIRIZINE	5 (1,7)	1 (0,7)
ACE INHIBITORS, PLAIN	11 (3,7)	4 (2,8)
LISINOPRIL	4 (1,3)	2 (1,4)
ENALAPRIL	3 (1,0)	0
PERINDOPRIL	2 (0,7)	1 (0,7)
RAMIPRIL	1 (0,3)	1 (0,7)
CILAZAPRIL	1 (0,3)	0
ANESTHETICS FOR TOPICAL USE	9 (3,0)	6 (4,1)
TETRACAINE	4 (1,3)	3 (2,1)
LIDOCAINE	3 (1,0)	2 (1,4)
OXYBUPROCAINE	2 (0,7)	0
CINCHOCAINE	0	1 (0,7)
ASCORBIC ACID (VITAMIN C), PLAIN	11 (3,7)	4 (2,8)
ASCORBIC ACID	11 (3,7)	4 (2,8)
CORTICOSTEROIDS, POTENT (GROUP III)	11 (3,7)	4 (2,8)
MOMETASONE	5 (1,7)	1 (0,7)
BETAMETHASONE	3 (1,0)	1 (0,7)
METHYLPREDNISOLONE	0	2 (1,4)
BECLOMETASONE	1 (0,3)	0
DIFLUCORTOLONE	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
DIFLUPREDNATE	1 (0,3)	0
FLUTICASONE	1 (0,3)	0
HALOMETASONE	1 (0,3)	0
NATURAL OPIUM ALKALOIDS	9 (3,0)	6 (4,1)
OXYCODONE	4 (1,3)	3 (2,1)
MORPHINE	4 (1,3)	1 (0,7)
HYDROMORPHONE	3 (1,0)	0
CODEINE	0	1 (0,7)
HYDROCODONE	0	1 (0,7)
OTHER PLAIN VITAMIN PREPARATIONS	11 (3,7)	4 (2,8)
PYRIDOXINE	8 (2,7)	2 (1,4)
BIOTIN	1 (0,3)	2 (1,4)
RIBOFLAVIN	2 (0,7)	1 (0,7)
TOCOPHEROL	1 (0,3)	0
VITAMIN E NOS	0	1 (0,7)
SOLUTIONS FOR PARENTERAL NUTRITION	12 (4,0)	3 (2,1)
GLUCOSE	3 (1,0)	1 (0,7)
ACETYLCYSTEINE;ALANINE;ARGININE;ASCORBIC ACID;ASPARTIC ACID;BIOTIN;CALCIUM CHLORIDE;CYANOCOBALAMIN;FOLIC ACID;GLUCOSE;GLUTAMIC ACID;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE;MAGN ESIUM SULFATE;	1 (0,3)	1 (0,7)
ACETIC ACID;ALANINE;ARGININE;ASPARTIC ACID;CALCIUM;CALCIUM CHLORIDE;CHLORIDE;GLUCOSE;GLUTAMIC ACID;GLYCEROL;GLYCINE;GLYCINE MAX;HISTIDINE;ISOLEUCINE;LECITHIN;LEUCINE;LYSINE;MAG NESIUM;	1 (0,3)	0
ALANINE;ARGININE;ASPARTIC ACID;CYSTEINE;GLUTAMIC ACID;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE;METH IONINE;PHENYLALANINE;PROLINE;SERINE;SODIUM BISULFITE;THREONINE;TRYPTOPHAN;TYROSINE;VALINE	1 (0,3)	0
ALANINE;ARGININE;ASPARTIC ACID;CYSTEINE;GLUTAMIC ACID;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE;METH IONINE;PHENYLALANINE;PROLINE;SERINE;THREONINE;TRYPT OPHAN;TYROSINE;VALINE	0	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
ALANINE;ARGININE;ASPARTIC ACID;CYSTINE;GLUTAMIC ACID;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE;METHIONINE;PHENYLALANINE;PROLINE;SERINE;THREONINE;TRYPTOPHAN;TYROSINE;VALINE	0	1 (0,7)
ALANINE;ARGININE;CALCIUM CHLORIDE;FISH OIL;GLUCOSE;GLYCINE;GLYCINE MAX;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE;MAGNESIUM SULFATE;MEDIUM-CHAIN TRIGLYCERIDES;METHIONINE;OLEA EUROPAEA;PHENYLALANINE;	1 (0,3)	0
ALANINE;ARGININE;CITRIC ACID;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE;MAGNESIUM CHLORIDE;METHIONINE;NICOTINAMIDE;ORNITHINE;PHENYLALANINE;POTASSIUM HYDROXIDE;PROLINE;PYRIDOXINE;RIBOFLAVIN;	1 (0,3)	0
AMINO ACIDS NOS;CALCIUM CHLORIDE;ELECTROLYTES NOS;GLUCOSE;LIPIDS NOS	1 (0,3)	0
AMINO ACIDS NOS;ELECTROLYTES NOS;GLUCOSE;LIPIDS NOS	1 (0,3)	0
ARGININE;BETA-ALANINE;CYSTEINE;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE;METHIONINE;PHENYLALANINE;PROLINE;SERINE;THREONINE;TRYPTOPHAN;VALINE	1 (0,3)	0
CARBOHYDRATES NOS;MINERALS NOS	1 (0,3)	0
FATS NOS	0	1 (0,7)
FISH OIL;GLYCEROL;PHOSPHOLIPIDS EGG	1 (0,3)	0
FRUCTOSE	0	1 (0,7)
NUTRIENTS NOS	1 (0,3)	0
TRIGLYCERIDES	1 (0,3)	0
CALCIUM	8 (2,7)	6 (4,1)
CALCIUM CARBONATE	4 (1,3)	3 (2,1)
CALCIUM	3 (1,0)	3 (2,1)
CALCIUM;CALCIUM CARBONATE	1 (0,3)	0
HEPARIN GROUP	12 (4,0)	2 (1,4)
ENOXAPARIN	5 (1,7)	1 (0,7)
HEPARIN	4 (1,3)	1 (0,7)
NADROPARIN	2 (0,7)	0
HEPARINOID	1 (0,3)	0
LOW MOLECULAR WEIGHT HEPARIN	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
PENICILLINS WITH EXTENDED SPECTRUM	9 (3,0)	5 (3,4)
AMOXICILLIN	9 (3,0)	4 (2,8)
AMPICILLIN	0	1 (0,7)
THYROID HORMONES	9 (3,0)	5 (3,4)
LEVOTHYROXINE	9 (3,0)	5 (3,4)
CORTICOSTEROIDS	6 (2,0)	7 (4,8)
FLUTICASONE	4 (1,3)	1 (0,7)
CINCHOCAINE;ESCULOSIDE;HYDROCORTISONE;NEOMYCIN	0	2 (1,4)
BECLOMETASONE	1 (0,3)	0
BETAMETHASONE;LIDOCAINE;PHENYLEPHRINE	0	1 (0,7)
BUDESONIDE	1 (0,3)	0
CINCHOCAINE;ESCULOSIDE;FRAMYCETIN;HYDROCORTISONE	0	1 (0,7)
HYDROCORTISONE;PRAMOCAINE	0	1 (0,7)
MOMETASONE	0	1 (0,7)
HYDRAZIDES	10 (3,3)	3 (2,1)
ISONIAZID	10 (3,3)	3 (2,1)
NITROIMIDAZOLE DERIVATIVES	6 (2,0)	7 (4,8)
METRONIDAZOLE	4 (1,3)	5 (3,4)
OFLOXACIN;SATRANIDAZOLE	1 (0,3)	1 (0,7)
ORNIDAZOLE	0	1 (0,7)
TINIDAZOLE	1 (0,3)	0
NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS	6 (2,0)	7 (4,8)
VALACICLOVIR	4 (1,3)	2 (1,4)
ACICLOVIR	1 (0,3)	3 (2,1)
MOLNUPIRAVIR	0	1 (0,7)
REMDESIVIR	0	1 (0,7)
RIBAVIRIN	1 (0,3)	0
OTHER ANTIBIOTICS FOR TOPICAL USE	11 (3,7)	2 (1,4)
BACITRACIN;LIDOCAINE;NEOMYCIN;POLYMYXIN B	4 (1,3)	0
FUSIDIC ACID	3 (1,0)	1 (0,7)
MUPIROCIN	2 (0,7)	0
BACITRACIN;NEOMYCIN	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
CHLORAMPHENICOL	1 (0,3)	0
ERYTHROMYCIN	0	1 (0,7)
NEOMYCIN;POLYMYXIN B;PRAMOCAINE	1 (0,3)	0
ANTIBIOTICS	7 (2,3)	5 (3,4)
RIFAXIMIN	4 (1,3)	0
NIFURATEL;NYSTATIN	1 (0,3)	1 (0,7)
RIFAMPICIN	1 (0,3)	1 (0,7)
ERYTHROMYCIN	1 (0,3)	0
FIDAXOMICIN	0	1 (0,7)
STREPTOMYCIN	0	1 (0,7)
VANCOMYCIN	0	1 (0,7)
ANTIINFLAMMATORY PREPARATIONS, NON-STERIODS FOR TOPICAL USE	7 (2,3)	5 (3,4)
KETOPROFEN	2 (0,7)	2 (1,4)
DICLOFENAC	1 (0,3)	2 (1,4)
LOXOPROFEN	2 (0,7)	1 (0,7)
ETOFENAMATE	1 (0,3)	0
FLURBIPROFEN	1 (0,3)	0
INDOMETACIN	1 (0,3)	0
DIHYDROPYRIDINE DERIVATIVES	8 (2,7)	4 (2,8)
AMLODIPINE	7 (2,3)	3 (2,1)
BARNIDIPINE	1 (0,3)	0
LERCANIDIPINE	0	1 (0,7)
ENEMAS	6 (2,0)	6 (4,1)
SODIUM PHOSPHATE	3 (1,0)	2 (1,4)
BISACODYL	2 (0,7)	2 (1,4)
GLYCEROL	0	2 (1,4)
ENEMAS	1 (0,3)	0
SODIUM PHOSPHATE;SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	1 (0,3)	0
IRON PREPARATIONS	9 (3,0)	3 (2,1)
IRON POLYSACCHARIDE COMPLEX	6 (2,0)	1 (0,7)
IRON	3 (1,0)	2 (1,4)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STERIODS	10 (3,3)	2 (1,4)
SULFASALAZINE	3 (1,0)	2 (1,4)
NIMESULIDE	3 (1,0)	0
BENZYDAMINE	1 (0,3)	0
CHONDROITIN	1 (0,3)	0
CURCUMIN	1 (0,3)	0
GLUCOSAMINE	0	1 (0,7)
NABUMETONE	1 (0,3)	0
OTHER CENTRALLY ACTING AGENTS	10 (3,3)	2 (1,4)
CYCLOBENZAPRINE	3 (1,0)	2 (1,4)
TIZANIDINE	4 (1,3)	0
BACLOFEN	2 (0,7)	0
DIAZEPAM	0	1 (0,7)
TOLPERISONE	1 (0,3)	0
AMINO ACIDS/CARBOHYDRATES/MINERALS/VITAMINS, COMBINATIONS	5 (1,7)	5 (3,4)
AMINO ACIDS NOS; CARBOHYDRATES NOS; FATS NOS; MINERALS NOS; VITAMINS NOS	5 (1,7)	5 (3,4)
AMINOALKYL ETHERS	6 (2,0)	4 (2,8)
DIPHENHYDRAMINE	5 (1,7)	3 (2,1)
CLEMASTINE	0	1 (0,7)
DOXYLAMINE	1 (0,3)	0
COXIBS	8 (2,7)	2 (1,4)
CELECOXIB	5 (1,7)	0
ETORICOXIB	2 (0,7)	1 (0,7)
COXIBS	1 (0,3)	0
IMRECOXIB	0	1 (0,7)
PARECOXIB	1 (0,3)	0
MAGNESIUM	10 (3,3)	0
MAGNESIUM	8 (2,7)	0
MAGNESIUM CITRATE	1 (0,3)	0
MAGNESIUM OXIDE	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
MUCOLYTICS	5 (1,7)	5 (3,4)
ACETYLCYSTEINE	2 (0,7)	1 (0,7)
CARBOCISTEINE	0	3 (2,1)
ERDOSTEINE	2 (0,7)	1 (0,7)
AMBROXOL	1 (0,3)	0
OPIUM ALKALOIDS AND DERIVATIVES	5 (1,7)	5 (3,4)
DIMEMORFAN	1 (0,3)	3 (2,1)
DEXTROMETHORPHAN	2 (0,7)	1 (0,7)
CODEINE	1 (0,3)	1 (0,7)
AMMONIUM CHLORIDE;CHLORPHENAMINE;DIHYDROCODEINE;METHYLEPH EDRINE	1 (0,3)	0
OTHER ANTIVIRALS	8 (2,7)	2 (1,4)
FAVIPIRAVIR	3 (1,0)	0
UMIFENOVIR	3 (1,0)	0
MOLNUPIRAVIR	1 (0,3)	1 (0,7)
CASIRIVIMAB	1 (0,3)	0
ENISAMIUM IODIDE	0	1 (0,7)
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	8 (2,7)	2 (1,4)
REBAMIPIDE	5 (1,7)	0
POLAPREZINC	1 (0,3)	1 (0,7)
BISMUTH	0	1 (0,7)
SUCRALFATE	1 (0,3)	0
TEPRENONE	1 (0,3)	0
PAPAVERINE AND DERIVATIVES	6 (2,0)	4 (2,8)
DROTAVERINE	5 (1,7)	4 (2,8)
PAPAVERINE	1 (0,3)	0
PROGESTOGENS	7 (2,3)	3 (2,1)
DESOGESTREL	4 (1,3)	1 (0,7)
LEVONORGESTREL	2 (0,7)	0
MEDROXYPROGESTERONE	1 (0,3)	1 (0,7)
DROSPIRENONE	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
ETONOGESTREL	0	1 (0,7)
SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS	8 (2,7)	2 (1,4)
SALBUTAMOL	6 (2,0)	2 (1,4)
FORMOTEROL	0	1 (0,7)
LEVOSALBUTAMOL	1 (0,3)	0
TERBUTALINE	1 (0,3)	0
THIAZIDES, PLAIN	5 (1,7)	5 (3,4)
HYDROCHLOROTHIAZIDE	5 (1,7)	5 (3,4)
BELLADONNA ALKALOIDS, TERTIARY AMINES	7 (2,3)	2 (1,4)
ATROPINE	3 (1,0)	1 (0,7)
ANISODAMINE	1 (0,3)	1 (0,7)
HYOSCYAMINE	2 (0,7)	0
RACEANISODAMINE	1 (0,3)	0
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	7 (2,3)	2 (1,4)
CLOSTRIDIUM BUTYRICUM	6 (2,0)	2 (1,4)
ESCHERICHIA COLI	1 (0,3)	0
OTHER INTESTINAL ADSORBENTS	6 (2,0)	3 (2,1)
MONTMORILLONITE	3 (1,0)	3 (2,1)
DIOSMECTITE	2 (0,7)	0
POLYMETHYLSILOXANE	1 (0,3)	0
SUBSTITUTED ALKYLAMINES	8 (2,7)	1 (0,7)
PHENIRAMINE	4 (1,3)	0
DEXCHLORPHENIRAMINE	2 (0,7)	0
DIMETINDENE	1 (0,3)	1 (0,7)
CHLORPHENAMINE	1 (0,3)	0
SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP	7 (2,3)	2 (1,4)
DICYCLOVERINE	6 (2,0)	1 (0,7)
MEBEVERINE	0	1 (0,7)
TRIMEBUTINE	1 (0,3)	0
ALL OTHER THERAPEUTIC PRODUCTS	7 (2,3)	1 (0,7)
ALL OTHER THERAPEUTIC PRODUCTS	6 (2,0)	1 (0,7)
DL-METHIONINE;GLYCINE;GLYCYRRHIZIC ACID	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
ALPHA-ADRENORECEPTOR ANTAGONISTS	5 (1,7)	3 (2,1)
TAMSULOSIN	2 (0,7)	1 (0,7)
DOXAZOSIN	2 (0,7)	0
TERAZOSIN	1 (0,3)	1 (0,7)
URAPIDIL	0	1 (0,7)
BENZODIAZEPINE RELATED DRUGS	6 (2,0)	2 (1,4)
ZOLPIDEM	4 (1,3)	2 (1,4)
ESZOPICLONE	1 (0,3)	0
ZOPICLONE	1 (0,3)	0
CORTICOSTEROIDS, MODERATELY POTENT (GROUP II)	5 (1,7)	3 (2,1)
TRIAMCINOLONE	2 (0,7)	3 (2,1)
DESONIDE	2 (0,7)	1 (0,7)
HYDROCORTISONE	2 (0,7)	0
EXPECTORANTS	2 (0,7)	6 (4,1)
GUAIFENESIN	1 (0,3)	5 (3,4)
BROMHEXINE;GUAIFENESIN;SALBUTAMOL	0	1 (0,7)
CINEOLE;DIPENTEN;PINENE	1 (0,3)	0
FIRST-GENERATION CEPHALOSPORINS	6 (2,0)	2 (1,4)
CEFALEXIN	4 (1,3)	2 (1,4)
CEFAZOLIN	3 (1,0)	0
IMIDAZOLE AND TRIAZOLE DERIVATIVES	6 (2,0)	2 (1,4)
KETOCONAZOLE	1 (0,3)	1 (0,7)
BIFONAZOLE	1 (0,3)	0
CLOBETASOL;KETOCONAZOLE	1 (0,3)	0
CLOTRIMAZOLE	1 (0,3)	0
DIFLUCORTOLONE;ISOCONAZOLE	0	1 (0,7)
EFINACONAZOLE	1 (0,3)	0
HYDROCORTISONE;MICONAZOLE	1 (0,3)	0
NETICONAZOLE	1 (0,3)	0
PREPARATIONS INHIBITING URIC ACID PRODUCTION	6 (2,0)	2 (1,4)
ALLOPURINOL	5 (1,7)	1 (0,7)
FEBUXOSTAT	1 (0,3)	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
SYMPATHOMIMETICS	6 (2,0)	2 (1,4)
PHENYLEPHRINE	1 (0,3)	1 (0,7)
PSEUDOEPHEDRINE	2 (0,7)	0
CHLORPHENAMINE;IBUPROFEN;PSEUDOEPHEDRINE	1 (0,3)	0
CHLORPHENAMINE;PSEUDOEPHEDRINE	1 (0,3)	0
DIPHENHYDRAMINE;PHENYLEPHRINE	1 (0,3)	0
FEXOFENADINE;PSEUDOEPHEDRINE	0	1 (0,7)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	6 (2,0)	2 (1,4)
PROBIOTICS NOS	1 (0,3)	1 (0,7)
SUCRALFATE	2 (0,7)	0
CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	0	1 (0,7)
PHOSPHORUS	1 (0,3)	0
THIOCTIC ACID	1 (0,3)	0
ZINC	1 (0,3)	0
AMINO ACIDS	6 (2,0)	1 (0,7)
ALANYL GLUTAMINE	3 (1,0)	0
ALANINE;ARGININE;ASPARTIC ACID;CYSTINE;GLUTAMIC ACID;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE;METHIONINE;PHENYLALANINE;PROLINE;SERINE;THREONINE;TRYPTOPHAN;TYROSINE;VALINE	1 (0,3)	1 (0,7)
ALANINE;ARGININE;ASPARTIC ACID;CYSTEINE;GLUTAMIC ACID;GLYCINE;HISTIDINE;ISOLEUCINE;LEUCINE;LYSINE;METHIONINE;PHENYLALANINE;PROLINE;SERINE;THREONINE;TRYPTOPHAN;TYROSINE;VALINE	1 (0,3)	0
AMINO ACIDS [UMBRELLA TERM]	1 (0,3)	0
TRANEXAMIC ACID	1 (0,3)	0
BULK-FORMING LAXATIVES	3 (1,0)	4 (2,8)
PLANTAGO OVATA	2 (0,7)	1 (0,7)
FIBRE, DIETARY;INULIN	0	1 (0,7)
LINUM USITATISSIMUM	0	1 (0,7)
POLYCARBOPHIL	0	1 (0,7)
PSYLLIUM HYDROPHILIC MUCILLOID	1 (0,3)	0
ENZYME PREPARATIONS	4 (1,3)	3 (2,1)
PANCREATIN	3 (1,0)	2 (1,4)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
DIASTASE;PANCREATIN;PEPSIN;SIMETICONE	1 (0,3)	0
DIMETICONE;HEMICELLULASE;OX BILE;PANCREATIN	0	1 (0,7)
IRON IN OTHER COMBINATIONS	5 (1,7)	2 (1,4)
ASCORBIC ACID;IRON	4 (1,3)	1 (0,7)
COPPER;IRON;MANGANESE	0	1 (0,7)
CYANOCOBALAMIN;FOLIC ACID;IRON	1 (0,3)	0
MULTIVITAMINS WITH MINERALS	2 (0,7)	5 (3,4)
MINERALS NOS;VITAMINS NOS	1 (0,3)	2 (1,4)
ASCORBIC ACID;BIOTIN;BORON;CHROMIUM;COLECALCIFEROL;CYANOCO BALAMIN;DL-ALPHA TOCOPHEROL;FOLIC ACID;INOSITOL NICOTINATE;MOLYBDENUM;PANTOTHENIC ACID;PYRIDOXINE;RETINOL;SODIUM	0	1 (0,7)
ASCORBIC ACID;BIOTIN;CALCIUM CARBONATE;CHROMIUM;COLECALCIFEROL;COPPER;CYANOC OBALAMIN;FOLIC ACID;IRON;MANGANESE;MOLYBDENUM;NICOTINAMIDE;PANT OTHENIC ACID;PHYTOMENADIONE;PYRIDOXINE;RETINOL;RIBOFLAVIN;	0	1 (0,7)
ASCORBIC ACID;CHROMIUM;COPPER;CYANOCOBALAMIN;FOLIC ACID;IODINE;MAGNESIUM;MANGANESE;MOLYBDENUM;NICOT INIC ACID;PANTOTHENIC ACID;POTASSIUM;PYRIDOXINE;RETINOL;RIBOFLAVIN;SELENIU M;THIAMINE;TOCOPHEROL;	0	1 (0,7)
CALCIUM CARBONATE;VITAMIN D NOS	1 (0,3)	0
IRON;VITAMINS NOS	0	1 (0,7)
OTHER IMMUNOSTIMULANTS	7 (2,3)	0
LEUCOGEN	5 (1,7)	0
ASCORBIC ACID;BENDAZOL;OGLUFANIDE	1 (0,3)	0
BATILOL	1 (0,3)	0
DEOXYRIBONUCLEOTIDE	1 (0,3)	0
PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN	6 (2,0)	1 (0,7)
ACETYLSALICYLIC ACID	5 (1,7)	1 (0,7)
CLOPIDOGREL	2 (0,7)	0
LIMAPROST	1 (0,3)	0
PURINE ANALOGUES	7 (2,3)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
MERCAPTOPURINE	7 (2,3)	0
TETRACYCLINES	7 (2,3)	0
DOXYCYCLINE	5 (1,7)	0
MINOCYCLINE	1 (0,3)	0
TETRACYCLINE	1 (0,3)	0
VITAMIN B1, PLAIN	4 (1,3)	3 (2,1)
THIAMINE	2 (0,7)	3 (2,1)
FURSULTIAMINE	1 (0,3)	0
VITAMIN B1 NOS	1 (0,3)	0
COMBINATIONS OF VITAMINS	3 (1,0)	3 (2,1)
ERGOCALCIFEROL;PHYTOMENADIONE;RETINOL;VITAMIN E NOS	2 (0,7)	1 (0,7)
ASCORBIC ACID;RIBOFLAVIN;VITAMIN B1 NOS	0	1 (0,7)
COLECALCIFEROL;MENAQUINONE	0	1 (0,7)
VITAMINS NOS	1 (0,3)	0
DIRECT FACTOR XA INHIBITORS	4 (1,3)	2 (1,4)
APIXABAN	2 (0,7)	1 (0,7)
RIVAROXABAN	2 (0,7)	1 (0,7)
GLYCOPEPTIDE ANTIBACTERIALS	4 (1,3)	2 (1,4)
VANCOMYCIN	3 (1,0)	2 (1,4)
TEICOPLANIN	1 (0,3)	0
HERBAL THROAT PREPARATIONS (TONSILLITIS)	3 (1,0)	3 (2,1)
ADENOPHORA TRIPHYLLA;CICADA SLOUGH;CITRUS AURANTIUM;MENTHA CANADENSIS;OPHIOPOGON JAPONICUS;PSEUDOSTELLARIA HETEROPHYLLA;REHMANNIA GLUTINOSA;SCAPHIUM AFFINE;SCROPHULARIA NINGPOENSIS;TERMINALIA CHEBULA	1 (0,3)	0
ALBIZIA JULIBRISSIN;ARECA CATECHU;ARISAEMA SPP.;CICADA SLOUGH;CITRUS AURANTIUM;MAGNOLIA OFFICINALIS;MASSA MEDICA FERMENTUM;OROXYLUM INDICUM;PERILLA FRUTESCENS;PINELLIA TERNATA;PORIA COCOS;	0	1 (0,7)
ANDROGRAPHIS PANICULATA;SOLIDAGO DECURRENS	1 (0,3)	0
ARDISIA JAPONICA;BOMBYX MORI;CARPESIUM SPP.;DUHALDEA CAPP;ELAEAGNUS SPP.;MENTHA CANADENSIS;NEPETA TENUIFOLIA	0	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
BORNEOL;CITRULLUS LANATUS;MENTHA CANADENSIS;MENTHOL;SODIUM SULFATE	0	1 (0,7)
CICADA SLOUGH;FORSYTHIA SUSPENS;FRITILLARIA THUNBERGII;GLYCYRRHIZA SPP.;LIGUSTICUM CHUANXIONG;MENTHA CANADENSIS;MENTHOL;PLATYCODON GRANDIFLORUS;RHEUM SPP.;SENEGALIA CATECHU;TERMINALIA CHEBULA	1 (0,3)	0
GARDENIA JASMINOIDES;ISATIS TINCTORIA;PHELLODENDRON CHINENSE;SCAPHIUM AFFINE;SCUTELLARIA BAICALENSIS	1 (0,3)	0
IRON IN COMBINATION WITH FOLIC ACID	3 (1,0)	3 (2,1)
FOLIC ACID;IRON	3 (1,0)	3 (2,1)
LEUKOTRIENE RECEPTOR ANTAGONISTS	3 (1,0)	3 (2,1)
MONTELUKAST	2 (0,7)	1 (0,7)
LEVOCETIRIZINE;MONTELUKAST	0	2 (1,4)
DESLOTRADINE;MONTELUKAST	1 (0,3)	0
LOCAL ANESTHETICS	4 (1,3)	2 (1,4)
LIDOCAINE;TRIBENOSIDE	1 (0,3)	2 (1,4)
CHONDRUS CRISPUS;LIDOCAINE;TITANIUM DIOXIDE;ZINC	1 (0,3)	0
LIDOCAINE	1 (0,3)	0
LIDOCAINE;ZINC	1 (0,3)	0
MELATONIN RECEPTOR AGONISTS	4 (1,3)	2 (1,4)
MELATONIN	3 (1,0)	2 (1,4)
RAMELTEON	1 (0,3)	0
NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS	5 (1,7)	1 (0,7)
AMITRIPTYLINE	1 (0,3)	1 (0,7)
IMIPRAMINE	2 (0,7)	0
NORTRIPTYLINE	2 (0,7)	0
OTHER ANTIDIARRHEALS	5 (1,7)	1 (0,7)
COLESTYRAMINE	3 (1,0)	1 (0,7)
BERBERINE	1 (0,3)	0
RACECADOTRIL	1 (0,3)	0
OTHER DERMATOLOGICALS	5 (1,7)	1 (0,7)
GUAIAZULENE	1 (0,3)	1 (0,7)
OTHER DERMATOLOGICALS	2 (0,7)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
FINASTERIDE	1 (0,3)	0
MINOXIDIL	1 (0,3)	0
PYRITHIONE	1 (0,3)	0
OTHER EMOLLIENTS AND PROTECTIVES	5 (1,7)	1 (0,7)
HEPARINOID	3 (1,0)	0
ALOE VERA;CALAMINE;PARAFFIN, LIQUID	0	1 (0,7)
BORIC ACID	1 (0,3)	0
CAMPHOR;MENTHOL	1 (0,3)	0
MAGNESIUM STEARATE	1 (0,3)	0
OTHER HYPNOTICS AND SEDATIVES	5 (1,7)	1 (0,7)
HYOSCINE	1 (0,3)	1 (0,7)
DEXMEDETOMIDINE	1 (0,3)	0
DIPHENHYDRAMINE	1 (0,3)	0
LEMBOREXANT	1 (0,3)	0
MAGNOLIA SPP.;PERILLA FRUTESCENS VAR. CRISPA;PINELLIA TERNATA;PORIA COCOS;ZINGIBER OFFICINALE	1 (0,3)	0
URINARY CONCREMENT SOLVENTS	5 (1,7)	1 (0,7)
ANETHOLE;BORNEOL;CAMPHENE;CINEOLE;FENCHONE;PINENE	2 (0,7)	0
ABUTILON THEOPHRASTI;ACHYRANTHES BIDENTATA;CHICKEN'S GIZZARD-MEMBRANE;CITRUS AURANTIUM;CLEMATIS SPP.;GRONA STYRACIFOLIA;LUFFA AEGYPTIACA;LYGODIUM JAPONICUM;PLANTAGO SPP.;PORIA COCOS	1 (0,3)	0
ACHYRANTHES BIDENTATA;CHICKEN'S GIZZARD- MEMBRANE;CORYDALIS YANHUSUO;DIANTHUS SPP.;DOLOMIAEA COSTUS;GYPSOPHILA VACCARIA;LYGODIUM JAPONICUM;LYSIMACHIA CHRISTINIAE;POLYGONUM AVICULARE;SALVIA MILTIORRHIZA	1 (0,3)	0
CENTAURIUM ERYTHRAEA;LEVISTICUM OFFICINALE;SALVIA ROSMARINUS	0	1 (0,7)
POTASSIUM CITRATE;SODIUM CITRATE	1 (0,3)	0
VITAMIN B-COMPLEX, PLAIN	4 (1,3)	2 (1,4)
VITAMIN B NOS	2 (0,7)	1 (0,7)
VITAMIN B COMPLEX	1 (0,3)	1 (0,7)
DEXPANTHENOL;NICOTINAMIDE;PYRIDOXINE;RIBOFLAVIN;TH IAMINE	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	1 (0,3)	0
ZINC	3 (1,0)	3 (2,1)
ZINC	3 (1,0)	3 (2,1)
ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS	4 (1,3)	1 (0,7)
BUDESONIDE;FORMOTEROL	1 (0,3)	1 (0,7)
BECLOMETASONE;FORMOTEROL	1 (0,3)	0
FLUTICASONE;SALMETEROL	1 (0,3)	0
FLUTICASONE;VILANTEROL	1 (0,3)	0
AGENTS FOR DERMATITIS, EXCLUDING CORTICOSTEROIDS	5 (1,7)	0
TACROLIMUS	4 (1,3)	0
DELGOCITINIB	1 (0,3)	0
ANTIINFECTIVES	1 (0,3)	4 (2,8)
GENTAMICIN	0	2 (1,4)
OFLOXACIN	0	2 (1,4)
LEVOFLOXACIN	1 (0,3)	0
ANTISEPTICS	5 (1,7)	0
BENZOXONIUM CHLORIDE;LIDOCAINE	1 (0,3)	0
BORIC ACID;GLYCEROL;PHENOL;SODIUM BICARBONATE	1 (0,3)	0
CETYLPYRIDINIUM	1 (0,3)	0
GUALENIC ACID;SODIUM BICARBONATE	1 (0,3)	0
POVIDONE-IODINE	1 (0,3)	0
SILVER	1 (0,3)	0
BIGUANIDES	2 (0,7)	3 (2,1)
METFORMIN	2 (0,7)	3 (2,1)
CALCIUM COMPOUNDS	5 (1,7)	0
CALCIUM CARBONATE	5 (1,7)	0
CARBAMIC ACID ESTERS	5 (1,7)	0
METHOCARBAMOL	3 (1,0)	0
CARISOPRODOL	1 (0,3)	0
METHOCARBAMOL;PARACETAMOL	1 (0,3)	0
CORTICOSTEROIDS, PLAIN	2 (0,7)	3 (2,1)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
HYDROCORTISONE	1 (0,3)	1 (0,7)
PREDNISOLONE	1 (0,3)	1 (0,7)
DEXAMETHASONE	1 (0,3)	0
LOTEPREDNOL	0	1 (0,7)
CORTICOSTEROIDS, POTENT, COMBINATIONS WITH ANTIBIOTICS	3 (1,0)	2 (1,4)
BETAMETHASONE;GENTAMICIN	3 (1,0)	2 (1,4)
BETAMETHASONE;CLOTRIMAZOLE;GENTAMICIN	1 (0,3)	0
CORTICOSTEROIDS, VERY POTENT (GROUP IV)	4 (1,3)	1 (0,7)
CLOBETASOL	4 (1,3)	1 (0,7)
IMIDAZOLINE RECEPTOR AGONISTS	2 (0,7)	3 (2,1)
RILMENIDINE	1 (0,3)	2 (1,4)
CLONIDINE	1 (0,3)	1 (0,7)
INTERLEUKIN INHIBITORS	5 (1,7)	0
USTEKINUMAB	5 (1,7)	0
OPIUM DERIVATIVES AND EXPECTORANTS	3 (1,0)	2 (1,4)
CHLORPHENAMINE;DIHYDROCODEINE;GUAIFENESIN;METHYL EPHEDRINE	2 (0,7)	0
ADENOPHORA SPP.;ANDROGRAPHIS PANICULATA;ELAEAGNUS PUNGENS;EPHEDRA SPP.;PAPAV SOMNIFERUM;PLATYCODON GRANDIFLORUS;PSEUDOSTELLARIA HETEROPHYLLA;STEMONA SPP.;VITEX NEGUNDO	0	1 (0,7)
AMMONIA;BENZOIC ACID;CAMPHOR;GLYCEROL;GLYCYRRHIZA SPP.;GUAIFENESIN;ILLICIUM VERUM;PAPAV SOMNIFERUM	0	1 (0,7)
DISPORUM SPP.;EPHEDRA SPP.;ERIOBOTRYA JAPONICA;MORUS ALBA;PAPAV SOMNIFERUM;PLATYCODON GRANDIFLORUS;POLYGONATUM SPP.;REINECKEA CARNEA;SAXIFRAGA STOLONIFERA	1 (0,3)	0
OTHER AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE	3 (1,0)	2 (1,4)
CHONDRUS CRISPUS;TITANIUM DIOXIDE;ZINC	2 (0,7)	1 (0,7)
OTHER AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE	0	1 (0,7)
RUSCOGENIN;TRIMEBUTINE	1 (0,3)	0
OTHER ANTIEMETICS	3 (1,0)	2 (1,4)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
PROMETHAZINE	1 (0,3)	1 (0,7)
DIMENHYDRINATE	0	1 (0,7)
DRONABINOL	1 (0,3)	0
HYDROXYZINE	1 (0,3)	0
HYOSCINE	1 (0,3)	0
TRIMETHOBENZAMIDE	1 (0,3)	0
OTHER ANTIEPILEPTICS	5 (1,7)	0
LEVETIRACETAM	3 (1,0)	0
LAMOTRIGINE	2 (0,7)	0
TOPIRAMATE	2 (0,7)	0
OTHER COUGH SUPPRESSANTS	1 (0,3)	4 (2,8)
BENZONATATE	0	1 (0,7)
DROPROPIZINE	0	1 (0,7)
LEVODROPROPIZINE	0	1 (0,7)
OXOLAMINE	1 (0,3)	0
SIRAITIA GROSVENORII	0	1 (0,7)
OTHER DRUGS FOR CONSTIPATION	3 (1,0)	2 (1,4)
POTASSIUM;SODIUM BICARBONATE;SODIUM SULFATE	1 (0,3)	2 (1,4)
PANAX GINSENG;ZANTHOXYLUM PIPERITUM;ZINGIBER OFFICINALE	1 (0,3)	1 (0,7)
OTHER DRUGS FOR CONSTIPATION	1 (0,3)	0
RUMEX CRISPUS	1 (0,3)	0
OXICAMS	4 (1,3)	1 (0,7)
MELOXICAM	4 (1,3)	1 (0,7)
SULFONYLUREAS	2 (0,7)	3 (2,1)
GLICLAZIDE	1 (0,3)	1 (0,7)
GLIMEPIRIDE	0	2 (1,4)
GLIPIZIDE	1 (0,3)	0
VISCOELASTIC SUBSTANCES	1 (0,3)	4 (2,8)
HYALURONIC ACID	1 (0,3)	4 (2,8)
VITAMIN B1 IN COMBINATION WITH VITAMIN B6 AND/OR VITAMIN B12	2 (0,7)	3 (2,1)
BENFOTIAMINE;CYANOCOBALAMIN;PYRIDOXINE	0	2 (1,4)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
CYANOCOBALAMIN;PYRIDOXINE;THIAMINE	1 (0,3)	1 (0,7)
PYRIDOXINE;RIBOFLAVIN;THIAMINE	1 (0,3)	0
ADRENERGIC AND DOPAMINERGIC AGENTS	2 (0,7)	2 (1,4)
NOREPINEPHRINE	1 (0,3)	1 (0,7)
EPHEDRINE	0	1 (0,7)
EPINEPHRINE	1 (0,3)	0
ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT	4 (1,3)	0
NYSTATIN	2 (0,7)	0
MAGIC MOUTHWASH	1 (0,3)	0
TINIDAZOLE	1 (0,3)	0
ANTIINFECTIVES FOR TREATMENT OF ACNE	3 (1,0)	1 (0,7)
CLINDAMYCIN	2 (0,7)	0
ERYTHROMYCIN	1 (0,3)	0
NADIFLOXACIN	0	1 (0,7)
BILE ACID SEQUESTRANTS	2 (0,7)	2 (1,4)
COLESEVELAM	1 (0,3)	1 (0,7)
COLESTIPOL	0	1 (0,7)
COLESTYRAMINE	1 (0,3)	0
BILE ACIDS AND DERIVATIVES	1 (0,3)	3 (2,1)
URSODEOXYCHOLIC ACID	1 (0,3)	3 (2,1)
BISPHOSPHONATES	0	4 (2,8)
ALENDRONIC ACID	0	2 (1,4)
ZOLEDRONIC ACID	0	2 (1,4)
CARBAPENEMS	3 (1,0)	1 (0,7)
MEROPENEM	2 (0,7)	1 (0,7)
ERTAPENEM	2 (0,7)	0
CORTICOSTEROIDS, MODERATELY POTENT, OTHER COMBINATIONS	3 (1,0)	1 (0,7)
FLUMETASONE;SALICYLIC ACID	2 (0,7)	0
CAMPHOR;DEXAMETHASONE;MENTHOL	0	1 (0,7)
TRIAMCINOLONE;UREA	1 (0,3)	0
COVID-19 VACCINES	2 (0,7)	2 (1,4)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
COVID-19 VACCINE	2 (0,7)	2 (1,4)
DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES	1 (0,3)	3 (2,1)
QUETIAPINE	0	3 (2,1)
OLANZAPINE	1 (0,3)	1 (0,7)
DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	2 (0,7)	2 (1,4)
MONTMORILLONITE	1 (0,3)	2 (1,4)
TEPRENONE	1 (0,3)	0
DRUGS FOR URINARY FREQUENCY AND INCONTINENCE	2 (0,7)	2 (1,4)
DROTAVERINE	0	1 (0,7)
OXYBUTYNIN	1 (0,3)	0
SOLIFENACIN	1 (0,3)	0
VIBEGRON	0	1 (0,7)
ENZYMES	3 (1,0)	1 (0,7)
PRONASE	1 (0,3)	1 (0,7)
BROMELAINS	1 (0,3)	0
STREPTOKINASE	1 (0,3)	0
ESTERS OF AMINOBENZOIC ACID	3 (1,0)	1 (0,7)
OXYBUPROCAINE	2 (0,7)	0
TETRACAINE	1 (0,3)	1 (0,7)
FIBRATES	3 (1,0)	1 (0,7)
FENOFIBRATE	2 (0,7)	0
BEZAFIBRATE	1 (0,3)	0
GEMFIBROZIL	0	1 (0,7)
HERBAL CARMINATIVES	2 (0,7)	2 (1,4)
CURCUMA LONGA	1 (0,3)	1 (0,7)
ANGELICA ARCHANGELICA; CARUM CARVI; CHELIDONIUM MAJUS; GLYCYRRHIZA GLABRA; IBERIS AMARA; MATRICARIA CHAMOMILLA; MELISSA OFFICINALIS; MENTHA X PIPERITA; SILYBUM MARIANUM	0	1 (0,7)
MENTHA X PIPERITA	1 (0,3)	0
NIGELLA SATIVA	1 (0,3)	0
HERBAL DIAPHORETICS AND OTHER HERBAL COUGH AND COLD REMEDIES	1 (0,3)	3 (2,1)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
ANGELICA DAHURICA; CINNAMOMUM CASSIA; CITRUS AURANTIUM; EPHEDRA SPP.; GLYCYRRHIZA SPP.; PERILLA FRUTESCENS; PLATYCODON GRANDIFLORUS; PRUNUS SPP.; PUERARIA MONTANA VAR. LOBATA; SAPOSHNIKOVIA DIVARICATA;	1 (0,3)	0
ARTEMISIA ANNUA; GARDENIA JASMINOIDES; LONICERA JAPONICA	0	1 (0,7)
CINNAMOMUM CASSIA; EPHEDRA SPP.; GLYCYRRHIZA SPP.; PAEONIA LACTIFLORA; PUERARIA MONTANA VAR. LOBATA; ZINGIBER OFFICINALE; ZIZIPHUS JUJUBA	0	1 (0,7)
FORSYTHIA SUSPENSAS; LONICERA JAPONICA; SCUTELLARIA BAICALENSIS	0	1 (0,7)
INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING	1 (0,3)	3 (2,1)
INSULIN	0	2 (1,4)
INSULIN ASPART	0	1 (0,7)
INSULIN HUMAN	1 (0,3)	0
INTRAUTERINE CONTRACEPTIVES	1 (0,3)	3 (2,1)
LEVONORGESTREL	0	2 (1,4)
COPPER	0	1 (0,7)
INTRAUTERINE CONTRACEPTIVE DEVICE	1 (0,3)	0
NEURAMINIDASE INHIBITORS	2 (0,7)	2 (1,4)
OSELTAMIVIR	1 (0,3)	2 (1,4)
PERAMIVIR	1 (0,3)	0
OTHER ANTIALLERGICS	2 (0,7)	2 (1,4)
AZELASTINE	1 (0,3)	0
EMEDASTINE	0	1 (0,7)
LEVOCABASTINE	1 (0,3)	0
OLOPATADINE	0	1 (0,7)
OTHER ANTIFUNGALS FOR TOPICAL USE	3 (1,0)	1 (0,7)
TERBINAFINE	2 (0,7)	1 (0,7)
UREA	1 (0,3)	0
OTHER NASAL PREPARATIONS	4 (1,3)	0
OTHER NASAL PREPARATIONS	2 (0,7)	0
CAMPHOR; MENTHOL	1 (0,3)	0
DEXPANTHENOL; RETINOL; VITAMIN E NOS	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
OTHER OPHTHALMOLOGICALS	1 (0,3)	3 (2,1)
CARBOMER	0	1 (0,7)
CARMELLOSE	1 (0,3)	0
CICLOSPORIN	0	1 (0,7)
DIQUAFOSOL	0	1 (0,7)
MACROGOL	0	1 (0,7)
OTHER SYSTEMIC HEMOSTATICS	3 (1,0)	1 (0,7)
CARBAZOCHROME;SODIUM CHLORIDE	2 (0,7)	0
CARBAZOCHROME	0	1 (0,7)
ETAMSILATE	1 (0,3)	0
OTHER THROAT PREPARATIONS	3 (1,0)	1 (0,7)
IBUPROFEN	2 (0,7)	0
ALOE VERA;RETINOL;VITAMIN E NOS	1 (0,3)	0
FLURBIPROFEN	0	1 (0,7)
PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM	4 (1,3)	0
COLCHICINE	4 (1,3)	0
SOFTENERS, EMOLLIENTS	2 (0,7)	2 (1,4)
PARAFFIN, LIQUID	1 (0,3)	2 (1,4)
DOCUSATE	1 (0,3)	0
SULFONAMIDES, PLAIN	3 (1,0)	1 (0,7)
FUROSEMIDE	3 (1,0)	1 (0,7)
SYNTHETIC ANTICHOLINERGICS, QUATERNARY AMMONIUM COMPOUNDS	3 (1,0)	1 (0,7)
OTILONIUM	2 (0,7)	0
GLYCOPYRRONIUM	0	1 (0,7)
TROSPIUM	1 (0,3)	0
TETANUS VACCINES	4 (1,3)	0
TETANUS VACCINE	3 (1,0)	0
DIPHThERIA VACCINE;TETANUS VACCINE	1 (0,3)	0
TUMOR NECROSIS FACTOR ALPHA (TNF-) INHIBITORS	1 (0,3)	3 (2,1)
ADALIMUMAB	0	2 (1,4)
INFLIXIMAB	1 (0,3)	1 (0,7)
VITAMINS, OTHER COMBINATIONS	2 (0,7)	2 (1,4)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
ASCORBIC ACID;BIOTIN;CHROMIUM;COLECALCIFEROL;COPPER;FOLIC ACID;IODINE;MAGNESIUM;MANGANESE;NICOTINAMIDE;PANT OTHENIC ACID;PYRIDOXINE;RETINOL;RIBOFLAVIN;SELENIUM;VITAMIN B1 NOS;VITAMIN B12 NOS;	1 (0,3)	1 (0,7)
ASCORBIC ACID;BENFOTIAMINE;BIOTIN;CHOLINE;CYANOCOBALAMIN;FO LIC ACID;INOSITOL;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;ZINC	1 (0,3)	0
ASCORBIC ACID;BETA VULGARIS;BIOFLAVONOIDS NOS;CALCIUM;COPPER;CYSTEINE;FOLIC ACID;IRON;MANGANESE;MECOBALAMIN;NICOTINAMIDE;PANT OTHENIC ACID;PIPER NIGRUM;PROANTHOCYANIDIN;PYRIDOXINE;RIBOFLAVIN;SELE NIUM;	0	1 (0,7)
ACE INHIBITORS AND DIURETICS	2 (0,7)	1 (0,7)
FOSINOPRIL;HYDROCHLOROTHIAZIDE	0	1 (0,7)
HYDROCHLOROTHIAZIDE;LISINOPRIL	1 (0,3)	0
HYDROCHLOROTHIAZIDE;RAMIPRIL	1 (0,3)	0
ALDOSTERONE ANTAGONISTS	2 (0,7)	1 (0,7)
SPIRONOLACTONE	2 (0,7)	1 (0,7)
ANTIEMETICS AND ANTINAUSEANTS	2 (0,7)	1 (0,7)
METOCLOPRAMIDE	1 (0,3)	1 (0,7)
DROPERIDOL	1 (0,3)	0
ANTIFUNGALS FOR SYSTEMIC USE	3 (1,0)	0
TERBINAFINE	3 (1,0)	0
ANTIHISTAMINES FOR TOPICAL USE	2 (0,7)	1 (0,7)
DIPHENHYDRAMINE	1 (0,3)	1 (0,7)
PROMETHAZINE	1 (0,3)	0
ANTIVIRALS	3 (1,0)	0
ACICLOVIR	2 (0,7)	0
INTERFERON ALFA-2B	1 (0,3)	0
BETA BLOCKING AGENTS, NON-SELECTIVE	1 (0,3)	2 (1,4)
PROPRANOLOL	0	2 (1,4)
SOTALOL	1 (0,3)	0
BIOFLAVONOIDS	1 (0,3)	2 (1,4)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
DIOSMIN	0	1 (0,7)
DIOSMIN;HESPERIDIN	0	1 (0,7)
TROXERUTIN	1 (0,3)	0
BUTYROPHENONE DERIVATIVES	2 (0,7)	1 (0,7)
DROPERIDOL	1 (0,3)	0
HALOPERIDOL	1 (0,3)	0
LUMATEPERONE	0	1 (0,7)
CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION	1 (0,3)	2 (1,4)
DEXAMETHASONE;TOBRAMYCIN	1 (0,3)	1 (0,7)
DEXAMETHASONE;NEOMYCIN	0	1 (0,7)
CORTICOSTEROIDS, WEAK (GROUP I)	1 (0,3)	2 (1,4)
HYDROCORTISONE	1 (0,3)	2 (1,4)
DRUGS USED IN ERECTILE DYSFUNCTION	3 (1,0)	0
TADALAFIL	2 (0,7)	0
SILDENAFIL	1 (0,3)	0
GENERAL NUTRIENTS	2 (0,7)	1 (0,7)
NUTRIENTS NOS	2 (0,7)	1 (0,7)
HERBAL ANTIINFLAMMATORY AND ANTIRHEUMATIC REMEDIES	3 (1,0)	0
BORNEOL;CALCIUM SULFATE;COW BEZOAR;GLYCYRRHIZA URALENSIS;PLATYCODON GRANDIFLORUS;REALGAR;RHEUM OFFICINALE;SCUTELLARIA BAICALENSIS	1 (0,3)	0
BOSWELLIA SPP.;CURCUMA LONGA	1 (0,3)	0
GLYCYRRHIZA SPP.;PAEONIA LACTIFLORA	1 (0,3)	0
HERBAL EXPECTORANTS AND EMOLLIENTS	1 (0,3)	2 (1,4)
ARCTIUM LAPPA;CICADA SLOUGH;EPHEDRA SPP.;ERIOBOTRYA JAPONICA;KITAGAWIA PRAERUPTORA;PERILLA FRUTESCENS;PHERETIMA SPP.;SCHISANDRA CHINENSIS	1 (0,3)	1 (0,7)
CITRUS MAXIMA;DELPHINIUM GRANDIFLORUM;GLYCYRRHIZA SPP.;PINELLIA TERNATA;PORIA COCOS;PRUNUS SPP.;SCHISANDRA CHINENSIS;VINCETOXICUM STAUNTONII	0	1 (0,7)
ERIOBOTRYA JAPONICA	1 (0,3)	0
FRITILLARIA SPP.;GLYCYRRHIZA SPP.;MENTHA CANADENSIS;OPHIOPOGON JAPONICUS;PAEONIA LACTIFLORA;PAEONIA X SUFFRUTICOSA;REHMANNIA GLUTINOSA;SCROPHULARIA NINGPOENSIS	0	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
IODINE PRODUCTS	3 (1,0)	0
POVIDONE-IODINE	3 (1,0)	0
LIVER THERAPY	3 (1,0)	0
ADENINE;CARNITINE;CYANOCOBALAMIN;LIVER;PYRIDOXINE; RIBOFLAVIN	1 (0,3)	0
DL-METHIONINE;GLYCINE;GLYCYRRHIZIC ACID	1 (0,3)	0
POLYENE PHOSPHATIDYLCHOLINE	1 (0,3)	0
SILYBUM MARIANUM	1 (0,3)	0
MAGNESIUM COMPOUNDS	3 (1,0)	0
MAGNESIUM HYDROXIDE	2 (0,7)	0
MAGNESIUM OXIDE	1 (0,3)	0
MINERALOCORTICOIDS	3 (1,0)	0
FLUDROCORTISONE	3 (1,0)	0
MULTIVITAMINS, OTHER COMBINATIONS	3 (1,0)	0
MULTIVITAMINS, OTHER COMBINATIONS	2 (0,7)	0
AMINO ACIDS NOS;ASCORBIC ACID;BIOTIN;FOLIC ACID;GLUCOSE;HONEY;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RETINOL;RIBOFLAVIN;ROYAL JELLY;TOCOPHEROL;VITAMIN B1 NOS;VITAMIN B12 NOS;VITAMIN D NOS	1 (0,3)	0
NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN	1 (0,3)	2 (1,4)
ESTRADIOL	0	2 (1,4)
ETHINYLESTRADIOL	1 (0,3)	0
ORAL REHYDRATION SALT FORMULATIONS	3 (1,0)	0
GLUCOSE;POTASSIUM;SODIUM CHLORIDE;SODIUM CITRATE	1 (0,3)	0
GLUCOSE;POTASSIUM;SODIUM CITRATE	1 (0,3)	0
ORAL REHYDRATION SALT FORMULATIONS	1 (0,3)	0
OTHER AGENTS FOR LOCAL ORAL TREATMENT	3 (1,0)	0
BENZYDAMINE	1 (0,3)	0
LIDOCAINE	1 (0,3)	0
SUCRALFATE	1 (0,3)	0
OTHER ANTIBACTERIALS	1 (0,3)	2 (1,4)
FOSFOMYCIN	1 (0,3)	2 (1,4)
OTHER BLOOD PRODUCTS	3 (1,0)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
RED BLOOD CELLS	2 (0,7)	0
BLOOD, WHOLE	1 (0,3)	0
OTHER CARDIAC PREPARATIONS	3 (1,0)	0
IVABRADINE	1 (0,3)	0
MEGLUMINE ADENOSINE CYCLOPHOSPHATE	1 (0,3)	0
TRIMETAZIDINE	1 (0,3)	0
OTHER LOCAL ANESTHETICS	1 (0,3)	2 (1,4)
DYCLONINE	1 (0,3)	2 (1,4)
PREPARATIONS WITH SALICYLIC ACID DERIVATIVES	3 (1,0)	0
ACETYLSALICYLIC ACID	2 (0,7)	0
SALICYLIC ACID	1 (0,3)	0
SELECTIVE SEROTONIN (5HT1) AGONISTS	3 (1,0)	0
SUMATRIPTAN	2 (0,7)	0
RIZATRIPTAN	1 (0,3)	0
SOFT PARAFFIN AND FAT PRODUCTS	2 (0,7)	1 (0,7)
WHITE SOFT PARAFFIN	2 (0,7)	0
BISABOOL; CERESIN; PARAFFIN SOFT; PARAFFIN, LIQUID; WOOL ALCOHOLS	0	1 (0,7)
SOLUTIONS PRODUCING OSMOTIC DIURESIS	2 (0,7)	1 (0,7)
MANNITOL	2 (0,7)	0
GLYCEROL	0	1 (0,7)
SOMATOSTATIN AND ANALOGUES	3 (1,0)	0
SOMATOSTATIN	2 (0,7)	0
OCTREOTIDE	1 (0,3)	0
3-OXOANDROSTEN (4) DERIVATIVES	1 (0,3)	1 (0,7)
TESTOSTERONE	1 (0,3)	1 (0,7)
ACE INHIBITORS, OTHER COMBINATIONS	2 (0,7)	0
AMLODIPINE; INDAPAMIDE; PERINDOPRIL	2 (0,7)	0
ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS	1 (0,3)	1 (0,7)
FENOTEROL; IPRATROPIUM	1 (0,3)	0
IPRATROPIUM; SALBUTAMOL	0	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE	0	2 (1,4)
GLYCERYL TRINITRATE;LIDOCAINE	0	1 (0,7)
LIDOCAINE;METRONIDAZOLE;SUCRALFATE	0	1 (0,7)
ALPHA AND BETA BLOCKING AGENTS	2 (0,7)	0
CARVEDILOL	2 (0,7)	0
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS	1 (0,3)	1 (0,7)
HYDROCHLOROTHIAZIDE;TELMISARTAN	1 (0,3)	0
HYDROCHLOROTHIAZIDE;VALSARTAN	0	1 (0,7)
ANTACIDS	2 (0,7)	0
ANTACIDS	2 (0,7)	0
ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS	1 (0,3)	1 (0,7)
AZELASTINE	1 (0,3)	0
OLOPATADINE	0	1 (0,7)
ANTIBACTERIALS FOR SYSTEMIC USE	2 (0,7)	0
ANTIBIOTICS	2 (0,7)	0
ANTICHOLINERGICS	2 (0,7)	0
PHENYLEPHRINE;TROPICAMIDE	1 (0,3)	0
TIOTROPIUM	1 (0,3)	0
AVERMECTINES	2 (0,7)	0
IVERMECTIN	2 (0,7)	0
AZASPIRODECANEDIONE DERIVATIVES	2 (0,7)	0
BUSPIRONE	2 (0,7)	0
BETA-LACTAMASE SENSITIVE PENICILLINS	1 (0,3)	1 (0,7)
PHENOXYMETHYLPENICILLIN	1 (0,3)	1 (0,7)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	1 (0,3)	1 (0,7)
CARBOHYDRATES NOS;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	1 (0,3)	1 (0,7)
BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS	2 (0,7)	0
ALBUMIN HUMAN	2 (0,7)	0
GELATIN	1 (0,3)	0
CARBAMIDE PRODUCTS	2 (0,7)	0
UREA	2 (0,7)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM AND MAGNESIUM COMPOUNDS	2 (0,7)	0
ALMAGATE	1 (0,3)	0
ALUMINIUM OXIDE;CALCIUM OXIDE;IRON;POTASSIUM;SILICON DIOXIDE	1 (0,3)	0
COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS	2 (0,7)	0
METFORMIN;SITAGLIPTIN	1 (0,3)	0
METFORMIN;VILDAGLIPTIN	1 (0,3)	0
COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES	1 (0,3)	1 (0,7)
SULFAMETHOXAZOLE;TRIMETHOPRIM	1 (0,3)	1 (0,7)
DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS	0	2 (1,4)
SITAGLIPTIN	0	1 (0,7)
TENELIGLIPTIN	0	1 (0,7)
HERBAL ANTIHEMORRHOIDS FOR TOPICAL USE	1 (0,3)	1 (0,7)
AMBER (FOSSILIZED TREE RESIN);BORIC ACID;BORNEOL;CALAMINE;COW BEZOAR;MUSK;PEARL	1 (0,3)	1 (0,7)
HERBAL ANTISPASMODIC AGENTS, OTHER	1 (0,3)	1 (0,7)
CORYDALIS YANHUSUO;IPOMOEA NIL	1 (0,3)	1 (0,7)
HERBAL ANTIVIRALS FOR SYSTEMIC USE	1 (0,3)	1 (0,7)
CALCIUM SULFATE;DRYOPTERIS CRASSIRHIZOMA;EPHEDRA SPP.;FORSYTHIA SUSPENSIA;GLYCYRRHIZA SPP.;HOULTTUYNIA CORDATA;ISATIS TINCTORIA;LONICERA JAPONICA;MENTHOL;POGOSTEMON CABLIN;PRUNUS SPP.;RHEUM SPP.;	1 (0,3)	1 (0,7)
ACORUS CALAMUS VAR. ANGUSTATUS;ANEMARRHENA ASPHODELOIDES;CALCIUM SULFATE;CURCUMA SPP.;FORSYTHIA SUSPENSIA;ISATIS TINCTORIA;PHRAGMITES AUSTRALIS SUBSP. AUSTRALIS;POGOSTEMON CABLIN;REHMANNIA GLUTINOSA	0	1 (0,7)
HERBAL DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	2 (0,7)	0
SERENOA REPENS	2 (0,7)	0
HERBAL GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	0	2 (1,4)
ACORUS CALAMUS VAR. ANGUSTATUS;ANGELICA BISERRATA;ARTEMISIA ARGYI;ARTEMISIA SPP.;ATRACTYLODES LANCEA;BASSIA SCOPARIA;CNIDIUM MONNIERI;GARDENIA JASMINOIDES;LONICERA SPP.;MENTHA CANADENSIS;	0	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
BASSIA SCOPARIA;CNIDIUM MONNIERI;COPTIS SPP.;DICTAMNUS DASYCARPUS;ISATIS TINCTORIA;PAEONIA SPP.;PHELLODENDRON CHINENSE;REYNOUTRIA MULTIFLORA;SMILAX GLABRA;SOPHORA FLAVESCENS;ZANTHOXYLUM SPP.	0	1 (0,7)
INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING	1 (0,3)	1 (0,7)
INSULIN DEGLUDEC	0	1 (0,7)
INSULIN GLARGINE	1 (0,3)	0
INTRAVAGINAL CONTRACEPTIVES	2 (0,7)	0
ETHINYLESTRADIOL;ETONOGESTREL	2 (0,7)	0
LINCOSAMIDES	2 (0,7)	0
CLINDAMYCIN	2 (0,7)	0
MORPHINAN DERIVATIVES	2 (0,7)	0
BUTORPHANOL	1 (0,3)	0
NALBUPHINE	1 (0,3)	0
ORIPAVINE DERIVATIVES	1 (0,3)	1 (0,7)
BUPRENORPHINE	1 (0,3)	1 (0,7)
OTHER AMINOGLYCOSIDES	2 (0,7)	0
GENTAMICIN	2 (0,7)	0
OTHER ANTIPRURITICS	1 (0,3)	1 (0,7)
CALAMINE	0	1 (0,7)
CALAMINE;GLYCEROL;ZINC	1 (0,3)	0
OTHER ANTISEPTICS AND DISINFECTANTS	1 (0,3)	1 (0,7)
POTASSIUM PERMANGANATE	1 (0,3)	1 (0,7)
OTHER CEPHALOSPORINS AND PENEMS	1 (0,3)	1 (0,7)
FAROPENEM	1 (0,3)	1 (0,7)
OTHER CICATRIZANTS	1 (0,3)	1 (0,7)
ACIDIC FIBROBLAST GROWTH FACTOR	0	1 (0,7)
BOVINE BASIC FIBROBLAST GROWTH FACTOR	1 (0,3)	0
OTHER COLD PREPARATIONS	2 (0,7)	0
DEXTROMETHORPHAN;DIPHENHYDRAMINE;MENTHOL	1 (0,3)	0
OTHER COLD PREPARATIONS	1 (0,3)	0
OTHER COUGH SUPPRESSANTS AND EXPECTORANTS	1 (0,3)	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
ASTER TATARICUS;CITRUS AURANTIUM;GLYCYRRHIZA SPP.;HOULTTUYNIA CORDATA;KITAGAWIA PRAERUPTORA;MORUS ALBA;PERILLA FRUTESCENS;PINELLIA TERNATA;PORIA COCOS;PRUNUS SPP.;TRICHOSANTHES SPP.;TUSSILAGO FARFARA	1 (0,3)	0
ERIOBOTRYA JAPONICA;FRITILLARIA SPP.;MENTHOL;PLATYCODON GRANDIFLORUS;SNAKE BILE;TYPHONIUM FLAGELLIFORME	0	1 (0,7)
OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION	1 (0,3)	1 (0,7)
DENOSUMAB	1 (0,3)	1 (0,7)
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	1 (0,3)	1 (0,7)
HYALURONIC ACID	1 (0,3)	1 (0,7)
OTHER LIPID MODIFYING AGENTS	2 (0,7)	0
EZETIMIBE	1 (0,3)	0
OMEGA-3-ACID ETHYL ESTER	1 (0,3)	0
OTHER NERVOUS SYSTEM DRUGS	2 (0,7)	0
GABAPENTIN	1 (0,3)	0
MECOBALAMIN	1 (0,3)	0
OTHER QUATERNARY AMMONIUM COMPOUNDS	1 (0,3)	1 (0,7)
CISATRACURIUM	0	1 (0,7)
ROCURONIUM	1 (0,3)	0
OTHER TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	2 (0,7)	0
MENTHOL	2 (0,7)	0
CAMPHOR	1 (0,3)	0
PARAMAGNETIC CONTRAST MEDIA	2 (0,7)	0
GADOPENTETIC ACID	1 (0,3)	0
GADOTERIC ACID	1 (0,3)	0
PERIPHERAL OPIOID RECEPTOR ANTAGONISTS	1 (0,3)	1 (0,7)
NALOXONE	1 (0,3)	1 (0,7)
PHENOTHIAZINE DERIVATIVES	1 (0,3)	1 (0,7)
PROMETHAZINE	1 (0,3)	1 (0,7)
PREGNADIEN DERIVATIVES	2 (0,7)	0
DIENOGEST	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
DYDROGESTERONE	1 (0,3)	0
PROSTAGLANDIN ANALOGUES	1 (0,3)	1 (0,7)
LATANOPROST	0	1 (0,7)
TRAVOPROST	1 (0,3)	0
RETINOIDS FOR TOPICAL USE IN ACNE	2 (0,7)	0
ADAPALENE;BENZOYL PEROXIDE	2 (0,7)	0
SALICYLIC ACID AND DERIVATIVES	1 (0,3)	1 (0,7)
ACETYLSALICYLIC ACID	1 (0,3)	0
SALICYLIC ACID	0	1 (0,7)
SULFUR-CONTAINING IMIDAZOLE DERIVATIVES	2 (0,7)	0
THIAMAZOLE	2 (0,7)	0
SYMPATHOMIMETICS, PLAIN	2 (0,7)	0
OXYMETAZOLINE	1 (0,3)	0
XYLOMETAZOLINE	1 (0,3)	0
TRIAZOLE AND TETRAZOLE DERIVATIVES	2 (0,7)	0
FLUCONAZOLE	2 (0,7)	0
TRIAZOLE DERIVATIVES	2 (0,7)	0
FLUCONAZOLE	2 (0,7)	0
VITAMIN A, PLAIN	1 (0,3)	1 (0,7)
VITAMIN A NOS	1 (0,3)	1 (0,7)
VITAMINS	1 (0,3)	1 (0,7)
FAT SOLUBLE VITAMINS NOS	1 (0,3)	0
VITAMINS NOS	0	1 (0,7)
WATER SOLUBLE VITAMINS NOS	1 (0,3)	0
VITAMINS WITH MINERALS	1 (0,3)	1 (0,7)
VITAMINS WITH MINERALS	1 (0,3)	1 (0,7)
WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA	2 (0,7)	0
IOHEXOL	1 (0,3)	0
IOPAMIDOL	1 (0,3)	0
ZINC PRODUCTS	2 (0,7)	0
ZINC	2 (0,7)	0
ACE INHIBITORS AND CALCIUM CHANNEL BLOCKERS	0	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
AMLODIPINE;PERINDOPRIL	0	1 (0,7)
ACID PREPARATIONS	1 (0,3)	0
CITRIC ACID	1 (0,3)	0
ACRIDINE DERIVATIVES	0	1 (0,7)
ETHACRIDINE	0	1 (0,7)
ALL OTHER NON-THERAPEUTIC PRODUCTS	1 (0,3)	0
ASCORBIC ACID	1 (0,3)	0
AMINO ACIDS AND DERIVATIVES	1 (0,3)	0
LEVOGLUTAMIDE	1 (0,3)	0
AMINO ACIDS, INCL. COMBINATIONS WITH POLYPEPTIDES	0	1 (0,7)
GELATINE HYDROLYSATE	0	1 (0,7)
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs), OTHER COMBINATIONS	0	1 (0,7)
AMLODIPINE;HYDROCHLOROTHIAZIDE;VALSARTAN	0	1 (0,7)
ANTIARRHYTHMICS, CLASS IC	0	1 (0,7)
FLECAINIDE	0	1 (0,7)
ANTIBIOTICS AND CORTICOSTEROIDS	0	1 (0,7)
NYSTATIN;TRIAMCINOLONE	0	1 (0,7)
ANTICHOLINESTERASES	0	1 (0,7)
NEOSTIGMINE	0	1 (0,7)
ANTIHISTAMINES FOR SYSTEMIC USE	1 (0,3)	0
ANTIHISTAMINES	1 (0,3)	0
ANTIINFLAMMATORY AGENTS, NON-STERIODS	0	1 (0,7)
PRANOPROFEN	0	1 (0,7)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.	1 (0,3)	0
DIMETINDENE	1 (0,3)	0
BARBITURATES, PLAIN	1 (0,3)	0
THIOPENTAL	1 (0,3)	0
BARIUM SULFATE CONTAINING X-RAY CONTRAST MEDIA	0	1 (0,7)
BARIUM	0	1 (0,7)
BENZIMIDAZOLE DERIVATIVES	1 (0,3)	0
ALBENDAZOLE	1 (0,3)	0
BENZOTHIAZEPINE DERIVATIVES	0	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
DILTIAZEM	0	1 (0,7)
BETA BLOCKING AGENTS AND CALCIUM CHANNEL BLOCKERS	0	1 (0,7)
AMLODIPINE;BISOPROLOL	0	1 (0,7)
BETA-LACTAMASE RESISTANT PENICILLINS	1 (0,3)	0
FLUCLOXACILLIN	1 (0,3)	0
BISMUTH PREPARATIONS	1 (0,3)	0
BISMUTH	1 (0,3)	0
BISPHOSPHONATES, COMBINATIONS	1 (0,3)	0
ALENDRONIC ACID;COLECALCIFEROL	1 (0,3)	0
BORIC ACID PRODUCTS	1 (0,3)	0
BORIC ACID	1 (0,3)	0
CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS	1 (0,3)	0
RIMEGEPANT	1 (0,3)	0
CARBONIC ANHYDRASE INHIBITORS	1 (0,3)	0
BRINZOLAMIDE	1 (0,3)	0
CENTRALLY ACTING ANTI OBESITY PRODUCTS	1 (0,3)	0
AMFETAMINE;DEXAMFETAMINE	1 (0,3)	0
COLONY STIMULATING FACTORS	1 (0,3)	0
GRANULOCYTE COLONY STIMULATING FACTOR	1 (0,3)	0
COMBINATIONS OF VARIOUS LIPID MODIFYING AGENTS	1 (0,3)	0
ATORVASTATIN;EZETIMIBE	1 (0,3)	0
CORTICOSTEROIDS FOR LOCAL ORAL TREATMENT	1 (0,3)	0
DEXAMETHASONE	1 (0,3)	0
CORTICOSTEROIDS, POTENT, COMBINATIONS WITH ANTISEPTICS	1 (0,3)	0
HALOMETASONE;TRICLOSAN	1 (0,3)	0
CORTICOSTEROIDS, WEAK, COMBINATIONS WITH ANTIBIOTICS	0	1 (0,7)
CHLORAMPHENICOL;PREDNISOLONE	0	1 (0,7)
COUGH AND COLD PREPARATIONS	0	1 (0,7)
COUGH AND COLD PREPARATIONS	0	1 (0,7)
DIPHENYLMETHANE DERIVATIVES	0	1 (0,7)
HYDROXYZINE	0	1 (0,7)
DIRECT THROMBIN INHIBITORS	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
DABIGATRAN	1 (0,3)	0
DOPAMINE AGONISTS	1 (0,3)	0
ROPINIROLE	1 (0,3)	0
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	1 (0,3)	0
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	1 (0,3)	0
DRUGS USED IN NICOTINE DEPENDENCE	1 (0,3)	0
NICOTINE	1 (0,3)	0
EMOLLIENTS AND PROTECTIVES	1 (0,3)	0
RETINOL;TOCOPHEROL	1 (0,3)	0
ENCEPHALITIS VACCINES	1 (0,3)	0
TICK-BORNE ENCEPHALITIS VACCINE	1 (0,3)	0
ERGOT ALKALOIDS	0	1 (0,7)
DIHYDROERGOTAMINE	0	1 (0,7)
ESTREN DERIVATIVES	0	1 (0,7)
LYNESTRENOL	0	1 (0,7)
ETHERS CHEMICALLY CLOSE TO ANTIHISTAMINES	0	1 (0,7)
DIPHENHYDRAMINE	0	1 (0,7)
ETHERS, CHEMICALLY CLOSE TO ANTIHISTAMINES	0	1 (0,7)
CAFFEINE;METAMIZOLE;ORPHENADRINE	0	1 (0,7)
FENAMATES	0	1 (0,7)
DICYCLOVERINE;MEFENAMIC ACID	0	1 (0,7)
FOLIC ACID ANALOGUES	1 (0,3)	0
METHOTREXATE	1 (0,3)	0
FOURTH-GENERATION CEPHALOSPORINS	1 (0,3)	0
CEFEPIME	1 (0,3)	0
GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES	1 (0,3)	0
SEMAGLUTIDE	1 (0,3)	0
HALOGENATED HYDROCARBONS	0	1 (0,7)
SEVOFLURANE	0	1 (0,7)
HEPATITIS VACCINES	1 (0,3)	0
HEPATITIS B VACCINE	1 (0,3)	0
HERBAL ANTIANEMIC PREPARATIONS	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
ASTRAGALUS MONGHOLICUS;CIBOTIUM BAROMETZ;ECLIPTA PROSTRATA;LIGUSTRUM LUCIDUM;MORUS ALBA;PAEONIA LACTIFLORA;REYNOUTRIA MULTIFLORA	1 (0,3)	0
HERBAL ANTIEMETICS CONTAINING CANNABINOIDS	0	1 (0,7)
CANNABIS SATIVA	0	1 (0,7)
HERBAL ANTIMIGRAINE REMEDIES	1 (0,3)	0
PANAX GINSENG;TETRADIUM RUTICARPUM;ZINGIBER OFFICINALE;ZIZIPHUS JUJUBA	1 (0,3)	0
HERBAL COUGH AND COLD REMEDIES, OTHER	1 (0,3)	0
ANEMARRHENA ASPHODELOIDES;CALCIUM SULFATE;ISATIS TINCTORIA;PRUNUS SPP.;REHMANNIA GLUTINOSA;SCROPHULARIA NINGPOENSIS;TROLLIUS CHINENSIS	1 (0,3)	0
HERBAL IMMUNOMODULATORS	1 (0,3)	0
ANGELICA SINENSIS;ASINI CORII COLLA;ASTRAGALUS MONGHOLICUS;EPIMEDIUM BREVICORNU;LESPEDeza BUERGERI;SOPHORA FLAVESCENS;ZIZIPHUS JUJUBA	1 (0,3)	0
HERBAL PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS CONTAINING TANNINS	1 (0,3)	0
HAMAMELIS VIRGINIANA	1 (0,3)	0
HERBAL PREPARATIONS FOR TREATMENT OF WOUNDS AND ULCERS, OTHER	1 (0,3)	0
ANANAS COMOSUS	1 (0,3)	0
HERBAL REMEDIES FOR OBSTRUCTIVE AIRWAY DISEASES FOR SYSTEMIC USE, OTHER	1 (0,3)	0
ANEMARRHENA ASPHODELOIDES;CALCIUM SULFATE;GARDENIA JASMINOIDES;GENTIANA SPP.;MENTHOL;SCROPHULARIA NINGPOENSIS;SCUTELLARIA BAICALENSIS;STELLARIA DICHOTOMA VAR. LANCEOLATA	1 (0,3)	0
HERBAL REMEDIES FOR TREATMENT OF PEPTIC ULCER CONTAINING MUCILAGE	1 (0,3)	0
ULMUS RUBRA	1 (0,3)	0
HERBAL REMEDIES FOR TREATMENT OF PEPTIC ULCER, OTHER	1 (0,3)	0
PERIPLANETA AMERICANA	1 (0,3)	0
HERBAL VITAMIN REMEDIES CONTAINING VITAMIN B	0	1 (0,7)
SACCHAROMYCES CEREVISIAE	0	1 (0,7)
HIGH-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
AMILORIDE;FUROSEMIDE	1 (0,3)	0
HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	1 (0,3)	0
ESTRADIOL;NORETHISTERONE	1 (0,3)	0
HYDRAZINOPHTHALAZINE DERIVATIVES	1 (0,3)	0
HYDRALAZINE	1 (0,3)	0
HYPNOTICS AND SEDATIVES IN COMBINATION, EXCL. BARBITURATES	0	1 (0,7)
HYPNOTICS AND SEDATIVES IN COMBINATION, EXCL. BARBITURATES	0	1 (0,7)
IMIDAZOLINE DERIVATIVES	1 (0,3)	0
PHENTOLAMINE	1 (0,3)	0
IMMUNE SERA	1 (0,3)	0
TETANUS ANTITOXIN	1 (0,3)	0
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING	0	1 (0,7)
INSULIN ASPART	0	1 (0,7)
INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- ACTING	0	1 (0,7)
INSULIN HUMAN	0	1 (0,7)
INTERFERONS	0	1 (0,7)
INTERFERON ALFA-2B	0	1 (0,7)
LITHIUM	1 (0,3)	0
LITHIUM	1 (0,3)	0
MEDICATED DRESSINGS	0	1 (0,7)
ALGINIC ACID	0	1 (0,7)
CARMELLOSE	0	1 (0,7)
MEDICATED DRESSINGS WITH ANTIINFECTIVES	1 (0,3)	0
MEDICATED DRESSINGS WITH ANTIINFECTIVES	1 (0,3)	0
NASAL DECONGESTANTS FOR SYSTEMIC USE	1 (0,3)	0
ANGELICA DAHURICA;EPHEDRA SPP.;LIGUSTICUM CHUANXIONG;NOTOPTERYGIUM SPP.;SELAGINELLA SPP.;SENECIO SCANDENS;SENNA SPP.	1 (0,3)	0
NITROFURAN DERIVATIVES	0	1 (0,7)
NITROFURAL	0	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
Not coded	1 (0,3)	0
Not coded [CMTRT=Calcitriol]	1 (0,3)	0
OTHER AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES	1 (0,3)	0
NITAZOXANIDE	1 (0,3)	0
OTHER ANTI-ACNE PREPARATIONS FOR TOPICAL USE	1 (0,3)	0
LAURIC ACID;SALICYLIC ACID;ZINC	1 (0,3)	0
OTHER ANTIINFECTIVES AND ANTISEPTICS	0	1 (0,7)
NIFURATEL	0	1 (0,7)
OTHER ANTIPSORIATICS FOR TOPICAL USE	1 (0,3)	0
BETAMETHASONE;TAZAROTENE	1 (0,3)	0
CALCIPOTRIOL	1 (0,3)	0
TAPINAROF	1 (0,3)	0
OTHER ANTIPSYCHOTICS	1 (0,3)	0
CARIPRAZINE	1 (0,3)	0
OTHER ANTISPASMODICS IN COMBINATION WITH ANALGESICS	0	1 (0,7)
METAMIZOLE;PITOFENONE	0	1 (0,7)
OTHER CAPILLARY STABILIZING AGENTS	1 (0,3)	0
ESCIN	1 (0,3)	0
OTHER COMBINATIONS OF NUTRIENTS	1 (0,3)	0
CREATINE	1 (0,3)	0
OTHER DIURETICS	0	1 (0,7)
ISOSORBIDE	0	1 (0,7)
OTHER DRUGS FOR ACID RELATED DISORDERS	1 (0,3)	0
POTASSIUM CITRATE;SODIUM CITRATE	1 (0,3)	0
OTHER ECTOPARASITICIDES, INCL. SCABICIDES	0	1 (0,7)
DIMETICONE	0	1 (0,7)
OTHER I.V. SOLUTION ADDITIVES	1 (0,3)	0
ASCORBIC ACID;BIOTIN;CYANOCOBALAMIN;FOLIC ACID;GLYCINE;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	1 (0,3)	0
OTHER IRRIGATING SOLUTIONS	1 (0,3)	0
GLUCOSE	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
OTHER MINERAL PRODUCTS	1 (0,3)	0
SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	1 (0,3)	0
OTHER NUTRIENTS	1 (0,3)	0
OMEGA-3 FATTY ACIDS	1 (0,3)	0
OTHER PERIPHERAL VASODILATORS	1 (0,3)	0
PAPAVERINE	1 (0,3)	0
OTHER THERAPEUTIC PRODUCTS	1 (0,3)	0
MUCOPOLYSACCHARIDES	1 (0,3)	0
PERTUSSIS VACCINES	0	1 (0,7)
DIPHTHERIA VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE	0	1 (0,7)
PROTEASE INHIBITORS	0	1 (0,7)
NIRMATRELVIR;RITONAVIR	0	1 (0,7)
PROTEIN SUPPLEMENTS	1 (0,3)	0
PROTEIN SUPPLEMENTS	1 (0,3)	0
PYRETHRINES, INCL. SYNTHETIC COMPOUNDS	1 (0,3)	0
PERMETHRIN	1 (0,3)	0
RABIES VACCINES	1 (0,3)	0
RABIES VACCINE	1 (0,3)	0
RETINOIDS FOR TREATMENT OF ACNE	1 (0,3)	0
ISOTRETINOIN	1 (0,3)	0
SALICYLIC ACID PREPARATIONS	1 (0,3)	0
MENTHOL;SALICYLIC ACID	1 (0,3)	0
SELECTIVE IMMUNOSUPPRESSANTS	1 (0,3)	0
VEDOLIZUMAB	1 (0,3)	0
SELENIUM	0	1 (0,7)
SELENIUM	0	1 (0,7)
SEROTONIN RECEPTOR ANTAGONISTS	0	1 (0,7)
ALOSETRON	0	1 (0,7)
SILICONE PRODUCTS	0	1 (0,7)
DIMETICONE	0	1 (0,7)
SPECIFIC IMMUNOGLOBULINS	0	1 (0,7)
BEZLOTOXUMAB	0	1 (0,7)

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
SYMPATHOMIMETICS IN GLAUCOMA THERAPY	0	1 (0,7)
BRIMONIDINE	0	1 (0,7)
SYMPATHOMIMETICS USED AS DECONGESTANTS	0	1 (0,7)
AMINOCAPROIC ACID;CHLORPHENAMINE;NEOSTIGMINE;POTASSIUM ASPARTATE;PYRIDOXINE;TAURINE;TETRYZOLINE	0	1 (0,7)
AMINOCAPROIC ACID;CHLORPHENAMINE;NEOSTIGMINE;POTASSIUM ASPARTATE;TAURINE;TETRYZOLINE	0	1 (0,7)
SYNTHETIC ANTISPASMODICS, AMIDES WITH TERTIARY AMINES	1 (0,3)	0
TIROPRAMIDE	1 (0,3)	0
TECHNETIUM (99MTC) COMPOUNDS	0	1 (0,7)
TECHNETIUM (99M TC) SESTAMIBI	0	1 (0,7)
TECHNICAL DISINFECTANTS	1 (0,3)	0
CHLORIDE	1 (0,3)	0
THIAZOLIDINEDIONES	0	1 (0,7)
PIOGLITAZONE	0	1 (0,7)
THROAT PREPARATIONS	0	1 (0,7)
ASPARAGUS COCHINCHINENSIS;CANARIUM ALBUM;CICADA SLOUGH;MENTHA CANADENSIS;OPHIOPOGON JAPONICUS;OROXYLUM INDICUM;PAEONIA X SUFFRUTICOSA;REHMANNIA GLUTINOSA;SCROPHULARIA NINGPOENSIS;STEMONA SPP.;	0	1 (0,7)
TONICS	1 (0,3)	0
CURCUMIN	1 (0,3)	0
VITAMIN K ANTAGONISTS	1 (0,3)	0
ACENOCOUMAROL	1 (0,3)	0
WATERSOLUBLE, NEPHROTROPIC, HIGH OSMOLAR X-RAY CONTRAST MEDIA	0	1 (0,7)
IOXITALAMIC ACID	0	1 (0,7)
XANTHINE DERIVATIVES	0	1 (0,7)
CAFFEINE	0	1 (0,7)
XANTHINES	1 (0,3)	0
AMBROXOL ACEFYLLINATE	1 (0,3)	0
THEOBROMINE	1 (0,3)	0

Medication Class Preferred Term	Mirikizumab (N=300) n (%)	Ustekinumab (N=145) n (%)
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; n: Anzahl der Patienten; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; TNF: Tumor Necrosis Factor.		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_conmed.sas
Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_conmed_ittb.rtf
Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/adcm
/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba
23SEP2024 / 04:34

Anhang 4-G.4.3 Behandlungsdauer in RCT VIVID-1 in Teilpopulation B

Behandlungsdauer (Wochen) in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Merkmal	Mirikizumab (N=300)	Ustekinumab (N=145)
Weeks of exposure, n (%)		
> 0 week	299 (99,7)	145 (100,0)
≥ 4 weeks	298 (99,3)	143 (98,6)
≥ 8 weeks	296 (98,7)	142 (97,9)
≥ 12 weeks	292 (97,3)	140 (96,6)
≥ 16 weeks	284 (94,7)	140 (96,6)
≥ 24 weeks	272 (90,7)	137 (94,5)
≥ 32 weeks	268 (89,3)	129 (89,0)
≥ 40 weeks	262 (87,3)	125 (86,2)
≥ 48 weeks	257 (85,7)	123 (84,8)
Weeks of exposure, n (%)		
> 0 to < 4 weeks	1 (0,3)	2 (1,4)
≥ 4 to < 8 weeks	2 (0,7)	1 (0,7)
≥ 8 to < 12 weeks	4 (1,3)	2 (1,4)
≥ 12 to < 16 weeks	8 (2,7)	0
≥ 16 to < 24 weeks	12 (4,0)	3 (2,1)
≥ 24 to < 32 weeks	4 (1,3)	8 (5,5)
≥ 32 to < 40 weeks	6 (2,0)	4 (2,8)
≥ 40 to < 48 weeks	5 (1,7)	2 (1,4)
≥ 48 weeks	257 (85,7)	123 (84,8)
Patient weeks of exposure		
Number of patients	299	145
Mean weeks of exposure	48,93	48,98
SD	11,887	11,834
Minimum	3,1	1,1
Q1	51,86	51,86
Median	52,43	52,43
Q3	53,14	53,29
Maximum	68,0	67,9
Total patient-years ^a	280,36	136,11

Merkmal	Mirikizumab (N=300)	Ustekinumab (N=145)
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; n: Anzahl der Patienten; N: Anzahl der Patienten in der Analyse; Q1 (Q3): Quartil 1 (3); RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung. Behandlungsdauer ist berechnet als (Datum der letzten Visite der Behandlungsperiode - Datum der ersten Dosis + 1 Tag). a: Berechnet als (Summe der Behandlungsdauern über alle Patienten der jeweiligen Behandlungsgruppe / 365.25).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_exp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_exp_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/adex

/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba

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Anhang 4-G.4.4 Patientenberichtete Endpunkte in RCT VIVID-1 in Teilpopulation B

Anhang 4-G.4.4.1 Anzahl der imputierten Werte je Endpunkt in RCT VIVID-1 in Teilpopulation B

Overview of imputed values by endpoint in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpoint (at week 52)	Mirikizumab n/N (%)	Ustekinumab n/N (%)
Reduction in Urgency NRS Score by at least 3 points		
NRI due to missing values	4/300 (1,3)	7/145 (4,8)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	49/300 (16,3)	29/145 (20,0)
Increase in FACIT-Fatigue Score by at least 8 points		
NRI due to missing values	14/300 (4,7)	6/145 (4,1)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	59/300 (19,7)	28/145 (19,3)
Increase in FACIT-Fatigue Score by at least 9 points		
NRI due to missing values	14/300 (4,7)	6/145 (4,1)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	59/300 (19,7)	28/145 (19,3)
Resolution of extra-intestinal manifestations^a		
NRI due to missing values	0	0
NRI due to discontinuation of study medication	11/73 (15,1)	6/37 (16,2)
Total imputed values	11/73 (15,1)	6/37 (16,2)
Reduction in Abdominal pain by at least 0.45 points		
NRI due to missing values	4/300 (1,3)	7/145 (4,8)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	49/300 (16,3)	29/145 (20,0)
Reduction in Stool Frequency by at least 15 percent-points		
NRI due to missing values	7/300 (2,3)	7/145 (4,8)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	52/300 (17,3)	29/145 (20,0)
Closure of draining cutaneous fistulae^b		
NRI due to missing values	3/25 (12,0)	2/14 (14,3)
NRI due to discontinuation of study medication	2/25 (8,0)	2/14 (14,3)

Endpoint (at week 52)	Mirikizumab n/N (%)	Ustekinumab n/N (%)
Total imputed values	5/25 (20,0)	4/14 (28,6)
Reduction in QIDS-SR16 Total Score by at least 4.05 points		
NRI due to missing values	17/300 (5,7)	7/145 (4,8)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	62/300 (20,7)	29/145 (20,0)
Increase in EQ-5D VAS Score by at least 15 points		
NRI due to missing values	13/300 (4,3)	4/145 (2,8)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	58/300 (19,3)	26/145 (17,9)
Reduction in percentage of impairment in activities by at least 15 percent-points^c		
NRI due to missing values	7/173 (4,0)	2/80 (2,5)
NRI due to discontinuation of study medication	24/173 (13,9)	11/80 (13,8)
Total imputed values	31/173 (17,9)	13/80 (16,3)
Reduction in PGRS score by at least 1 point		
NRI due to missing values	5/300 (1,7)	7/145 (4,8)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	50/300 (16,7)	29/145 (20,0)
Reaching a value of 1 or 2 or 3 of PGIC Score		
NRI due to missing values	12/300 (4,0)	4/145 (2,8)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	57/300 (19,0)	26/145 (17,9)
Increase in SF-36 PCS Score by at least 9.4 points		
NRI due to missing values	13/300 (4,3)	4/145 (2,8)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	58/300 (19,3)	26/145 (17,9)
Increase in SF-36 MCS Score by at least 9.6 points		
NRI due to missing values	13/300 (4,3)	4/145 (2,8)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	58/300 (19,3)	26/145 (17,9)
Increase in IBDQ Total Score by at least 28.8 points		
NRI due to missing values	13/300 (4,3)	4/145 (2,8)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	58/300 (19,3)	26/145 (17,9)

Endpoint (at week 52)	Mirikizumab n/N (%)	Ustekinumab n/N (%)
Increase in IBDQ Bowel Symptoms by at least 9 points		
NRI due to missing values	13/300 (4,3)	4/145 (2,8)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	58/300 (19,3)	26/145 (17,9)
Increase in IBDQ Systemic Symptoms by at least 4.5 points		
NRI due to missing values	13/300 (4,3)	4/145 (2,8)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	58/300 (19,3)	26/145 (17,9)
Increase in IBDQ Emotional Function by at least 10.8 points		
NRI due to missing values	13/300 (4,3)	4/145 (2,8)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	58/300 (19,3)	26/145 (17,9)
Increase in IBDQ Social Function by at least 4.5 points		
NRI due to missing values	13/300 (4,3)	4/145 (2,8)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	58/300 (19,3)	26/145 (17,9)
Reduction in General well being score by at least 0.6 points		
NRI due to missing values	4/300 (1,3)	7/145 (4,8)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	49/300 (16,3)	29/145 (20,0)
Clinical remission by PRO, defined as SF$\leq$3 and AP$\leq$1		
NRI due to missing values	7/300 (2,3)	7/145 (4,8)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	52/300 (17,3)	29/145 (20,0)
Clinical Remission by PRO (AP=0)		
NRI due to missing values	4/300 (1,3)	7/145 (4,8)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	49/300 (16,3)	29/145 (20,0)
Corticosteroid-free from week 40 to week 52 and achieving clinical remission by PRO at week 52		
NRI due to missing values	7/300 (2,3)	7/145 (4,8)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	52/300 (17,3)	29/145 (20,0)
Urgency NRS Score $\leq$ 2		

Endpoint (at week 52)	Mirikizumab n/N (%)	Ustekinumab n/N (%)
NRI due to missing values	4/300 (1,3)	7/145 (4,8)
NRI due to discontinuation of study medication	45/300 (15,0)	22/145 (15,2)
Total imputed values	49/300 (16,3)	29/145 (20,0)

Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; EIMs: Extra-Intestinal Manifestations; EQ-5D: Fragebogen der EuroQol-Gruppe zur Lebensqualität auf 5 Dimensionen; FACIT: Functional Assessment of Chronic Illness Therapy-Fatigue; GWB: General Well Being; IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; MCS: Mental Health Component Summary Score; n: Anzahl der Patienten; N: Anzahl der Patienten in der Analyse; NRI: Nonresponder Imputation; NRS: Numeric Rating Scale; PCS: Physical Health Component Summary Score; PGIC: Patient Global Impression of Change; PGRS: Patient Global Rating of Severity; PRO: Patient Reported Outcome, defined as 2 of the patient-reported items of the CDAI (SF and AP); QIDS-SR16: Quick Inventory of Depressive Symptomatology - Self Report (16 items); RCT: randomisierte, kontrollierte Studie; SF-36: 36-Item Short Form Health Survey; SF: Stool Frequency; VAS: Visuelle Analogskala.

a: Calculated for participants with EIMs at baseline.

b: Calculated for participants with draining cutaneous fistulae at baseline.

c: Calculated for participants with baseline employment status of Yes.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_observed.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_observed_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adresp_gba, adsl_gba

/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/adds

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Anhang 4-G.4.4.2 Rücklaufquoten der patientenberichteten Endpunkte in RCT VIVID-1 in Teilpopulation B

Anhang 4-G.4.4.2.1 Klinische Remission

Angaben zur Vollständigkeit der Daten für PRO (AP+SF) zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
PRO (AP+SF)		
Baseline		
N-obs (%2)	295 (98,3)	145 (100,0)
N-miss (%2)	5 (1,7)	0 (0,0)
Woche 2		
N-visit	300 (100,0)	145 (100,0)
N-obs (%1) (%2)	294 (98,0) (98,0)	145 (100,0) (100,0)
N-miss (%1) (%2)	6 (2,0) (2,0)	0 (0,0) (0,0)
N-miss (%2)	0 (0,0)	0 (0,0)
Woche 4		
N-visit	296 (98,7)	143 (98,6)
N-obs (%1) (%2)	292 (98,6) (97,3)	143 (100,0) (98,6)
N-miss (%1) (%2)	4 (1,4) (1,3)	0 (0,0) (0,0)
N-miss (%2)	4 (1,3)	2 (1,4)
Woche 6		
N-visit	295 (98,3)	143 (98,6)
N-obs (%1) (%2)	290 (98,3) (96,7)	142 (99,3) (97,9)
N-miss (%1) (%2)	5 (1,7) (1,7)	1 (0,7) (0,7)
N-miss (%2)	5 (1,7)	2 (1,4)
Woche 8		
N-visit	295 (98,3)	142 (97,9)
N-obs (%1) (%2)	290 (98,3) (96,7)	142 (100,0) (97,9)
N-miss (%1) (%2)	5 (1,7) (1,7)	0 (0,0) (0,0)
N-miss (%2)	5 (1,7)	3 (2,1)
Woche 12		
N-visit	293 (97,7)	140 (96,6)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
N-obs (%1) (%2)	291 (99,3) (97,0)	139 (99,3) (95,9)
N-miss (%1) (%2)	2 (0,7) (0,7)	1 (0,7) (0,7)
N-miss (%2)	7 (2,3)	5 (3,4)
Woche 16		
N-visit	286 (95,3)	140 (96,6)
N-obs (%1) (%2)	284 (99,3) (94,7)	138 (98,6) (95,2)
N-miss (%1) (%2)	2 (0,7) (0,7)	2 (1,4) (1,4)
N-miss (%2)	14 (4,7)	5 (3,4)
Woche 20		
N-visit	279 (93,0)	140 (96,6)
N-obs (%1) (%2)	273 (97,8) (91,0)	138 (98,6) (95,2)
N-miss (%1) (%2)	6 (2,2) (2,0)	2 (1,4) (1,4)
N-miss (%2)	21 (7,0)	5 (3,4)
Woche 24		
N-visit	273 (91,0)	136 (93,8)
N-obs (%1) (%2)	268 (98,2) (89,3)	134 (98,5) (92,4)
N-miss (%1) (%2)	5 (1,8) (1,7)	2 (1,5) (1,4)
N-miss (%2)	27 (9,0)	9 (6,2)
Woche 28		
N-visit	269 (89,7)	134 (92,4)
N-obs (%1) (%2)	263 (97,8) (87,7)	128 (95,5) (88,3)
N-miss (%1) (%2)	6 (2,2) (2,0)	6 (4,5) (4,1)
N-miss (%2)	31 (10,3)	11 (7,6)
Woche 32		
N-visit	265 (88,3)	128 (88,3)
N-obs (%1) (%2)	263 (99,2) (87,7)	125 (97,7) (86,2)
N-miss (%1) (%2)	2 (0,8) (0,7)	3 (2,3) (2,1)
N-miss (%2)	35 (11,7)	17 (11,7)
Woche 36		
N-visit	264 (88,0)	126 (86,9)
N-obs (%1) (%2)	258 (97,7) (86,0)	122 (96,8) (84,1)
N-miss (%1) (%2)	6 (2,3) (2,0)	4 (3,2) (2,8)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
N-miss (%2)	36 (12,0)	19 (13,1)
Woche 40		
N-visit	260 (86,7)	125 (86,2)
N-obs (%1) (%2)	259 (99,6) (86,3)	121 (96,8) (83,4)
N-miss (%1) (%2)	1 (0,4) (0,3)	4 (3,2) (2,8)
N-miss (%2)	40 (13,3)	20 (13,8)
Woche 44		
N-visit	259 (86,3)	123 (84,8)
N-obs (%1) (%2)	251 (96,9) (83,7)	117 (95,1) (80,7)
N-miss (%1) (%2)	8 (3,1) (2,7)	6 (4,9) (4,1)
N-miss (%2)	41 (13,7)	22 (15,2)
Woche 48		
N-visit	257 (85,7)	123 (84,8)
N-obs (%1) (%2)	255 (99,2) (85,0)	119 (96,7) (82,1)
N-miss (%1) (%2)	2 (0,8) (0,7)	4 (3,3) (2,8)
N-miss (%2)	43 (14,3)	22 (15,2)
Woche 52		
N-visit	255 (85,0)	123 (84,8)
N-obs (%1) (%2)	251 (98,4) (83,7)	116 (94,3) (80,0)
N-miss (%1) (%2)	4 (1,6) (1,3)	7 (5,7) (4,8)
N-miss (%2)	45 (15,0)	22 (15,2)
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; PRO: Patient Reported Outcome, defined as 2 of the patient-reported items of the CDAI (SF and AP); RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_pro2cmp_itb.rtf

Dataset Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adef_gba

/lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

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Anhang 4-G.4.4.2.2 Symptomatik**Darm- und systemische Symptome IBDQ**

Die Ergebnisse sind Anhang 4-G.3.4.2.4 zu entnehmen.

Stuhlfrequenz – CDAI-SF

Angaben zur Vollständigkeit der Daten für Stool frequency zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
Stool frequency		
Baseline		
N-obs (%2)	296 (98,7)	145 (100,0)
N-miss (%2)	4 (1,3)	0 (0,0)
Woche 2		
N-visit	300 (100,0)	145 (100,0)
N-obs (%1) (%2)	294 (98,0) (98,0)	145 (100,0) (100,0)
N-miss (%1) (%2)	6 (2,0) (2,0)	0 (0,0) (0,0)
N-miss (%2)	0 (0,0)	0 (0,0)
Woche 4		
N-visit	296 (98,7)	143 (98,6)
N-obs (%1) (%2)	292 (98,6) (97,3)	143 (100,0) (98,6)
N-miss (%1) (%2)	4 (1,4) (1,3)	0 (0,0) (0,0)
N-miss (%2)	4 (1,3)	2 (1,4)
Woche 6		
N-visit	295 (98,3)	143 (98,6)
N-obs (%1) (%2)	290 (98,3) (96,7)	142 (99,3) (97,9)
N-miss (%1) (%2)	5 (1,7) (1,7)	1 (0,7) (0,7)
N-miss (%2)	5 (1,7)	2 (1,4)
Woche 8		
N-visit	295 (98,3)	142 (97,9)
N-obs (%1) (%2)	290 (98,3) (96,7)	142 (100,0) (97,9)
N-miss (%1) (%2)	5 (1,7) (1,7)	0 (0,0) (0,0)
N-miss (%2)	5 (1,7)	3 (2,1)
Woche 12		

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
N-visit	293 (97,7)	140 (96,6)
N-obs (%1) (%2)	291 (99,3) (97,0)	139 (99,3) (95,9)
N-miss (%1) (%2)	2 (0,7) (0,7)	1 (0,7) (0,7)
N-miss (%2)	7 (2,3)	5 (3,4)
Woche 16		
N-visit	286 (95,3)	140 (96,6)
N-obs (%1) (%2)	284 (99,3) (94,7)	138 (98,6) (95,2)
N-miss (%1) (%2)	2 (0,7) (0,7)	2 (1,4) (1,4)
N-miss (%2)	14 (4,7)	5 (3,4)
Woche 20		
N-visit	279 (93,0)	140 (96,6)
N-obs (%1) (%2)	273 (97,8) (91,0)	138 (98,6) (95,2)
N-miss (%1) (%2)	6 (2,2) (2,0)	2 (1,4) (1,4)
N-miss (%2)	21 (7,0)	5 (3,4)
Woche 24		
N-visit	273 (91,0)	136 (93,8)
N-obs (%1) (%2)	268 (98,2) (89,3)	134 (98,5) (92,4)
N-miss (%1) (%2)	5 (1,8) (1,7)	2 (1,5) (1,4)
N-miss (%2)	27 (9,0)	9 (6,2)
Woche 28		
N-visit	269 (89,7)	134 (92,4)
N-obs (%1) (%2)	263 (97,8) (87,7)	128 (95,5) (88,3)
N-miss (%1) (%2)	6 (2,2) (2,0)	6 (4,5) (4,1)
N-miss (%2)	31 (10,3)	11 (7,6)
Woche 32		
N-visit	265 (88,3)	128 (88,3)
N-obs (%1) (%2)	263 (99,2) (87,7)	125 (97,7) (86,2)
N-miss (%1) (%2)	2 (0,8) (0,7)	3 (2,3) (2,1)
N-miss (%2)	35 (11,7)	17 (11,7)
Woche 36		
N-visit	264 (88,0)	126 (86,9)
N-obs (%1) (%2)	258 (97,7) (86,0)	122 (96,8) (84,1)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
N-miss (%1) (%2)	6 (2,3) (2,0)	4 (3,2) (2,8)
N-miss (%2)	36 (12,0)	19 (13,1)
Woche 40		
N-visit	260 (86,7)	125 (86,2)
N-obs (%1) (%2)	259 (99,6) (86,3)	121 (96,8) (83,4)
N-miss (%1) (%2)	1 (0,4) (0,3)	4 (3,2) (2,8)
N-miss (%2)	40 (13,3)	20 (13,8)
Woche 44		
N-visit	259 (86,3)	123 (84,8)
N-obs (%1) (%2)	251 (96,9) (83,7)	117 (95,1) (80,7)
N-miss (%1) (%2)	8 (3,1) (2,7)	6 (4,9) (4,1)
N-miss (%2)	41 (13,7)	22 (15,2)
Woche 48		
N-visit	257 (85,7)	123 (84,8)
N-obs (%1) (%2)	255 (99,2) (85,0)	119 (96,7) (82,1)
N-miss (%1) (%2)	2 (0,8) (0,7)	4 (3,3) (2,8)
N-miss (%2)	43 (14,3)	22 (15,2)
Woche 52		
N-visit	255 (85,0)	123 (84,8)
N-obs (%1) (%2)	251 (98,4) (83,7)	116 (94,3) (80,0)
N-miss (%1) (%2)	4 (1,6) (1,3)	7 (5,7) (4,8)
N-miss (%2)	45 (15,0)	22 (15,2)
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_sfcmp_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adef_gba

/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Imperativer Stuhldrang - Urgency NRS

Angaben zur Vollständigkeit der Daten für Urgency NRS zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
Urgency NRS		
Baseline		
N-obs (%2)	299 (99,7)	145 (100,0)
N-miss (%2)	1 (0,3)	0 (0,0)
Woche 2		
N-visit	300 (100,0)	145 (100,0)
N-obs (%1) (%2)	295 (98,3) (98,3)	145 (100,0) (100,0)
N-miss (%1) (%2)	5 (1,7) (1,7)	0 (0,0) (0,0)
N-miss (%2)	0 (0,0)	0 (0,0)
Woche 4		
N-visit	296 (98,7)	143 (98,6)
N-obs (%1) (%2)	294 (99,3) (98,0)	143 (100,0) (98,6)
N-miss (%1) (%2)	2 (0,7) (0,7)	0 (0,0) (0,0)
N-miss (%2)	4 (1,3)	2 (1,4)
Woche 6		
N-visit	295 (98,3)	143 (98,6)
N-obs (%1) (%2)	291 (98,6) (97,0)	142 (99,3) (97,9)
N-miss (%1) (%2)	4 (1,4) (1,3)	1 (0,7) (0,7)
N-miss (%2)	5 (1,7)	2 (1,4)
Woche 8		
N-visit	295 (98,3)	142 (97,9)
N-obs (%1) (%2)	291 (98,6) (97,0)	142 (100,0) (97,9)
N-miss (%1) (%2)	4 (1,4) (1,3)	0 (0,0) (0,0)
N-miss (%2)	5 (1,7)	3 (2,1)
Woche 12		
N-visit	293 (97,7)	140 (96,6)
N-obs (%1) (%2)	291 (99,3) (97,0)	139 (99,3) (95,9)
N-miss (%1) (%2)	2 (0,7) (0,7)	1 (0,7) (0,7)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
N-miss (%2)	7 (2,3)	5 (3,4)
Woche 16		
N-visit	286 (95,3)	140 (96,6)
N-obs (%1) (%2)	284 (99,3) (94,7)	138 (98,6) (95,2)
N-miss (%1) (%2)	2 (0,7) (0,7)	2 (1,4) (1,4)
N-miss (%2)	14 (4,7)	5 (3,4)
Woche 20		
N-visit	279 (93,0)	140 (96,6)
N-obs (%1) (%2)	273 (97,8) (91,0)	138 (98,6) (95,2)
N-miss (%1) (%2)	6 (2,2) (2,0)	2 (1,4) (1,4)
N-miss (%2)	21 (7,0)	5 (3,4)
Woche 24		
N-visit	273 (91,0)	136 (93,8)
N-obs (%1) (%2)	268 (98,2) (89,3)	134 (98,5) (92,4)
N-miss (%1) (%2)	5 (1,8) (1,7)	2 (1,5) (1,4)
N-miss (%2)	27 (9,0)	9 (6,2)
Woche 28		
N-visit	269 (89,7)	134 (92,4)
N-obs (%1) (%2)	263 (97,8) (87,7)	128 (95,5) (88,3)
N-miss (%1) (%2)	6 (2,2) (2,0)	6 (4,5) (4,1)
N-miss (%2)	31 (10,3)	11 (7,6)
Woche 32		
N-visit	265 (88,3)	128 (88,3)
N-obs (%1) (%2)	263 (99,2) (87,7)	125 (97,7) (86,2)
N-miss (%1) (%2)	2 (0,8) (0,7)	3 (2,3) (2,1)
N-miss (%2)	35 (11,7)	17 (11,7)
Woche 36		
N-visit	264 (88,0)	126 (86,9)
N-obs (%1) (%2)	258 (97,7) (86,0)	122 (96,8) (84,1)
N-miss (%1) (%2)	6 (2,3) (2,0)	4 (3,2) (2,8)
N-miss (%2)	36 (12,0)	19 (13,1)
Woche 40		

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
N-visit	260 (86,7)	125 (86,2)
N-obs (%1) (%2)	259 (99,6) (86,3)	121 (96,8) (83,4)
N-miss (%1) (%2)	1 (0,4) (0,3)	4 (3,2) (2,8)
N-miss (%2)	40 (13,3)	20 (13,8)
Woche 44		
N-visit	259 (86,3)	123 (84,8)
N-obs (%1) (%2)	251 (96,9) (83,7)	117 (95,1) (80,7)
N-miss (%1) (%2)	8 (3,1) (2,7)	6 (4,9) (4,1)
N-miss (%2)	41 (13,7)	22 (15,2)
Woche 48		
N-visit	257 (85,7)	123 (84,8)
N-obs (%1) (%2)	255 (99,2) (85,0)	119 (96,7) (82,1)
N-miss (%1) (%2)	2 (0,8) (0,7)	4 (3,3) (2,8)
N-miss (%2)	43 (14,3)	22 (15,2)
Woche 52		
N-visit	255 (85,0)	123 (84,8)
N-obs (%1) (%2)	251 (98,4) (83,7)	116 (94,3) (80,0)
N-miss (%1) (%2)	4 (1,6) (1,3)	7 (5,7) (4,8)
N-miss (%2)	45 (15,0)	22 (15,2)
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; NRS: Numeric Rating Scale; RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_urcgmpt_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adef_gba
/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Abdominelle Schmerzen – CDAI-AP

Angaben zur Vollständigkeit der Daten für Abdominal pain zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
Abdominal pain		
Baseline		
N-obs (%2)	298 (99,3)	145 (100,0)
N-miss (%2)	2 (0,7)	0 (0,0)
Woche 2		
N-visit	300 (100,0)	145 (100,0)
N-obs (%1) (%2)	296 (98,7) (98,7)	145 (100,0) (100,0)
N-miss (%1) (%2)	4 (1,3) (1,3)	0 (0,0) (0,0)
N-miss (%2)	0 (0,0)	0 (0,0)
Woche 4		
N-visit	296 (98,7)	143 (98,6)
N-obs (%1) (%2)	294 (99,3) (98,0)	143 (100,0) (98,6)
N-miss (%1) (%2)	2 (0,7) (0,7)	0 (0,0) (0,0)
N-miss (%2)	4 (1,3)	2 (1,4)
Woche 6		
N-visit	295 (98,3)	143 (98,6)
N-obs (%1) (%2)	291 (98,6) (97,0)	142 (99,3) (97,9)
N-miss (%1) (%2)	4 (1,4) (1,3)	1 (0,7) (0,7)
N-miss (%2)	5 (1,7)	2 (1,4)
Woche 8		
N-visit	295 (98,3)	142 (97,9)
N-obs (%1) (%2)	291 (98,6) (97,0)	142 (100,0) (97,9)
N-miss (%1) (%2)	4 (1,4) (1,3)	0 (0,0) (0,0)
N-miss (%2)	5 (1,7)	3 (2,1)
Woche 12		
N-visit	293 (97,7)	140 (96,6)
N-obs (%1) (%2)	291 (99,3) (97,0)	139 (99,3) (95,9)
N-miss (%1) (%2)	2 (0,7) (0,7)	1 (0,7) (0,7)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
N-miss (%2)	7 (2,3)	5 (3,4)
Woche 16		
N-visit	286 (95,3)	140 (96,6)
N-obs (%1) (%2)	284 (99,3) (94,7)	138 (98,6) (95,2)
N-miss (%1) (%2)	2 (0,7) (0,7)	2 (1,4) (1,4)
N-miss (%2)	14 (4,7)	5 (3,4)
Woche 20		
N-visit	279 (93,0)	140 (96,6)
N-obs (%1) (%2)	273 (97,8) (91,0)	138 (98,6) (95,2)
N-miss (%1) (%2)	6 (2,2) (2,0)	2 (1,4) (1,4)
N-miss (%2)	21 (7,0)	5 (3,4)
Woche 24		
N-visit	273 (91,0)	136 (93,8)
N-obs (%1) (%2)	268 (98,2) (89,3)	134 (98,5) (92,4)
N-miss (%1) (%2)	5 (1,8) (1,7)	2 (1,5) (1,4)
N-miss (%2)	27 (9,0)	9 (6,2)
Woche 28		
N-visit	269 (89,7)	134 (92,4)
N-obs (%1) (%2)	263 (97,8) (87,7)	128 (95,5) (88,3)
N-miss (%1) (%2)	6 (2,2) (2,0)	6 (4,5) (4,1)
N-miss (%2)	31 (10,3)	11 (7,6)
Woche 32		
N-visit	265 (88,3)	128 (88,3)
N-obs (%1) (%2)	263 (99,2) (87,7)	125 (97,7) (86,2)
N-miss (%1) (%2)	2 (0,8) (0,7)	3 (2,3) (2,1)
N-miss (%2)	35 (11,7)	17 (11,7)
Woche 36		
N-visit	264 (88,0)	126 (86,9)
N-obs (%1) (%2)	258 (97,7) (86,0)	122 (96,8) (84,1)
N-miss (%1) (%2)	6 (2,3) (2,0)	4 (3,2) (2,8)
N-miss (%2)	36 (12,0)	19 (13,1)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
Woche 40		
N-visit	260 (86,7)	125 (86,2)
N-obs (%1) (%2)	259 (99,6) (86,3)	121 (96,8) (83,4)
N-miss (%1) (%2)	1 (0,4) (0,3)	4 (3,2) (2,8)
N-miss (%2)	40 (13,3)	20 (13,8)
Woche 44		
N-visit	259 (86,3)	123 (84,8)
N-obs (%1) (%2)	251 (96,9) (83,7)	117 (95,1) (80,7)
N-miss (%1) (%2)	8 (3,1) (2,7)	6 (4,9) (4,1)
N-miss (%2)	41 (13,7)	22 (15,2)
Woche 48		
N-visit	257 (85,7)	123 (84,8)
N-obs (%1) (%2)	255 (99,2) (85,0)	119 (96,7) (82,1)
N-miss (%1) (%2)	2 (0,8) (0,7)	4 (3,3) (2,8)
N-miss (%2)	43 (14,3)	22 (15,2)
Woche 52		
N-visit	255 (85,0)	123 (84,8)
N-obs (%1) (%2)	251 (98,4) (83,7)	116 (94,3) (80,0)
N-miss (%1) (%2)	4 (1,6) (1,3)	7 (5,7) (4,8)
N-miss (%2)	45 (15,0)	22 (15,2)
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_apcmp_ittb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adefeff_gba

/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Fatigue – FACIT Fatigue

Angaben zur Vollständigkeit der Daten für FACIT-Fatigue zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
FACIT-Fatigue		
Baseline		
N-obs (%2)	298 (99,3)	145 (100,0)
N-miss (%2)	2 (0,7)	0 (0,0)
Woche 12		
N-visit	293 (97,7)	140 (96,6)
N-obs (%1) (%2)	290 (99,0) (96,7)	139 (99,3) (95,9)
N-miss (%1) (%2)	3 (1,0) (1,0)	1 (0,7) (0,7)
N-miss (%2)	7 (2,3)	5 (3,4)
Woche 52		
N-visit	255 (85,0)	123 (84,8)
N-obs (%1) (%2)	242 (94,9) (80,7)	117 (95,1) (80,7)
N-miss (%1) (%2)	13 (5,1) (4,3)	6 (4,9) (4,1)
N-miss (%2)	45 (15,0)	22 (15,2)
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: FACIT: Functional Assessment of Chronic Illness Therapy-Fatigue; ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_facitcmp_itb.rtf

Dataset Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adefl_gba

/lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Depressionen – QIDS-SR16

Angaben zur Vollständigkeit der Daten für QIDS-SR16 Total Score zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
QIDS-SR16 Total Score		
Baseline		
N-obs (%2)	296 (98,7)	144 (99,3)
N-miss (%2)	4 (1,3)	1 (0,7)
Woche 12		
N-visit	293 (97,7)	140 (96,6)
N-obs (%1) (%2)	292 (99,7) (97,3)	139 (99,3) (95,9)
N-miss (%1) (%2)	1 (0,3) (0,3)	1 (0,7) (0,7)
N-miss (%2)	7 (2,3)	5 (3,4)
Woche 24		
N-visit	273 (91,0)	136 (93,8)
N-obs (%1) (%2)	267 (97,8) (89,0)	134 (98,5) (92,4)
N-miss (%1) (%2)	6 (2,2) (2,0)	2 (1,5) (1,4)
N-miss (%2)	27 (9,0)	9 (6,2)
Woche 36		
N-visit	264 (88,0)	126 (86,9)
N-obs (%1) (%2)	253 (95,8) (84,3)	124 (98,4) (85,5)
N-miss (%1) (%2)	11 (4,2) (3,7)	2 (1,6) (1,4)
N-miss (%2)	36 (12,0)	19 (13,1)
Woche 52		
N-visit	255 (85,0)	123 (84,8)
N-obs (%1) (%2)	243 (95,3) (81,0)	119 (96,7) (82,1)
N-miss (%1) (%2)	12 (4,7) (4,0)	4 (3,3) (2,8)
N-miss (%2)	45 (15,0)	22 (15,2)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; QIDS-SR16: Quick Inventory of Depressive Symptomatology - Self Report (16 items); RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_qidscmp_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adefl_gba
/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Anhang 4-G.4.4.2.3 Gesundheitszustand**Gesundheitszustand – EQ-5D VAS**

Angaben zur Vollständigkeit der Daten für EQ-5D VAS zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
EQ-5D VAS		
Baseline		
N-obs (%2)	299 (99,7)	145 (100,0)
N-miss (%2)	1 (0,3)	0 (0,0)
Woche 12		
N-visit	293 (97,7)	140 (96,6)
N-obs (%1) (%2)	292 (99,7) (97,3)	139 (99,3) (95,9)
N-miss (%1) (%2)	1 (0,3) (0,3)	1 (0,7) (0,7)
N-miss (%2)	7 (2,3)	5 (3,4)
Woche 52		
N-visit	255 (85,0)	123 (84,8)
N-obs (%1) (%2)	243 (95,3) (81,0)	119 (96,7) (82,1)
N-miss (%1) (%2)	12 (4,7) (4,0)	4 (3,3) (2,8)
N-miss (%2)	45 (15,0)	22 (15,2)
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: EQ-5D: Fragebogen der EuroQol-Gruppe zur Lebensqualität auf 5 Dimensionen; ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; VAS: Visuelle Analogskala. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_vascmp_itb.rtf

Dataset Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adef_gba

/lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Gesundheitszustand – PGRS

Angaben zur Vollständigkeit der Daten für Patient Global Rating of severity (PGRS) zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
PGRS		
Baseline		
N-obs (%2)	298 (99,3)	145 (100,0)
N-miss (%2)	2 (0,7)	0 (0,0)
Woche 2		
N-visit	300 (100,0)	145 (100,0)
N-obs (%1) (%2)	295 (98,3) (98,3)	145 (100,0) (100,0)
N-miss (%1) (%2)	5 (1,7) (1,7)	0 (0,0) (0,0)
N-miss (%2)	0 (0,0)	0 (0,0)
Woche 4		
N-visit	296 (98,7)	143 (98,6)
N-obs (%1) (%2)	294 (99,3) (98,0)	143 (100,0) (98,6)
N-miss (%1) (%2)	2 (0,7) (0,7)	0 (0,0) (0,0)
N-miss (%2)	4 (1,3)	2 (1,4)
Woche 6		
N-visit	295 (98,3)	143 (98,6)
N-obs (%1) (%2)	291 (98,6) (97,0)	142 (99,3) (97,9)
N-miss (%1) (%2)	4 (1,4) (1,3)	1 (0,7) (0,7)
N-miss (%2)	5 (1,7)	2 (1,4)
Woche 8		
N-visit	295 (98,3)	142 (97,9)
N-obs (%1) (%2)	291 (98,6) (97,0)	142 (100,0) (97,9)
N-miss (%1) (%2)	4 (1,4) (1,3)	0 (0,0) (0,0)
N-miss (%2)	5 (1,7)	3 (2,1)
Woche 12		
N-visit	293 (97,7)	140 (96,6)
N-obs (%1) (%2)	291 (99,3) (97,0)	139 (99,3) (95,9)
N-miss (%1) (%2)	2 (0,7) (0,7)	1 (0,7) (0,7)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
N-miss (%2)	7 (2,3)	5 (3,4)
Woche 16		
N-visit	286 (95,3)	140 (96,6)
N-obs (%1) (%2)	284 (99,3) (94,7)	138 (98,6) (95,2)
N-miss (%1) (%2)	2 (0,7) (0,7)	2 (1,4) (1,4)
N-miss (%2)	14 (4,7)	5 (3,4)
Woche 20		
N-visit	279 (93,0)	140 (96,6)
N-obs (%1) (%2)	273 (97,8) (91,0)	138 (98,6) (95,2)
N-miss (%1) (%2)	6 (2,2) (2,0)	2 (1,4) (1,4)
N-miss (%2)	21 (7,0)	5 (3,4)
Woche 24		
N-visit	273 (91,0)	136 (93,8)
N-obs (%1) (%2)	268 (98,2) (89,3)	134 (98,5) (92,4)
N-miss (%1) (%2)	5 (1,8) (1,7)	2 (1,5) (1,4)
N-miss (%2)	27 (9,0)	9 (6,2)
Woche 28		
N-visit	269 (89,7)	134 (92,4)
N-obs (%1) (%2)	263 (97,8) (87,7)	128 (95,5) (88,3)
N-miss (%1) (%2)	6 (2,2) (2,0)	6 (4,5) (4,1)
N-miss (%2)	31 (10,3)	11 (7,6)
Woche 32		
N-visit	265 (88,3)	128 (88,3)
N-obs (%1) (%2)	263 (99,2) (87,7)	125 (97,7) (86,2)
N-miss (%1) (%2)	2 (0,8) (0,7)	3 (2,3) (2,1)
N-miss (%2)	35 (11,7)	17 (11,7)
Woche 36		
N-visit	264 (88,0)	126 (86,9)
N-obs (%1) (%2)	258 (97,7) (86,0)	122 (96,8) (84,1)
N-miss (%1) (%2)	6 (2,3) (2,0)	4 (3,2) (2,8)
N-miss (%2)	36 (12,0)	19 (13,1)
Woche 40		

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
N-visit	260 (86,7)	125 (86,2)
N-obs (%1) (%2)	259 (99,6) (86,3)	121 (96,8) (83,4)
N-miss (%1) (%2)	1 (0,4) (0,3)	4 (3,2) (2,8)
N-miss (%2)	40 (13,3)	20 (13,8)
Woche 44		
N-visit	259 (86,3)	123 (84,8)
N-obs (%1) (%2)	251 (96,9) (83,7)	117 (95,1) (80,7)
N-miss (%1) (%2)	8 (3,1) (2,7)	6 (4,9) (4,1)
N-miss (%2)	41 (13,7)	22 (15,2)
Woche 48		
N-visit	257 (85,7)	123 (84,8)
N-obs (%1) (%2)	255 (99,2) (85,0)	119 (96,7) (82,1)
N-miss (%1) (%2)	2 (0,8) (0,7)	4 (3,3) (2,8)
N-miss (%2)	43 (14,3)	22 (15,2)
Woche 52		
N-visit	255 (85,0)	123 (84,8)
N-obs (%1) (%2)	251 (98,4) (83,7)	116 (94,3) (80,0)
N-miss (%1) (%2)	4 (1,6) (1,3)	7 (5,7) (4,8)
N-miss (%2)	45 (15,0)	22 (15,2)
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; PGRS: Patient Global Rating of Severity; RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_pgrscmp_ittb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adefl_gba

/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Gesundheitszustand – PGIC

Angaben zur Vollständigkeit der Daten für Patient Reported Impression of Change (PGIC) zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
PGIC		
Woche 4		
N-visit	296 (98,7)	143 (98,6)
N-obs (%1) (%2)	289 (97,6) (96,3)	142 (99,3) (97,9)
N-miss (%1) (%2)	7 (2,4) (2,3)	1 (0,7) (0,7)
N-miss (%2)	4 (1,3)	2 (1,4)
Woche 8		
N-visit	295 (98,3)	142 (97,9)
N-obs (%1) (%2)	289 (98,0) (96,3)	142 (100,0) (97,9)
N-miss (%1) (%2)	6 (2,0) (2,0)	0 (0,0) (0,0)
N-miss (%2)	5 (1,7)	3 (2,1)
Woche 12		
N-visit	293 (97,7)	140 (96,6)
N-obs (%1) (%2)	292 (99,7) (97,3)	139 (99,3) (95,9)
N-miss (%1) (%2)	1 (0,3) (0,3)	1 (0,7) (0,7)
N-miss (%2)	7 (2,3)	5 (3,4)
Woche 52		
N-visit	255 (85,0)	123 (84,8)
N-obs (%1) (%2)	243 (95,3) (81,0)	119 (96,7) (82,1)
N-miss (%1) (%2)	12 (4,7) (4,0)	4 (3,3) (2,8)
N-miss (%2)	45 (15,0)	22 (15,2)
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; PGIC: Patient Global Impression of Change; RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_pgiccmp_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Gesundheitszustand – WPAI-CD (Aktivitätsbeeinträchtigung)

Angaben zur Vollständigkeit der Daten für WPAI (Activity impairment) zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population, Participants with baseline employment status of Yes)

Endpunkt Zeitpunkt	Mirikizumab (N=173)	Ustekinumab (N=80)
WPAI (Activity impairment)		
Baseline		
N-obs (%2)	173 (100,0)	80 (100,0)
N-miss (%2)	0 (0,0)	0 (0,0)
Woche 12		
N-visit	171 (98,8)	77 (96,3)
N-obs (%1) (%2)	170 (99,4) (98,3)	77 (100,0) (96,3)
N-miss (%1) (%2)	1 (0,6) (0,6)	0 (0,0) (0,0)
N-miss (%2)	2 (1,2)	3 (3,8)
Woche 52		
N-visit	149 (86,1)	69 (86,3)
N-obs (%1) (%2)	142 (95,3) (82,1)	67 (97,1) (83,8)
N-miss (%1) (%2)	7 (4,7) (4,0)	2 (2,9) (2,5)
N-miss (%2)	24 (13,9)	11 (13,8)
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; WPAI: Work Productivity and Activity Impairment Questionnaire. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_wpaicmp_empl_itb.rtf

Dataset Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

/lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Allgemeinbefinden - CDAI-GWP

Angaben zur Vollständigkeit der Daten für General well being zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
General well being		
Baseline		
N-obs (%2)	299 (99,7)	145 (100,0)
N-miss (%2)	1 (0,3)	0 (0,0)
Woche 2		
N-visit	300 (100,0)	145 (100,0)
N-obs (%1) (%2)	296 (98,7) (98,7)	145 (100,0) (100,0)
N-miss (%1) (%2)	4 (1,3) (1,3)	0 (0,0) (0,0)
N-miss (%2)	0 (0,0)	0 (0,0)
Woche 4		
N-visit	296 (98,7)	143 (98,6)
N-obs (%1) (%2)	294 (99,3) (98,0)	143 (100,0) (98,6)
N-miss (%1) (%2)	2 (0,7) (0,7)	0 (0,0) (0,0)
N-miss (%2)	4 (1,3)	2 (1,4)
Woche 6		
N-visit	295 (98,3)	143 (98,6)
N-obs (%1) (%2)	291 (98,6) (97,0)	142 (99,3) (97,9)
N-miss (%1) (%2)	4 (1,4) (1,3)	1 (0,7) (0,7)
N-miss (%2)	5 (1,7)	2 (1,4)
Woche 8		
N-visit	295 (98,3)	142 (97,9)
N-obs (%1) (%2)	291 (98,6) (97,0)	142 (100,0) (97,9)
N-miss (%1) (%2)	4 (1,4) (1,3)	0 (0,0) (0,0)
N-miss (%2)	5 (1,7)	3 (2,1)
Woche 12		
N-visit	293 (97,7)	140 (96,6)
N-obs (%1) (%2)	291 (99,3) (97,0)	139 (99,3) (95,9)
N-miss (%1) (%2)	2 (0,7) (0,7)	1 (0,7) (0,7)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
N-miss (%2)	7 (2,3)	5 (3,4)
Woche 16		
N-visit	286 (95,3)	140 (96,6)
N-obs (%1) (%2)	284 (99,3) (94,7)	138 (98,6) (95,2)
N-miss (%1) (%2)	2 (0,7) (0,7)	2 (1,4) (1,4)
N-miss (%2)	14 (4,7)	5 (3,4)
Woche 20		
N-visit	279 (93,0)	140 (96,6)
N-obs (%1) (%2)	273 (97,8) (91,0)	138 (98,6) (95,2)
N-miss (%1) (%2)	6 (2,2) (2,0)	2 (1,4) (1,4)
N-miss (%2)	21 (7,0)	5 (3,4)
Woche 24		
N-visit	273 (91,0)	136 (93,8)
N-obs (%1) (%2)	268 (98,2) (89,3)	134 (98,5) (92,4)
N-miss (%1) (%2)	5 (1,8) (1,7)	2 (1,5) (1,4)
N-miss (%2)	27 (9,0)	9 (6,2)
Woche 28		
N-visit	269 (89,7)	134 (92,4)
N-obs (%1) (%2)	263 (97,8) (87,7)	128 (95,5) (88,3)
N-miss (%1) (%2)	6 (2,2) (2,0)	6 (4,5) (4,1)
N-miss (%2)	31 (10,3)	11 (7,6)
Woche 32		
N-visit	265 (88,3)	128 (88,3)
N-obs (%1) (%2)	263 (99,2) (87,7)	125 (97,7) (86,2)
N-miss (%1) (%2)	2 (0,8) (0,7)	3 (2,3) (2,1)
N-miss (%2)	35 (11,7)	17 (11,7)
Woche 36		
N-visit	264 (88,0)	126 (86,9)
N-obs (%1) (%2)	258 (97,7) (86,0)	122 (96,8) (84,1)
N-miss (%1) (%2)	6 (2,3) (2,0)	4 (3,2) (2,8)
N-miss (%2)	36 (12,0)	19 (13,1)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
Woche 40		
N-visit	260 (86,7)	125 (86,2)
N-obs (%1) (%2)	259 (99,6) (86,3)	121 (96,8) (83,4)
N-miss (%1) (%2)	1 (0,4) (0,3)	4 (3,2) (2,8)
N-miss (%2)	40 (13,3)	20 (13,8)
Woche 44		
N-visit	259 (86,3)	123 (84,8)
N-obs (%1) (%2)	251 (96,9) (83,7)	117 (95,1) (80,7)
N-miss (%1) (%2)	8 (3,1) (2,7)	6 (4,9) (4,1)
N-miss (%2)	41 (13,7)	22 (15,2)
Woche 48		
N-visit	257 (85,7)	123 (84,8)
N-obs (%1) (%2)	255 (99,2) (85,0)	119 (96,7) (82,1)
N-miss (%1) (%2)	2 (0,8) (0,7)	4 (3,3) (2,8)
N-miss (%2)	43 (14,3)	22 (15,2)
Woche 52		
N-visit	255 (85,0)	123 (84,8)
N-obs (%1) (%2)	251 (98,4) (83,7)	116 (94,3) (80,0)
N-miss (%1) (%2)	4 (1,6) (1,3)	7 (5,7) (4,8)
N-miss (%2)	45 (15,0)	22 (15,2)
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_gwbcmp_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Anhang 4-G.4.4.2.4 Gesundheitsbezogene Lebensqualität**Krankheitsspezifische Lebensqualität**

Angaben zur Vollständigkeit der Daten für IBDQ zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
IBDQ Total Score		
Baseline		
N-obs (%2)	299 (99,7)	145 (100,0)
N-miss (%2)	1 (0,3)	0 (0,0)
Woche 12		
N-visit	293 (97,7)	140 (96,6)
N-obs (%1) (%2)	292 (99,7) (97,3)	139 (99,3) (95,9)
N-miss (%1) (%2)	1 (0,3) (0,3)	1 (0,7) (0,7)
N-miss (%2)	7 (2,3)	5 (3,4)
Woche 52		
N-visit	255 (85,0)	123 (84,8)
N-obs (%1) (%2)	243 (95,3) (81,0)	119 (96,7) (82,1)
N-miss (%1) (%2)	12 (4,7) (4,0)	4 (3,3) (2,8)
N-miss (%2)	45 (15,0)	22 (15,2)
IBDQ Bowel Symptoms		
Baseline		
N-obs (%2)	299 (99,7)	145 (100,0)
N-miss (%2)	1 (0,3)	0 (0,0)
Woche 12		
N-visit	293 (97,7)	140 (96,6)
N-obs (%1) (%2)	292 (99,7) (97,3)	139 (99,3) (95,9)
N-miss (%1) (%2)	1 (0,3) (0,3)	1 (0,7) (0,7)
N-miss (%2)	7 (2,3)	5 (3,4)
Woche 52		
N-visit	255 (85,0)	123 (84,8)
N-obs (%1) (%2)	243 (95,3) (81,0)	119 (96,7) (82,1)
N-miss (%1) (%2)	12 (4,7) (4,0)	4 (3,3) (2,8)
N-miss (%2)	45 (15,0)	22 (15,2)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
IBDQ Emotional Function		
Baseline		
N-obs (%2)	299 (99,7)	145 (100,0)
N-miss (%2)	1 (0,3)	0 (0,0)
Woche 12		
N-visit	293 (97,7)	140 (96,6)
N-obs (%1) (%2)	292 (99,7) (97,3)	139 (99,3) (95,9)
N-miss (%1) (%2)	1 (0,3) (0,3)	1 (0,7) (0,7)
N-miss (%2)	7 (2,3)	5 (3,4)
Woche 52		
N-visit	255 (85,0)	123 (84,8)
N-obs (%1) (%2)	243 (95,3) (81,0)	119 (96,7) (82,1)
N-miss (%1) (%2)	12 (4,7) (4,0)	4 (3,3) (2,8)
N-miss (%2)	45 (15,0)	22 (15,2)
IBDQ Social Function		
Baseline		
N-obs (%2)	299 (99,7)	145 (100,0)
N-miss (%2)	1 (0,3)	0 (0,0)
Woche 12		
N-visit	293 (97,7)	140 (96,6)
N-obs (%1) (%2)	292 (99,7) (97,3)	139 (99,3) (95,9)
N-miss (%1) (%2)	1 (0,3) (0,3)	1 (0,7) (0,7)
N-miss (%2)	7 (2,3)	5 (3,4)
Woche 52		
N-visit	255 (85,0)	123 (84,8)
N-obs (%1) (%2)	243 (95,3) (81,0)	119 (96,7) (82,1)
N-miss (%1) (%2)	12 (4,7) (4,0)	4 (3,3) (2,8)
N-miss (%2)	45 (15,0)	22 (15,2)
IBDQ Systemic Symptoms		
Baseline		
N-obs (%2)	299 (99,7)	145 (100,0)
N-miss (%2)	1 (0,3)	0 (0,0)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
Woche 12		
N-visit	293 (97,7)	140 (96,6)
N-obs (%1) (%2)	292 (99,7) (97,3)	139 (99,3) (95,9)
N-miss (%1) (%2)	1 (0,3) (0,3)	1 (0,7) (0,7)
N-miss (%2)	7 (2,3)	5 (3,4)
Woche 52		
N-visit	255 (85,0)	123 (84,8)
N-obs (%1) (%2)	243 (95,3) (81,0)	119 (96,7) (82,1)
N-miss (%1) (%2)	12 (4,7) (4,0)	4 (3,3) (2,8)
N-miss (%2)	45 (15,0)	22 (15,2)
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_ibdqcmp_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adefl_gba

/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Gesundheitsbezogene Lebensqualität

Angaben zur Vollständigkeit der Daten für SF-36 zu den jeweiligen Erhebungszeitpunkten in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
SF-36 MCS Score		
Baseline		
N-obs (%2)	299 (99,7)	145 (100,0)
N-miss (%2)	1 (0,3)	0 (0,0)
Woche 12		
N-visit	293 (97,7)	140 (96,6)
N-obs (%1) (%2)	292 (99,7) (97,3)	139 (99,3) (95,9)
N-miss (%1) (%2)	1 (0,3) (0,3)	1 (0,7) (0,7)
N-miss (%2)	7 (2,3)	5 (3,4)
Woche 52		
N-visit	255 (85,0)	123 (84,8)
N-obs (%1) (%2)	243 (95,3) (81,0)	119 (96,7) (82,1)
N-miss (%1) (%2)	12 (4,7) (4,0)	4 (3,3) (2,8)
N-miss (%2)	45 (15,0)	22 (15,2)
SF-36 PCS Score		
Baseline		
N-obs (%2)	299 (99,7)	145 (100,0)
N-miss (%2)	1 (0,3)	0 (0,0)
Woche 12		
N-visit	293 (97,7)	140 (96,6)
N-obs (%1) (%2)	292 (99,7) (97,3)	139 (99,3) (95,9)
N-miss (%1) (%2)	1 (0,3) (0,3)	1 (0,7) (0,7)
N-miss (%2)	7 (2,3)	5 (3,4)
Woche 52		
N-visit	255 (85,0)	123 (84,8)
N-obs (%1) (%2)	243 (95,3) (81,0)	119 (96,7) (82,1)
N-miss (%1) (%2)	12 (4,7) (4,0)	4 (3,3) (2,8)
N-miss (%2)	45 (15,0)	22 (15,2)

Endpunkt Zeitpunkt	Mirikizumab (N=300)	Ustekinumab (N=145)
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; MCS: Mental Health Component Summary Score; N-miss: Anzahl der Patienten mit fehlenden Angaben; N-obs: Anzahl der Patienten mit Angaben; N-visit: Anzahl der Patienten mit einer Visite/noch in der Studie; N: Anzahl der Patienten in der Analyse; PCS: Physical Health Component Summary Score; RCT: randomisierte, kontrollierte Studie; SF-36: 36-Item Short Form Health Survey. Prozente für (%1) basieren auf der Patientenzahl mit einer Visite/noch in der Studie (N-visit). Prozente für (%2) basieren auf der Patientenzahl in der Analyse Population (N).		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_cmp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_sf36cmp_ittb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

/lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/observed/restricted/sv

19DEC2024 / 12:52

Anhang 4-G.4.4.3 Ergebnisse für die Veränderung der kontinuierlichen Endpunkte bis Woche 52 in RCT VIVID-1 in Teilpopulation B

Anhang 4-G.4.4.3.1 Klinische Remission

Ergebnisse für die Veränderung des PRO (AP+SF) von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline	Veränderung	Baseline	Veränderung	MWD
	N MW (SD)	ggü. Baseline N LS Mean (SE) ^a	N MW (SD)	ggü. Baseline N LS Mean (SE) ^a	[95 % KI] p-Wert ^a Hedges'g [95 % KI]
PRO (AP+SF)					
Woche 2	295 22,54 (7,57)	291 -4,28 (0,29)	145 22,01 (7,52)	145 -5,71 (0,41)	1,43 [0,44;2,42] 0,005 0,29 [0,09;0,49]
Woche 4	295 22,54 (7,57)	290 -6,07 (0,35)	145 22,01 (7,52)	143 -7,26 (0,50)	1,18 [-0,01;2,38] 0,052 0,20 [-0,00;0,40]
Woche 6	295 22,54 (7,57)	287 -8,33 (0,37)	145 22,01 (7,52)	142 -8,75 (0,52)	0,42 [-0,83;1,68] 0,509 0,07 [-0,13;0,27]
Woche 8	295 22,54 (7,57)	287 -9,03 (0,40)	145 22,01 (7,52)	142 -9,01 (0,56)	-0,02 [-1,37;1,33] 0,975 -0,00 [-0,20;0,20]
Woche 12	295 22,54 (7,57)	287 -10,07 (0,43)	145 22,01 (7,52)	139 -10,35 (0,61)	0,28 [-1,19;1,75] 0,706 0,04 [-0,16;0,24]
Woche 16	295 22,54 (7,57)	280 -11,22 (0,43)	145 22,01 (7,52)	138 -11,14 (0,61)	-0,08 [-1,54;1,38] 0,912 -0,01 [-0,22;0,19]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Woche 20	295 22,54 (7,57)	269 -11,64 (0,44)	145 22,01 (7,52)	138 -11,43 (0,62)	-0,20 [-1,69;1,28] 0,788 -0,03 [-0,23;0,18]
Woche 24	295 22,54 (7,57)	264 -12,10 (0,44)	145 22,01 (7,52)	134 -11,49 (0,62)	-0,61 [-2,09;0,87] 0,419 -0,09 [-0,29;0,12]
Woche 28	295 22,54 (7,57)	260 -12,51 (0,43)	145 22,01 (7,52)	128 -11,65 (0,61)	-0,86 [-2,33;0,61] 0,252 -0,12 [-0,34;0,09]
Woche 32	295 22,54 (7,57)	260 -12,81 (0,42)	145 22,01 (7,52)	125 -11,84 (0,60)	-0,98 [-2,41;0,46] 0,181 -0,14 [-0,36;0,07]
Woche 36	295 22,54 (7,57)	255 -13,28 (0,41)	145 22,01 (7,52)	122 -11,91 (0,58)	-1,36 [-2,77;0,04] 0,057 -0,21 [-0,42;0,01]
Woche 40	295 22,54 (7,57)	256 -13,25 (0,43)	145 22,01 (7,52)	121 -11,91 (0,61)	-1,34 [-2,80;0,12] 0,071 -0,20 [-0,41;0,02]
Woche 44	295 22,54 (7,57)	248 -13,30 (0,43)	145 22,01 (7,52)	117 -12,52 (0,61)	-0,77 [-2,23;0,68] 0,296 -0,12 [-0,34;0,10]
Woche 48	295 22,54 (7,57)	252 -13,38 (0,43)	145 22,01 (7,52)	119 -12,06 (0,61)	-1,32 [-2,79;0,15] 0,079 -0,19 [-0,41;0,02]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Woche 52	295 22,54 (7,57)	248 -13,79 (0,42)	145 22,01 (7,52)	116 -12,38 (0,60)	-1,41 [-2,85;0,04] 0,057 -0,21 [-0,43;0,01]
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; PRO: Patient Reported Outcome, defined as 2 of the patient-reported items of the CDAI (SF and AP); RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score (<12, ≥ 12), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).					

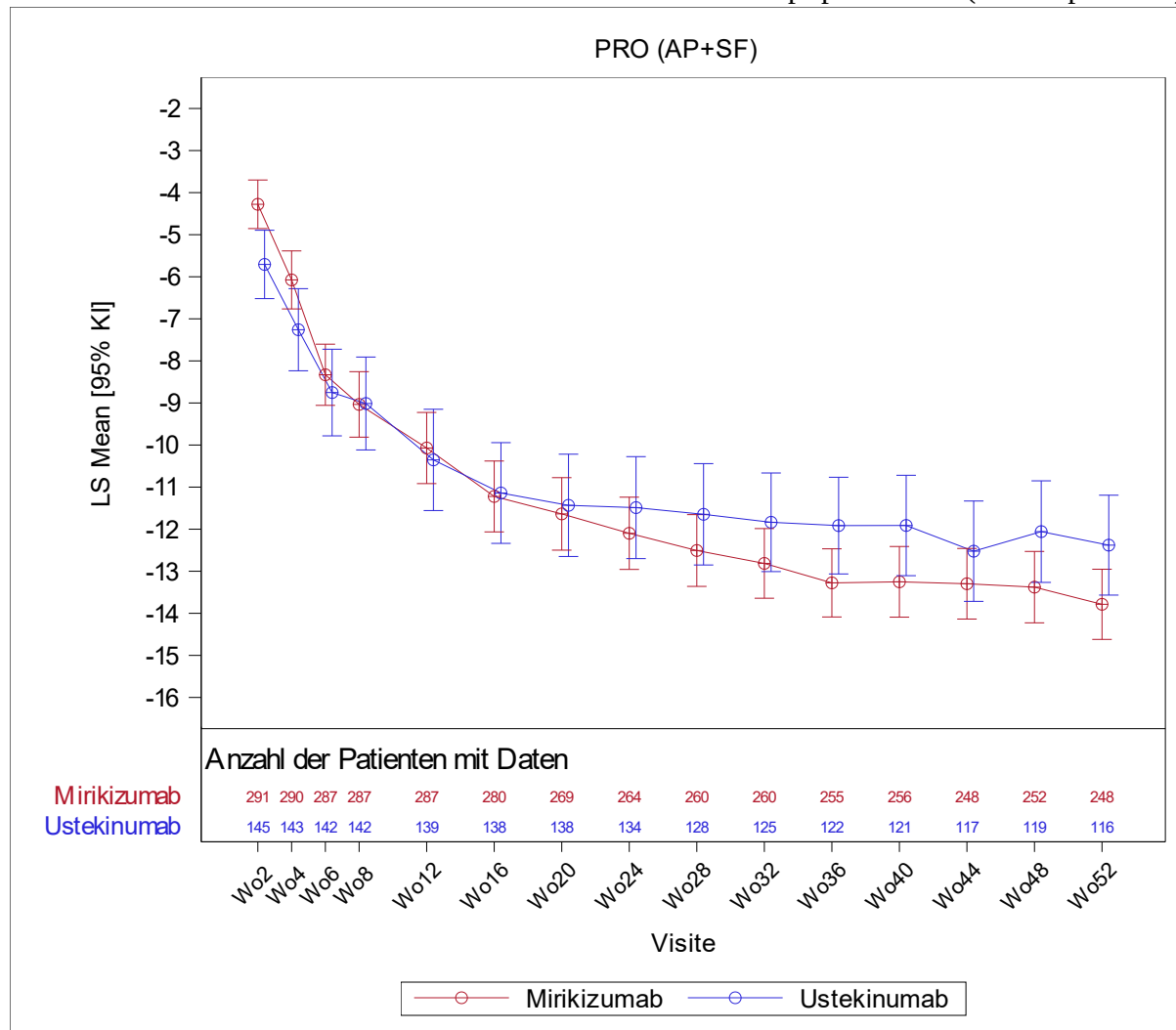
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Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_pro2rm_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des PRO (AP+SF) bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)



Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; PRO: Patient Reported Outcome, defined as 2 of the patient-reported items of the CDAI (SF and AP); RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Anhang 4-G.4.4.3.2 Symptomatik**Darm- und systemische Symptome IBDQ**

Die Ergebnisse sind Anhang 4-G.4.4.3.4 zu entnehmen.

Stuhlfrequenz – CDAI-SF

Ergebnisse für die Veränderung des Stool frequency von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Stool frequency					
Woche 2	296 5,97 (3,41)	292 -1,18 (0,10)	145 5,95 (3,20)	145 -1,64 (0,14)	0,45 [0,12;0,78] 0,007 0,27 [0,07;0,47]
Woche 4	296 5,97 (3,41)	291 -1,67 (0,12)	145 5,95 (3,20)	143 -2,12 (0,16)	0,45 [0,06;0,84] 0,025 0,23 [0,03;0,43]
Woche 6	296 5,97 (3,41)	288 -2,25 (0,12)	145 5,95 (3,20)	142 -2,51 (0,17)	0,26 [-0,15;0,68] 0,215 0,13 [-0,07;0,33]
Woche 8	296 5,97 (3,41)	288 -2,39 (0,14)	145 5,95 (3,20)	142 -2,62 (0,19)	0,23 [-0,24;0,69] 0,334 0,10 [-0,10;0,30]
Woche 12	296 5,97 (3,41)	288 -2,69 (0,15)	145 5,95 (3,20)	139 -2,96 (0,21)	0,28 [-0,22;0,77] 0,277 0,11 [-0,09;0,31]
Woche 16	296 5,97 (3,41)	281 -3,03 (0,14)	145 5,95 (3,20)	138 -3,22 (0,20)	0,19 [-0,30;0,68] 0,445 0,08 [-0,12;0,28]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Woche 20	296 5,97 (3,41)	270 -3,10 (0,15)	145 5,95 (3,20)	138 -3,21 (0,21)	0,11 [-0,39;0,61] 0,666 0,05 [-0,16;0,25]
Woche 24	296 5,97 (3,41)	265 -3,28 (0,14)	145 5,95 (3,20)	134 -3,24 (0,20)	-0,04 [-0,53;0,44] 0,865 -0,02 [-0,23;0,19]
Woche 28	296 5,97 (3,41)	260 -3,35 (0,14)	145 5,95 (3,20)	128 -3,32 (0,20)	-0,03 [-0,51;0,46] 0,908 -0,01 [-0,22;0,20]
Woche 32	296 5,97 (3,41)	260 -3,35 (0,14)	145 5,95 (3,20)	125 -3,37 (0,20)	0,02 [-0,45;0,49] 0,944 0,01 [-0,21;0,22]
Woche 36	296 5,97 (3,41)	255 -3,48 (0,14)	145 5,95 (3,20)	122 -3,31 (0,19)	-0,17 [-0,63;0,30] 0,480 -0,08 [-0,29;0,14]
Woche 40	296 5,97 (3,41)	256 -3,47 (0,14)	145 5,95 (3,20)	121 -3,29 (0,20)	-0,17 [-0,65;0,30] 0,479 -0,08 [-0,29;0,14]
Woche 44	296 5,97 (3,41)	248 -3,51 (0,14)	145 5,95 (3,20)	117 -3,44 (0,20)	-0,07 [-0,54;0,41] 0,777 -0,03 [-0,25;0,19]
Woche 48	296 5,97 (3,41)	252 -3,53 (0,14)	145 5,95 (3,20)	119 -3,23 (0,20)	-0,30 [-0,78;0,19] 0,235 -0,13 [-0,35;0,09]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline	Veränderung ggü. Baseline	Baseline	Veränderung ggü. Baseline	MWD
	N MW (SD)	N LS Mean (SE) ^a	N MW (SD)	N LS Mean (SE) ^a	[95 % KI] p-Wert ^a Hedges'g [95 % KI]
Woche 52	296 5,97 (3,41)	248 -3,65 (0,14)	145 5,95 (3,20)	116 -3,40 (0,19)	-0,26 [-0,72;0,21] 0,279 -0,12 [-0,34;0,10]
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score (<12, ≥ 12), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).					

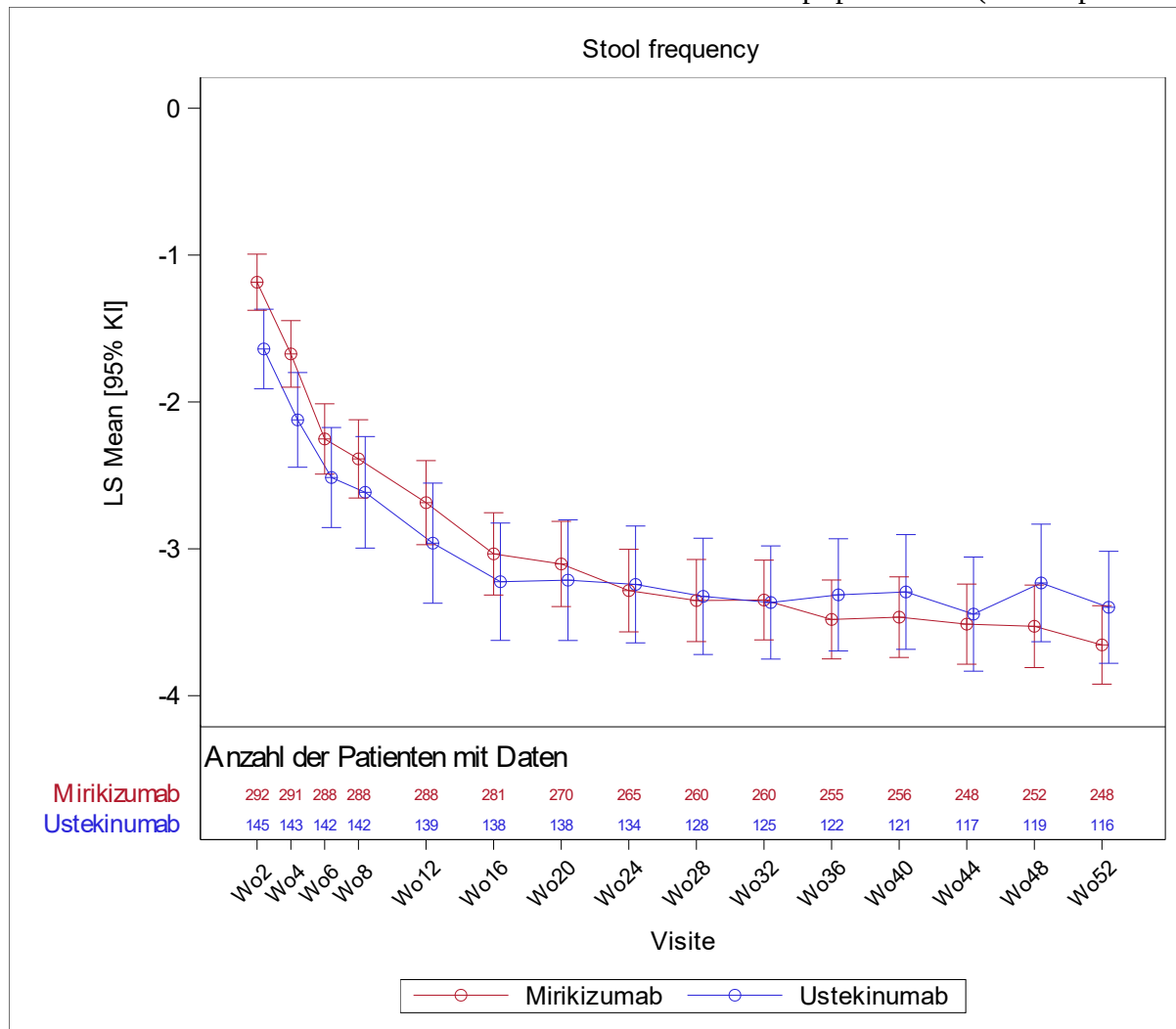
Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_sfrm_ittb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adefl_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des Stool frequency bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)



Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adef_gba

19DEC2024 / 13:38

Imperativer Stuhldrang - Urgency NRS

Ergebnisse für die Veränderung des Urgency NRS von Baseline bis Woche 52 in RCT
VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Urgency NRS					
Woche 2	299 6,71 (2,15)	295 -0,88 (0,09)	145 6,54 (2,16)	145 -1,18 (0,12)	0,30 [0,00;0,60] 0,047 0,20 [0,00;0,40]
Woche 4	299 6,71 (2,15)	294 -1,25 (0,11)	145 6,54 (2,16)	143 -1,68 (0,16)	0,42 [0,05;0,80] 0,027 0,22 [0,02;0,43]
Woche 6	299 6,71 (2,15)	291 -1,79 (0,11)	145 6,54 (2,16)	142 -1,97 (0,16)	0,18 [-0,21;0,57] 0,368 0,09 [-0,11;0,29]
Woche 8	299 6,71 (2,15)	291 -2,09 (0,12)	145 6,54 (2,16)	142 -2,06 (0,17)	-0,03 [-0,45;0,39] 0,887 -0,01 [-0,22;0,19]
Woche 12	299 6,71 (2,15)	291 -2,48 (0,14)	145 6,54 (2,16)	139 -2,44 (0,20)	-0,04 [-0,51;0,43] 0,862 -0,02 [-0,22;0,18]
Woche 16	299 6,71 (2,15)	284 -2,83 (0,14)	145 6,54 (2,16)	138 -2,73 (0,20)	-0,09 [-0,57;0,38] 0,704 -0,04 [-0,24;0,16]
Woche 20	299 6,71 (2,15)	273 -2,99 (0,14)	145 6,54 (2,16)	138 -2,82 (0,20)	-0,17 [-0,65;0,31] 0,492 -0,07 [-0,28;0,13]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Woche 24	299 6,71 (2,15)	268 -3,12 (0,14)	145 6,54 (2,16)	134 -2,91 (0,20)	-0,20 [-0,68;0,27] 0,400 -0,09 [-0,30;0,12]
Woche 28	299 6,71 (2,15)	263 -3,19 (0,14)	145 6,54 (2,16)	128 -2,94 (0,20)	-0,25 [-0,74;0,23] 0,305 -0,11 [-0,32;0,10]
Woche 32	299 6,71 (2,15)	263 -3,29 (0,14)	145 6,54 (2,16)	125 -3,02 (0,20)	-0,27 [-0,75;0,22] 0,280 -0,12 [-0,33;0,10]
Woche 36	299 6,71 (2,15)	258 -3,46 (0,14)	145 6,54 (2,16)	122 -3,15 (0,20)	-0,31 [-0,80;0,17] 0,204 -0,14 [-0,35;0,08]
Woche 40	299 6,71 (2,15)	259 -3,47 (0,15)	145 6,54 (2,16)	121 -3,12 (0,21)	-0,35 [-0,86;0,15] 0,167 -0,15 [-0,37;0,06]
Woche 44	299 6,71 (2,15)	251 -3,47 (0,14)	145 6,54 (2,16)	117 -3,32 (0,21)	-0,16 [-0,65;0,34] 0,530 -0,07 [-0,29;0,15]
Woche 48	299 6,71 (2,15)	255 -3,50 (0,15)	145 6,54 (2,16)	119 -3,29 (0,21)	-0,21 [-0,72;0,30] 0,417 -0,09 [-0,31;0,13]
Woche 52	299 6,71 (2,15)	251 -3,62 (0,15)	145 6,54 (2,16)	116 -3,23 (0,21)	-0,39 [-0,90;0,12] 0,131 -0,17 [-0,39;0,05]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline	Veränderung ggü. Baseline	Baseline	Veränderung ggü. Baseline	MWD
	N MW (SD)	N LS Mean (SE) ^a	N MW (SD)	N LS Mean (SE) ^a	[95 % KI] p-Wert ^a Hedges'g [95 % KI]
Datenschnitt:	23.	August	2023;	Biologic-failed	ITT
Population.					
Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; ITT: Intention-to-treat Population;					
KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW:					
Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; NRS: Numeric Rating Scale;					
RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple					
Endoscopy Score; SF: Stool Frequency; vs.: versus.					
a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score (<12 , ≥ 12), entweder Baseline SF $\geq$					
7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert,					
Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).					

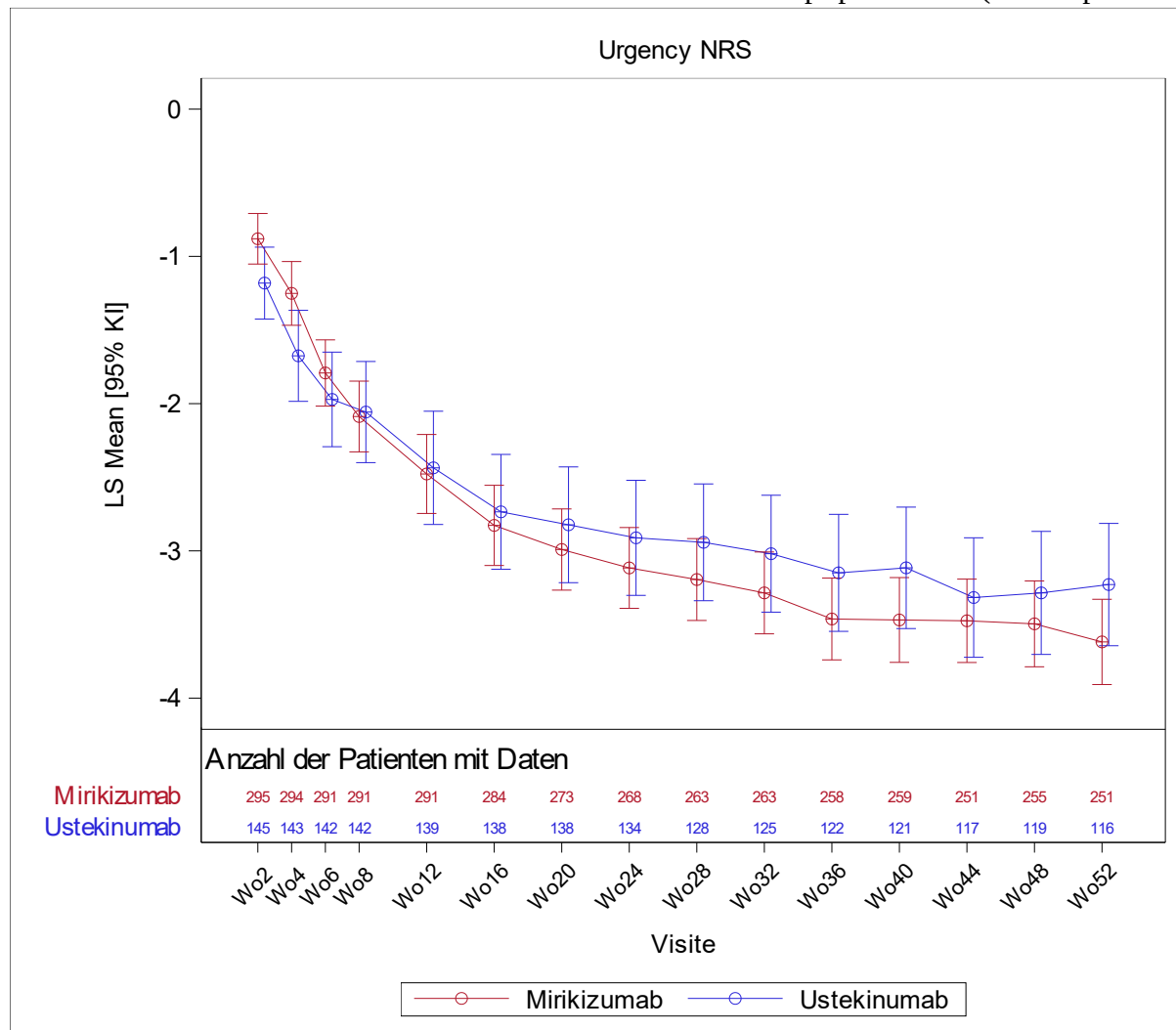
Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_urgrm_ittb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des Urgency NRS bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)



Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; NRS: Numeric Rating Scale; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/f_urgrm_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Abdominelle Schmerzen – CDAI-AP

Ergebnisse für die Veränderung des Abdominal pain von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline	Veränderung	Baseline	Veränderung	MWD
	N MW (SD)	ggü. Baseline N LS Mean (SE) ^a	N MW (SD)	ggü. Baseline N LS Mean (SE) ^a	[95 % KI] p-Wert ^a Hedges'g [95 % KI]
Abdominal pain					
Woche 2	298 2,12 (0,58)	294 -0,37 (0,03)	145 2,02 (0,70)	145 -0,48 (0,04)	0,11 [0,01;0,21] 0,026 0,23 [0,03;0,43]
Woche 4	298 2,12 (0,58)	293 -0,53 (0,04)	145 2,02 (0,70)	143 -0,61 (0,05)	0,08 [-0,04;0,20] 0,200 0,13 [-0,07;0,33]
Woche 6	298 2,12 (0,58)	290 -0,74 (0,04)	145 2,02 (0,70)	142 -0,75 (0,05)	0,00 [-0,13;0,13] 0,979 0,00 [-0,20;0,20]
Woche 8	298 2,12 (0,58)	290 -0,83 (0,04)	145 2,02 (0,70)	142 -0,76 (0,06)	-0,07 [-0,20;0,06] 0,304 -0,11 [-0,31;0,10]
Woche 12	298 2,12 (0,58)	290 -0,92 (0,04)	145 2,02 (0,70)	139 -0,89 (0,06)	-0,03 [-0,17;0,11] 0,706 -0,04 [-0,24;0,16]
Woche 16	298 2,12 (0,58)	283 -1,01 (0,04)	145 2,02 (0,70)	138 -0,95 (0,06)	-0,06 [-0,20;0,08] 0,409 -0,09 [-0,29;0,12]
Woche 20	298 2,12 (0,58)	272 -1,06 (0,04)	145 2,02 (0,70)	138 -1,01 (0,06)	-0,05 [-0,20;0,09] 0,466 -0,08 [-0,28;0,13]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Woche 24	298 2,12 (0,58)	267 -1,09 (0,04)	145 2,02 (0,70)	134 -1,01 (0,06)	-0,08 [-0,23;0,06] 0,263 -0,12 [-0,33;0,09]
Woche 28	298 2,12 (0,58)	263 -1,14 (0,04)	145 2,02 (0,70)	128 -1,00 (0,06)	-0,14 [-0,29;0,00] 0,054 -0,21 [-0,42;0,00]
Woche 32	298 2,12 (0,58)	263 -1,20 (0,04)	145 2,02 (0,70)	125 -1,02 (0,06)	-0,18 [-0,32;-0,04] 0,013 -0,27 [-0,48;-0,05]
Woche 36	298 2,12 (0,58)	258 -1,24 (0,04)	145 2,02 (0,70)	122 -1,06 (0,06)	-0,18 [-0,32;-0,04] 0,011 -0,28 [-0,49;-0,06]
Woche 40	298 2,12 (0,58)	259 -1,24 (0,04)	145 2,02 (0,70)	121 -1,07 (0,06)	-0,17 [-0,32;-0,03] 0,019 -0,26 [-0,47;-0,04]
Woche 44	298 2,12 (0,58)	251 -1,24 (0,04)	145 2,02 (0,70)	117 -1,14 (0,06)	-0,10 [-0,24;0,05] 0,191 -0,15 [-0,37;0,07]
Woche 48	298 2,12 (0,58)	255 -1,25 (0,04)	145 2,02 (0,70)	119 -1,12 (0,06)	-0,12 [-0,27;0,02] 0,096 -0,18 [-0,40;0,03]
Woche 52	298 2,12 (0,58)	251 -1,28 (0,04)	145 2,02 (0,70)	116 -1,13 (0,06)	-0,15 [-0,29;-0,00] 0,046 -0,22 [-0,44;-0,00]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline	Veränderung ggü. Baseline	Baseline	Veränderung ggü. Baseline	MWD
	N MW (SD)	N LS Mean (SE) ^a	N MW (SD)	N LS Mean (SE) ^a	[95 % KI] p-Wert ^a Hedges'g [95 % KI]
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score ($<12, \geq 12$), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).					

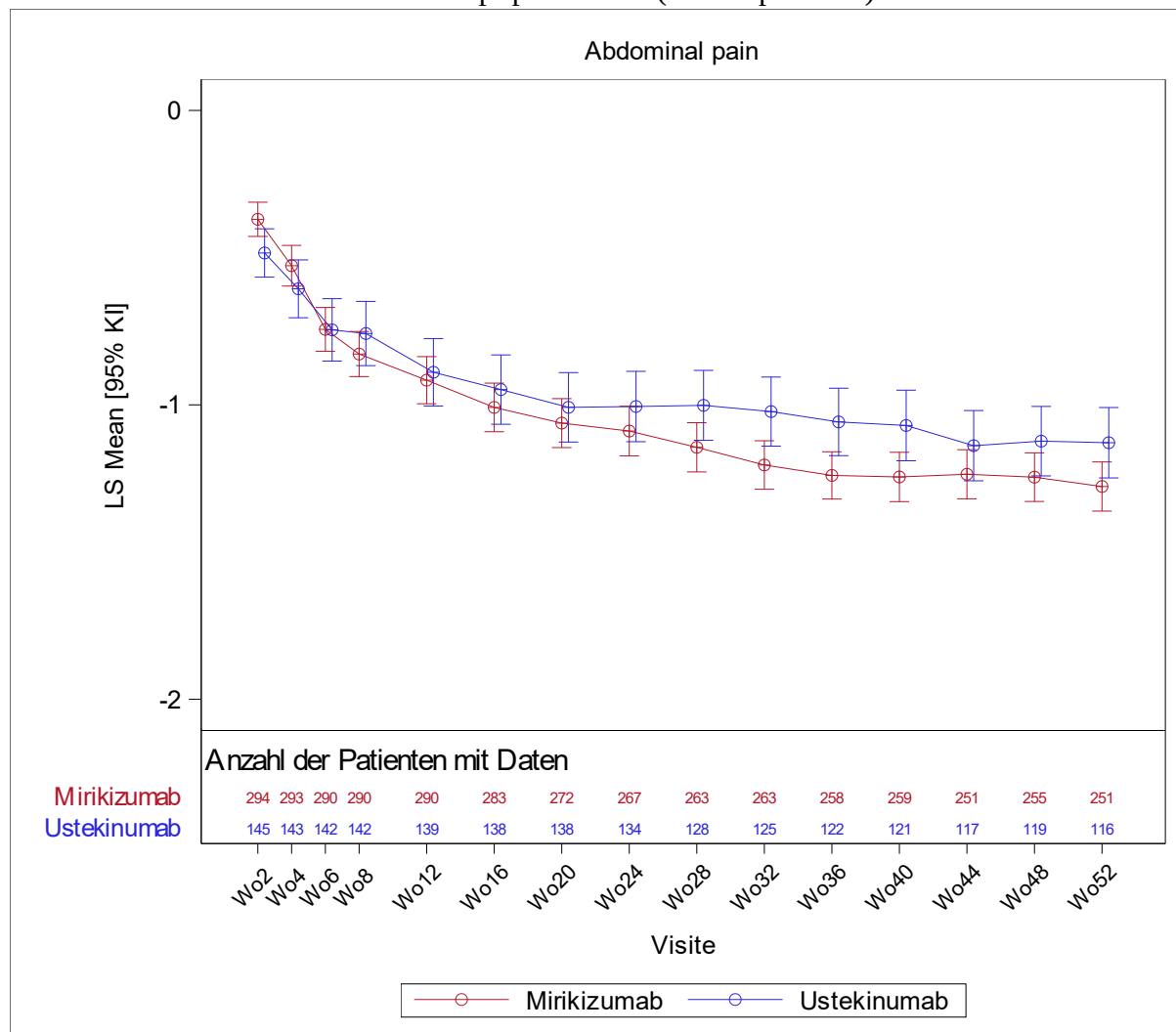
Program Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrm.sas

Output Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_aprm_itb.rtf

Dataset Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Ergebnisse für die Veränderung des Abdominal pain bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)



Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares;

RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/f_aprm_ittb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Fatigue – FACIT Fatigue

Ergebnisse für die Veränderung des FACIT-Fatigue von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

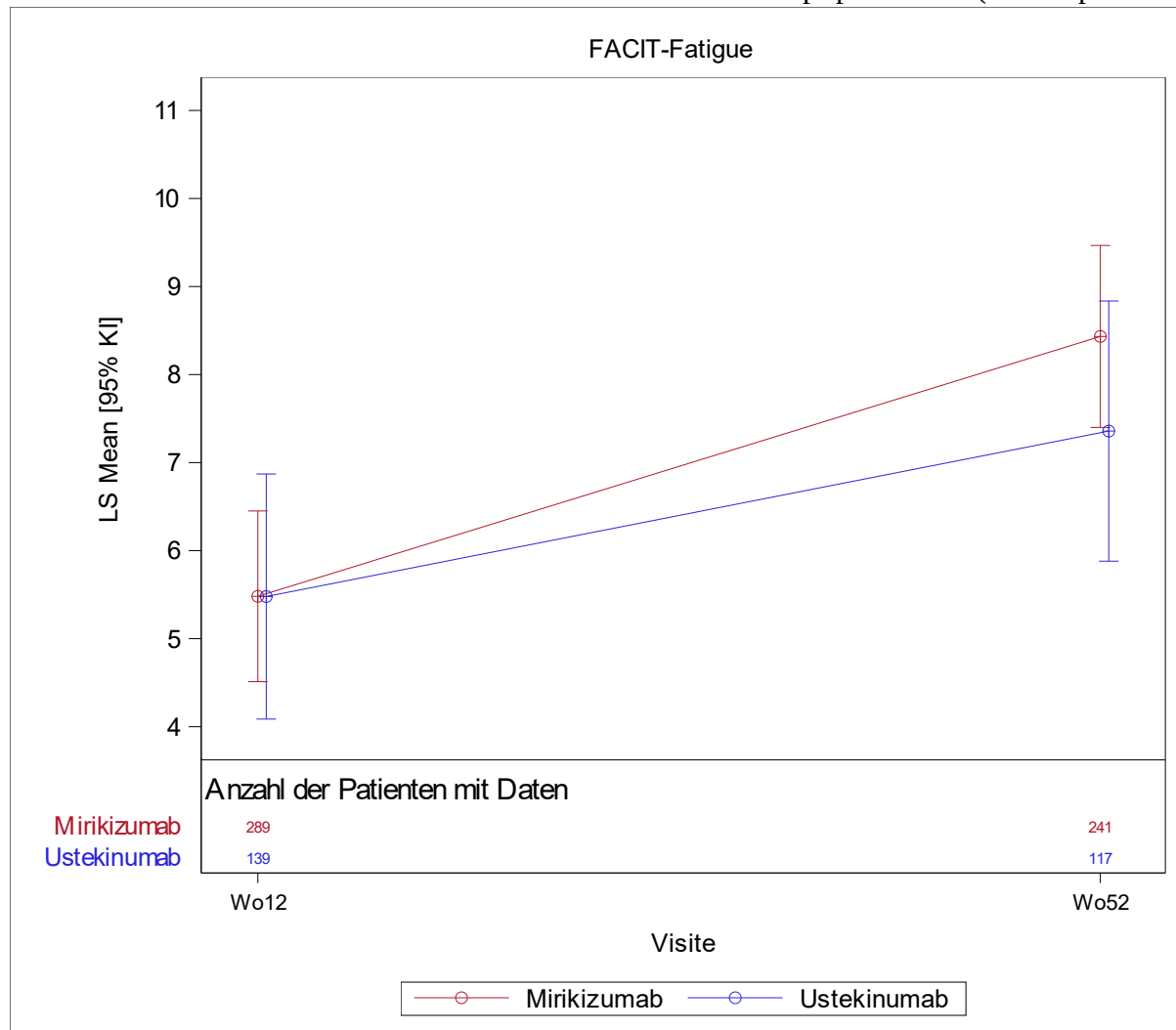
Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
FACIT-Fatigue					
Woche 12	298 31,48 (11,92)	289 5,48 (0,49)	145 31,94 (12,02)	139 5,48 (0,71)	0,00 [-1,69;1,69] 0,998 0,00 [-0,20;0,20]
Woche 52	298 31,48 (11,92)	241 8,43 (0,53)	145 31,94 (12,02)	117 7,36 (0,75)	1,08 [-0,72;2,87] 0,241 0,13 [-0,09;0,35]
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; FACIT: Functional Assessment of Chronic Illness Therapy-Fatigue; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score (<12, ≥12), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_facitrm_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba
19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des FACIT-Fatigue bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)



Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: FACIT: Functional Assessment of Chronic Illness Therapy-Fatigue; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/f_facitrm_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adef_gba

19DEC2024 / 13:38

Depressionen – QIDS-SR16

Ergebnisse für die Veränderung des QIDS-SR16 Total Score von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
QIDS-SR16 Total Score					
Woche 12	296 7,16 (4,84)	288 -1,67 (0,20)	144 6,66 (4,62)	138 -1,50 (0,29)	-0,17 [-0,86;0,53] 0,634 -0,05 [-0,25;0,15]
Woche 24	296 7,16 (4,84)	263 -1,93 (0,21)	144 6,66 (4,62)	133 -1,84 (0,29)	-0,09 [-0,79;0,61] 0,792 -0,03 [-0,24;0,18]
Woche 36	296 7,16 (4,84)	249 -2,24 (0,23)	144 6,66 (4,62)	123 -2,05 (0,33)	-0,19 [-0,99;0,61] 0,641 -0,05 [-0,27;0,16]
Woche 52	296 7,16 (4,84)	238 -2,50 (0,22)	144 6,66 (4,62)	116 -2,17 (0,31)	-0,33 [-1,08;0,42] 0,388 -0,10 [-0,32;0,12]

Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; QIDS-SR16: Quick Inventory of Depressive Symptomatology - Self Report (16 items); RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score (<12, ≥12), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).

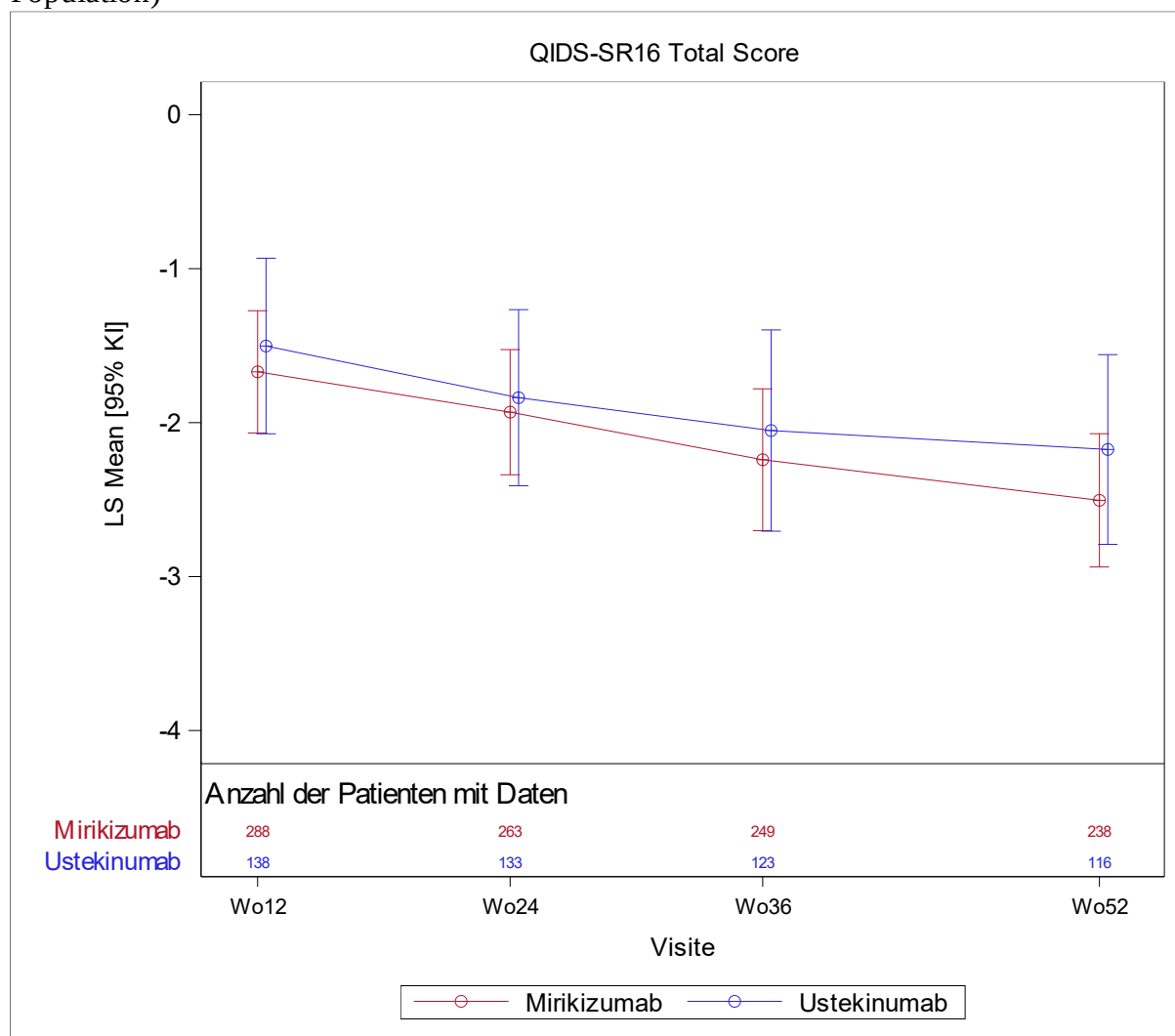
Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_qidsrm_ittb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des QIDS-SR16 Total Score bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)



Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; QIDS-SR16: Quick Inventory of Depressive Symptomatology - Self Report (16 items); RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/f_qidssr16rm_ittb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Anhang 4-G.4.4.3.3 Gesundheitszustand**Gesundheitszustand – EQ-5D VAS**

Ergebnisse für die Veränderung des EQ-5D VAS von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
EQ-5D VAS					
Woche 12	299 53,60 (20,23)	291 17,25 (1,04)	145 53,99 (21,04)	139 15,87 (1,50)	1,38 [-2,21;4,97] 0,450 0,08 [-0,12;0,28]
Woche 52	299 53,60 (20,23)	242 24,33 (0,99)	145 53,99 (21,04)	119 20,40 (1,40)	3,93 [0,57;7,29] 0,022 0,26 [0,04;0,48]
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; EQ-5D: Fragebogen der EuroQol-Gruppe zur Lebensqualität auf 5 Dimensionen; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; VAS: Visuelle Analogskala; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score ($<12, \geq 12$), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).					

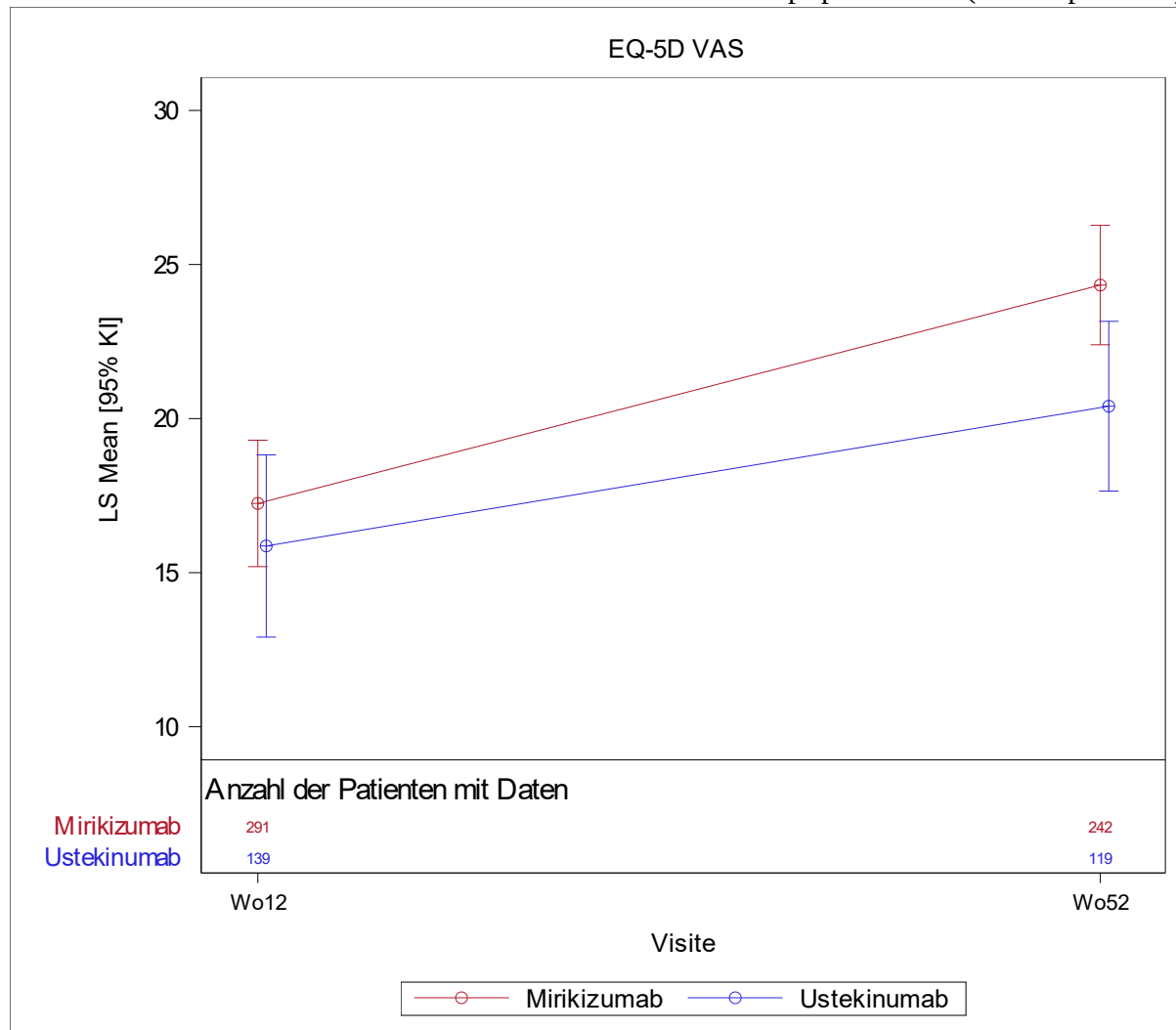
Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_vasrm_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des EQ-5D VAS bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)



Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: EQ-5D: Fragebogen der EuroQol-Gruppe zur Lebensqualität auf 5 Dimensionen; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; VAS: Visuelle Analogskala; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/f_vasrm_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Gesundheitszustand – PGRS

Ergebnisse für die Veränderung des Patient Global Rating of severity (PGRS) von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
PGRS					
Woche 2	298 4,46 (0,82)	294 -0,49 (0,04)	145 4,40 (0,83)	145 -0,67 (0,06)	0,18 [0,03;0,33] 0,018 0,24 [0,04;0,44]
Woche 4	298 4,46 (0,82)	293 -0,72 (0,05)	145 4,40 (0,83)	143 -0,93 (0,07)	0,20 [0,03;0,38] 0,025 0,23 [0,03;0,43]
Woche 6	298 4,46 (0,82)	290 -1,06 (0,06)	145 4,40 (0,83)	142 -1,10 (0,08)	0,03 [-0,16;0,23] 0,741 0,03 [-0,17;0,23]
Woche 8	298 4,46 (0,82)	290 -1,15 (0,06)	145 4,40 (0,83)	142 -1,13 (0,09)	-0,01 [-0,22;0,20] 0,907 -0,01 [-0,21;0,19]
Woche 12	298 4,46 (0,82)	290 -1,35 (0,06)	145 4,40 (0,83)	139 -1,32 (0,09)	-0,03 [-0,25;0,19] 0,777 -0,03 [-0,23;0,17]
Woche 16	298 4,46 (0,82)	283 -1,52 (0,07)	145 4,40 (0,83)	138 -1,41 (0,10)	-0,11 [-0,34;0,11] 0,323 -0,10 [-0,31;0,10]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Woche 20	298 4,46 (0,82)	272 -1,61 (0,07)	145 4,40 (0,83)	138 -1,53 (0,10)	-0,08 [-0,31;0,15] 0,512 -0,07 [-0,27;0,14]
Woche 24	298 4,46 (0,82)	267 -1,64 (0,07)	145 4,40 (0,83)	134 -1,47 (0,10)	-0,17 [-0,40;0,07] 0,163 -0,15 [-0,36;0,06]
Woche 28	298 4,46 (0,82)	262 -1,67 (0,07)	145 4,40 (0,83)	128 -1,50 (0,10)	-0,17 [-0,40;0,06] 0,154 -0,15 [-0,37;0,06]
Woche 32	298 4,46 (0,82)	262 -1,76 (0,07)	145 4,40 (0,83)	125 -1,54 (0,10)	-0,22 [-0,45;0,01] 0,059 -0,20 [-0,42;0,01]
Woche 36	298 4,46 (0,82)	257 -1,82 (0,07)	145 4,40 (0,83)	122 -1,58 (0,09)	-0,24 [-0,47;-0,01] 0,041 -0,22 [-0,44;-0,01]
Woche 40	298 4,46 (0,82)	258 -1,80 (0,07)	145 4,40 (0,83)	121 -1,59 (0,10)	-0,22 [-0,46;0,02] 0,069 -0,20 [-0,42;0,02]
Woche 44	298 4,46 (0,82)	250 -1,81 (0,07)	145 4,40 (0,83)	117 -1,72 (0,10)	-0,09 [-0,33;0,14] 0,448 -0,08 [-0,30;0,14]
Woche 48	298 4,46 (0,82)	254 -1,83 (0,07)	145 4,40 (0,83)	119 -1,71 (0,10)	-0,13 [-0,36;0,11] 0,295 -0,12 [-0,33;0,10]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Woche 52	298 4,46 (0,82)	250 -1,91 (0,07)	145 4,40 (0,83)	116 -1,74 (0,10)	-0,16 [-0,40;0,07] 0,177 -0,15 [-0,37;0,07]
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; PGRS: Patient Global Rating of Severity; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score ($<12, \geq 12$), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).					

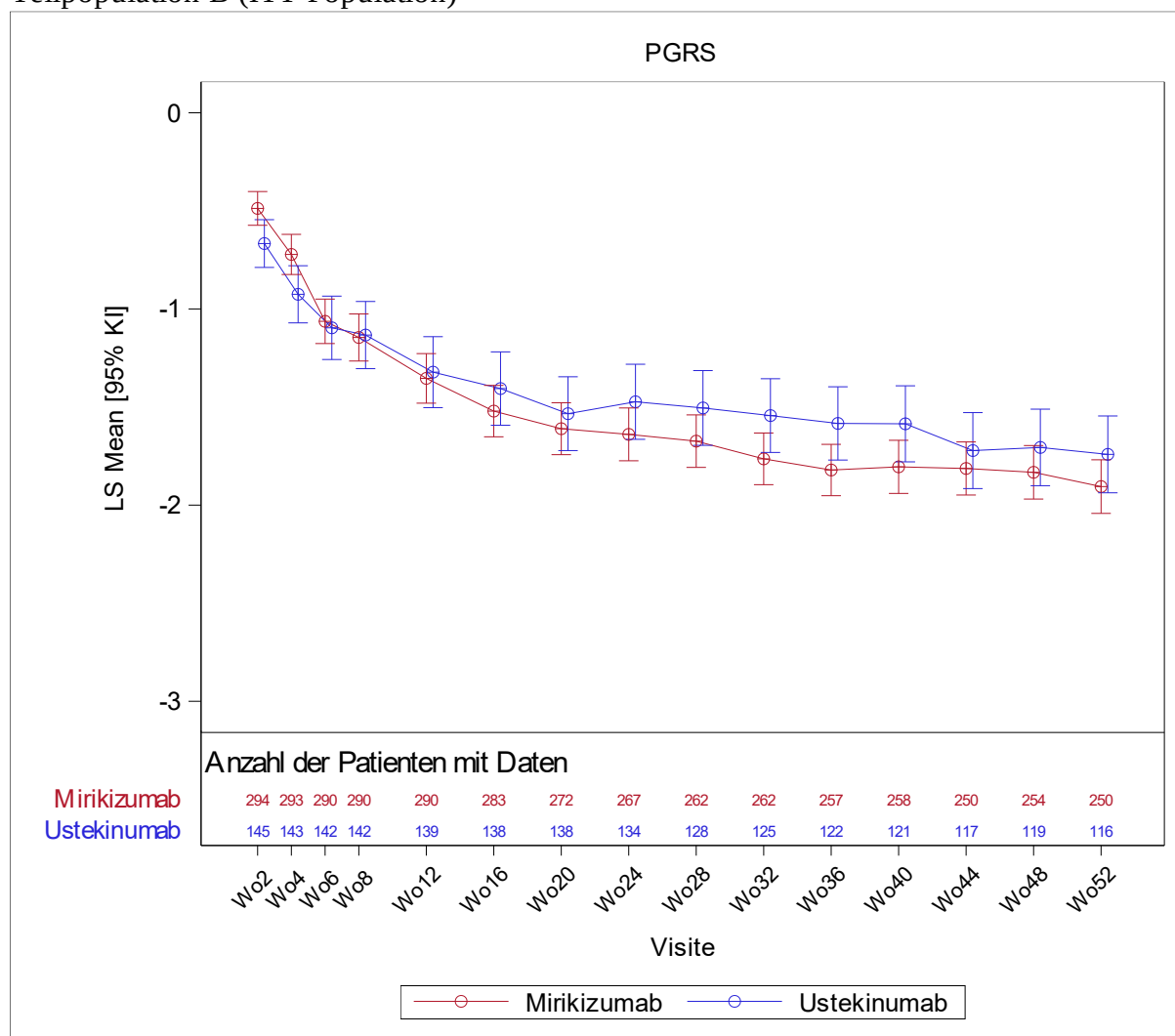
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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des Patient Global Rating of severity (PGRS) bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)



Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; PGRS: Patient Global Rating of Severity; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

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19DEC2024 / 13:38

Gesundheitszustand – PGIC

Ergebnisse für Patient Reported Impression of Change (PGIC) von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
PGIC					
Woche 4	NE	289 3,05 (0,06)	NE	142 2,96 (0,08)	0,09 [-0,11;0,28] 0,379 0,09 [-0,11;0,29]
Woche 8	NE	289 2,70 (0,06)	NE	142 2,78 (0,08)	-0,08 [-0,29;0,12] 0,414 -0,08 [-0,28;0,12]
Woche 12	NE	292 2,64 (0,07)	NE	139 2,62 (0,10)	0,02 [-0,22;0,26] 0,848 0,02 [-0,18;0,22]
Woche 52	NE	243 2,03 (0,06)	NE	119 2,25 (0,09)	-0,22 [-0,44;-0,00] 0,049 -0,22 [-0,44;-0,00]

Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; NE: Nicht errechenbar/nicht erreicht; PGIC: Patient Global Impression of Change; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score (<12, ≥12), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).

PGIC umfasst die Werte einer 5-stufigen Skala von 1 ('viel besser') bis 5 ('viel schlechter').

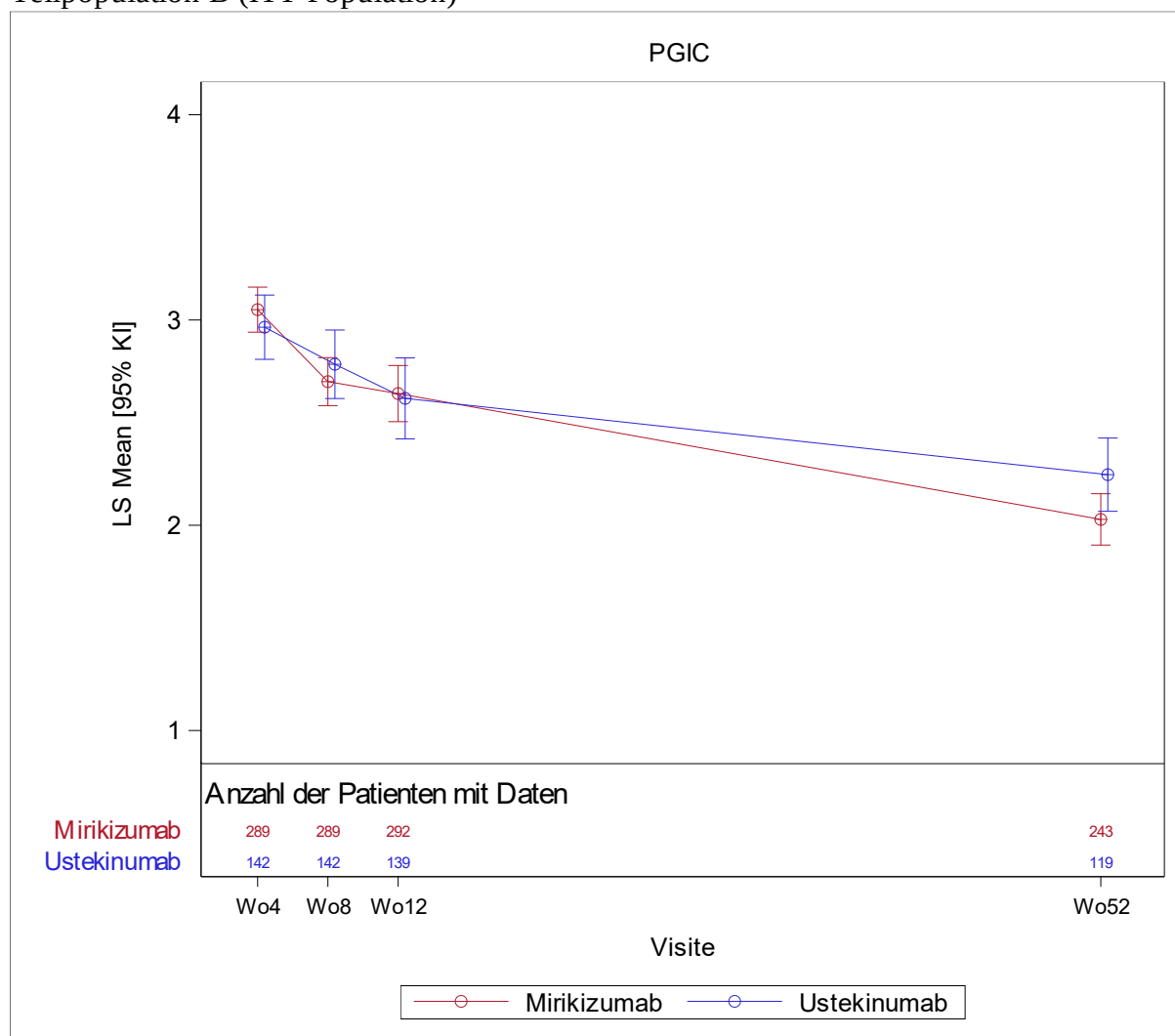
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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des Patient Reported Impression of Change (PGIC) bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)



Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; PGIC: Patient Global Impression of Change; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

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19DEC2024 / 13:38

Gesundheitszustand – WPAI-CD (Aktivitätsbeeinträchtigung)

Ergebnisse für die Veränderung des WPAI (Activity impairment) von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population, Participants with baseline employment status of Yes)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline	Veränderung ggü. Baseline	Baseline	Veränderung ggü. Baseline	MWD
	N MW (SD)	N LS Mean (SE) ^a	N MW (SD)	N LS Mean (SE) ^a	[95 % KI] p-Wert ^a Hedges'g [95 % KI]
WPAI (Activity impairment)					
Woche 12	173 50,64 (25,73)	170 -23,21 (1,79)	80 50,38 (25,83)	77 -24,92 (2,65)	1,71 [-4,53;7,95] 0,590 0,07 [-0,20;0,34]
Woche 52	173 50,64 (25,73)	142 -32,46 (1,75)	80 50,38 (25,83)	67 -29,69 (2,53)	-2,77 [-8,77;3,23] 0,364 -0,13 [-0,42;0,16]
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus; WPAI: Work Productivity and Activity Impairment Questionnaire. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score (<12 , ≥ 12), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz- Struktur).					

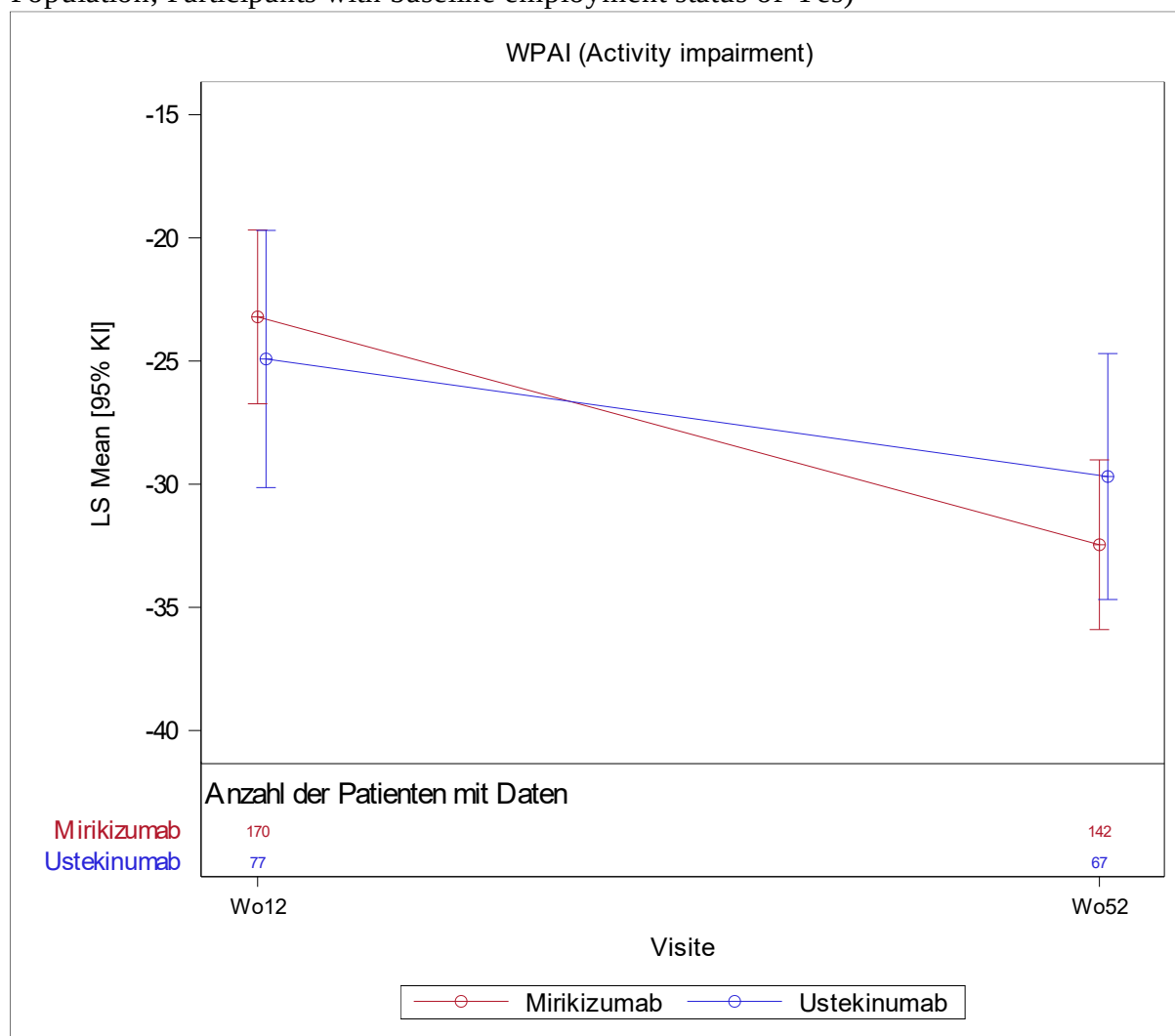
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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adef_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des WPAI (Activity impairment) bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population, Participants with baseline employment status of Yes)



Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; Wo: Woche; WPAI: Work Productivity and Activity Impairment Questionnaire.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

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19DEC2024 / 13:38

Allgemeinbefinden - CDAI-GWP

Ergebnisse für die Veränderung des General well being von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
General well being					
Woche 2	299 2,29 (0,87)	295 -0,44 (0,04)	145 2,27 (0,96)	145 -0,55 (0,05)	0,11 [-0,01;0,23] 0,074 0,18 [-0,02;0,38]
Woche 4	299 2,29 (0,87)	294 -0,62 (0,04)	145 2,27 (0,96)	143 -0,72 (0,06)	0,09 [-0,05;0,24] 0,212 0,13 [-0,07;0,33]
Woche 6	299 2,29 (0,87)	291 -0,86 (0,04)	145 2,27 (0,96)	142 -0,89 (0,06)	0,03 [-0,13;0,18] 0,736 0,03 [-0,17;0,24]
Woche 8	299 2,29 (0,87)	291 -0,90 (0,05)	145 2,27 (0,96)	142 -0,87 (0,07)	-0,04 [-0,20;0,12] 0,630 -0,05 [-0,25;0,15]
Woche 12	299 2,29 (0,87)	291 -1,04 (0,05)	145 2,27 (0,96)	139 -1,02 (0,07)	-0,01 [-0,18;0,15] 0,872 -0,02 [-0,22;0,19]
Woche 16	299 2,29 (0,87)	284 -1,15 (0,05)	145 2,27 (0,96)	138 -1,05 (0,07)	-0,10 [-0,27;0,07] 0,258 -0,12 [-0,32;0,09]
Woche 20	299 2,29 (0,87)	273 -1,24 (0,05)	145 2,27 (0,96)	138 -1,12 (0,07)	-0,12 [-0,29;0,05] 0,170 -0,14 [-0,35;0,06]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
Woche 24	299 2,29 (0,87)	268 -1,23 (0,05)	145 2,27 (0,96)	134 -1,08 (0,07)	-0,15 [-0,33;0,02] 0,092 -0,18 [-0,39;0,03]
Woche 28	299 2,29 (0,87)	263 -1,29 (0,05)	145 2,27 (0,96)	128 -1,14 (0,07)	-0,15 [-0,32;0,02] 0,081 -0,19 [-0,40;0,02]
Woche 32	299 2,29 (0,87)	263 -1,32 (0,05)	145 2,27 (0,96)	125 -1,13 (0,07)	-0,19 [-0,35;-0,02] 0,031 -0,23 [-0,45;-0,02]
Woche 36	299 2,29 (0,87)	258 -1,36 (0,05)	145 2,27 (0,96)	122 -1,16 (0,07)	-0,20 [-0,36;-0,04] 0,016 -0,26 [-0,48;-0,05]
Woche 40	299 2,29 (0,87)	259 -1,36 (0,05)	145 2,27 (0,96)	121 -1,14 (0,07)	-0,22 [-0,38;-0,05] 0,013 -0,27 [-0,49;-0,06]
Woche 44	299 2,29 (0,87)	251 -1,36 (0,05)	145 2,27 (0,96)	117 -1,25 (0,07)	-0,10 [-0,28;0,07] 0,237 -0,13 [-0,35;0,09]
Woche 48	299 2,29 (0,87)	255 -1,37 (0,05)	145 2,27 (0,96)	119 -1,26 (0,07)	-0,11 [-0,27;0,06] 0,200 -0,14 [-0,36;0,08]
Woche 52	299 2,29 (0,87)	251 -1,43 (0,05)	145 2,27 (0,96)	116 -1,24 (0,07)	-0,19 [-0,36;-0,03] 0,024 -0,25 [-0,47;-0,03]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline	Veränderung ggü. Baseline	Baseline	Veränderung ggü. Baseline	MWD
	N MW (SD)	N LS Mean (SE) ^a	N MW (SD)	N LS Mean (SE) ^a	[95 % KI] p-Wert ^a Hedges'g [95 % KI]
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score (<12 , ≥ 12), entweder Baseline SF $\geq$ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz- Struktur).					

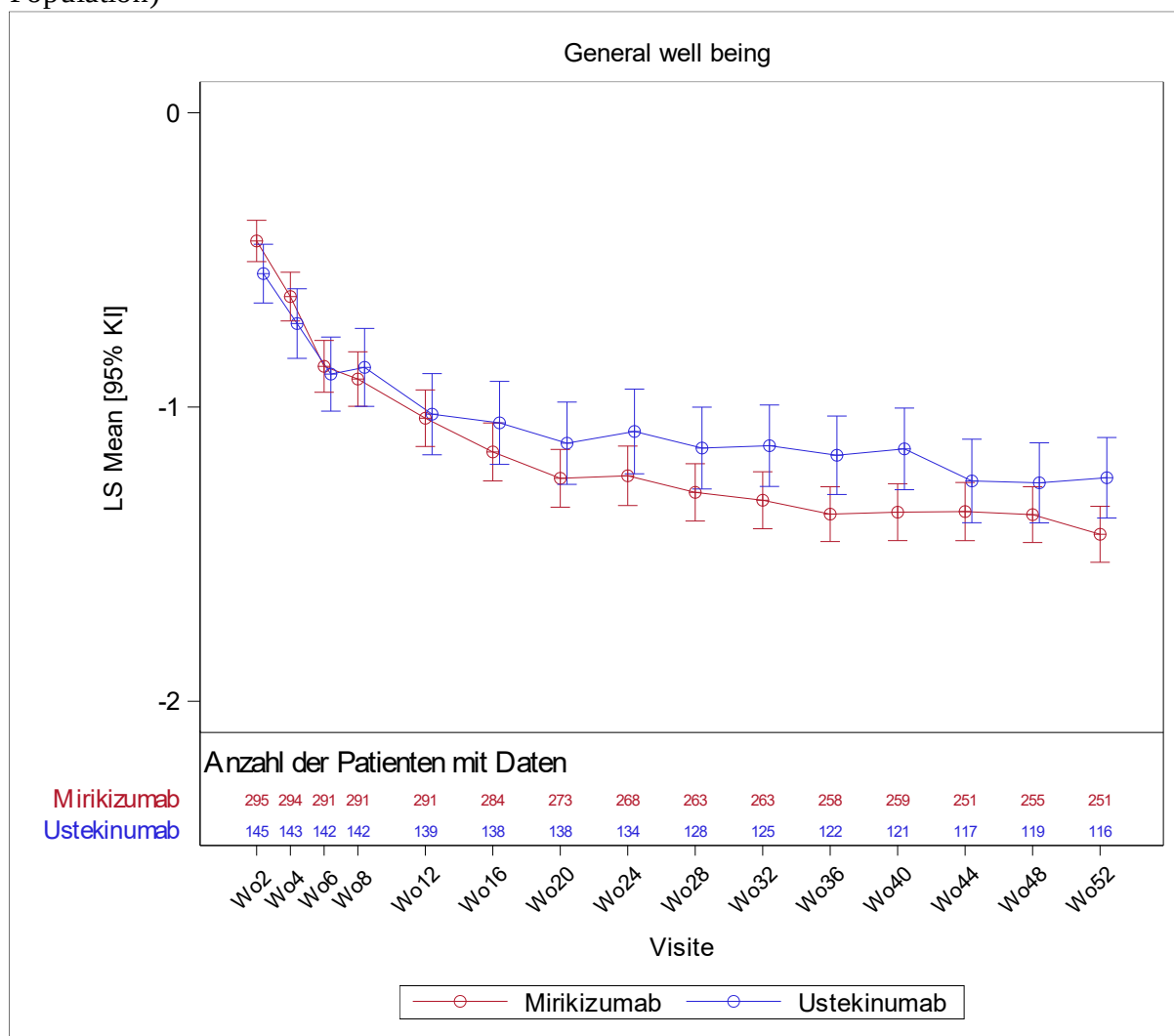
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Dataset Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des General well being bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)



Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

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19DEC2024 / 13:38

Anhang 4-G.4.4.3.4 Gesundheitsbezogene Lebensqualität**Krankheitsspezifische Lebensqualität**

Ergebnisse für die Veränderung des IBDQ von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
IBDQ Total Score					
Woche 12	299 127,45 (32,70)	291 36,16 (1,69)	145 126,51 (34,90)	139 37,63 (2,44)	-1,48 [-7,29;4,33] 0,617 -0,05 [-0,25;0,15]
Woche 52	299 127,45 (32,70)	242 49,80 (1,74)	145 126,51 (34,90)	119 45,87 (2,47)	3,94 [-1,98;9,86] 0,192 0,15 [-0,07;0,37]
IBDQ Bowel Symptoms					
Woche 12	299 37,80 (9,54)	291 13,60 (0,57)	145 37,26 (9,87)	139 14,09 (0,82)	-0,49 [-2,45;1,47] 0,626 -0,05 [-0,25;0,15]
Woche 52	299 37,80 (9,54)	242 18,27 (0,55)	145 37,26 (9,87)	119 16,43 (0,79)	1,84 [-0,05;3,73] 0,056 0,21 [-0,01;0,43]
IBDQ Emotional Function					
Woche 12	299 51,30 (14,32)	291 10,72 (0,67)	145 51,05 (15,25)	139 11,40 (0,97)	-0,68 [-2,98;1,63] 0,566 -0,06 [-0,26;0,14]
Woche 52	299 51,30 (14,32)	242 15,06 (0,71)	145 51,05 (15,25)	119 14,43 (1,01)	0,62 [-1,80;3,04] 0,614 0,06 [-0,16;0,28]

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
IBDQ Social Function					
Woche 12	299 20,77 (7,34)	291 5,96 (0,34)	145 20,46 (7,42)	139 6,33 (0,49)	-0,37 [-1,54;0,80] 0,532 -0,06 [-0,27;0,14]
Woche 52	299 20,77 (7,34)	242 8,32 (0,33)	145 20,46 (7,42)	119 8,09 (0,47)	0,23 [-0,90;1,35] 0,694 0,04 [-0,18;0,26]
IBDQ Systemic Symptoms					
Woche 12	299 17,58 (5,60)	291 5,86 (0,30)	145 17,74 (5,84)	139 5,73 (0,43)	0,12 [-0,90;1,14] 0,812 0,02 [-0,18;0,23]
Woche 52	299 17,58 (5,60)	242 8,17 (0,33)	145 17,74 (5,84)	119 6,88 (0,47)	1,28 [0,15;2,41] 0,027 0,25 [0,03;0,47]
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score (<12, ≥12), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).					

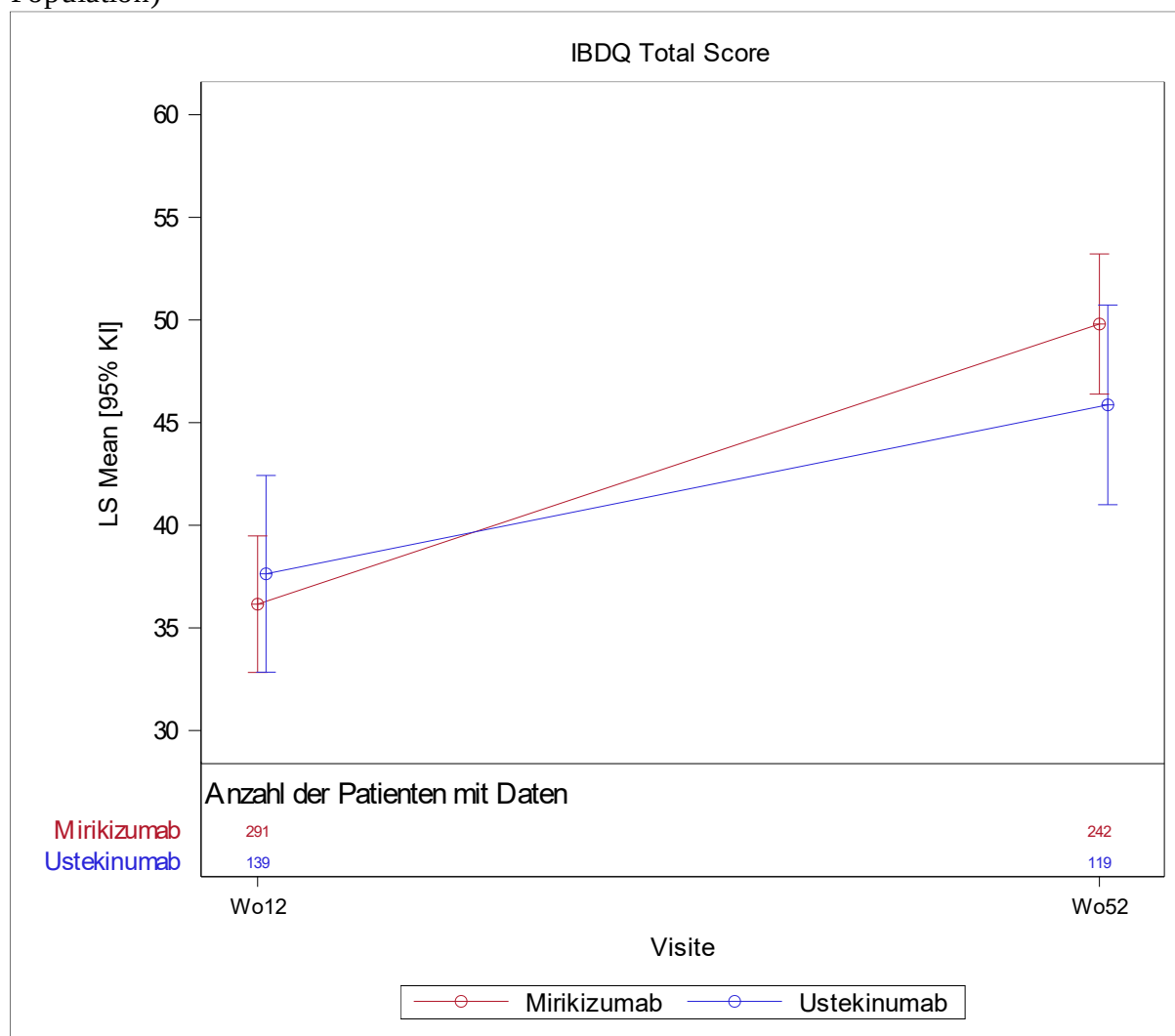
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19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des IBDQ Total Score bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)



Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

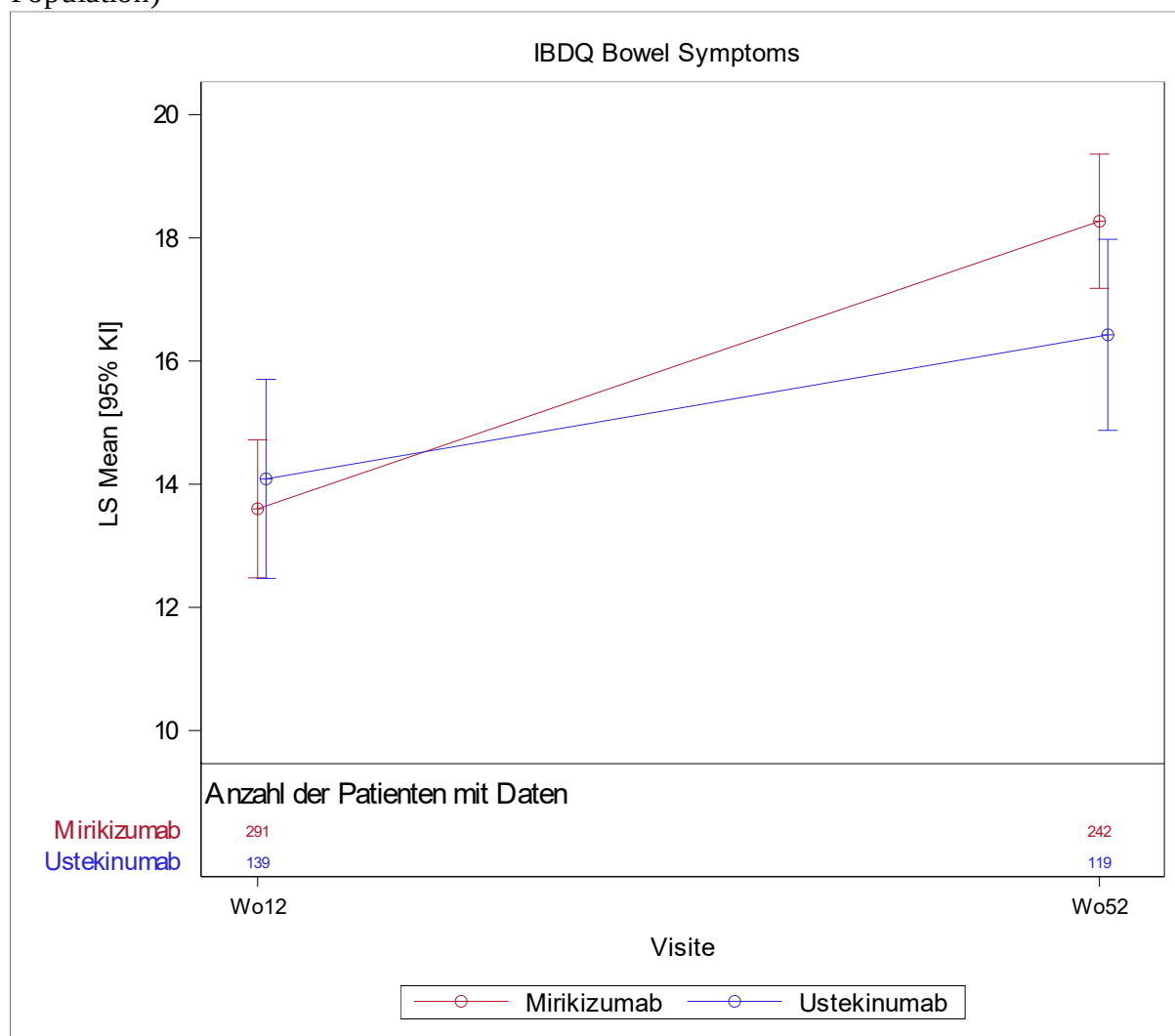
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19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des IBDQ Bowel Symptoms bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)



Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

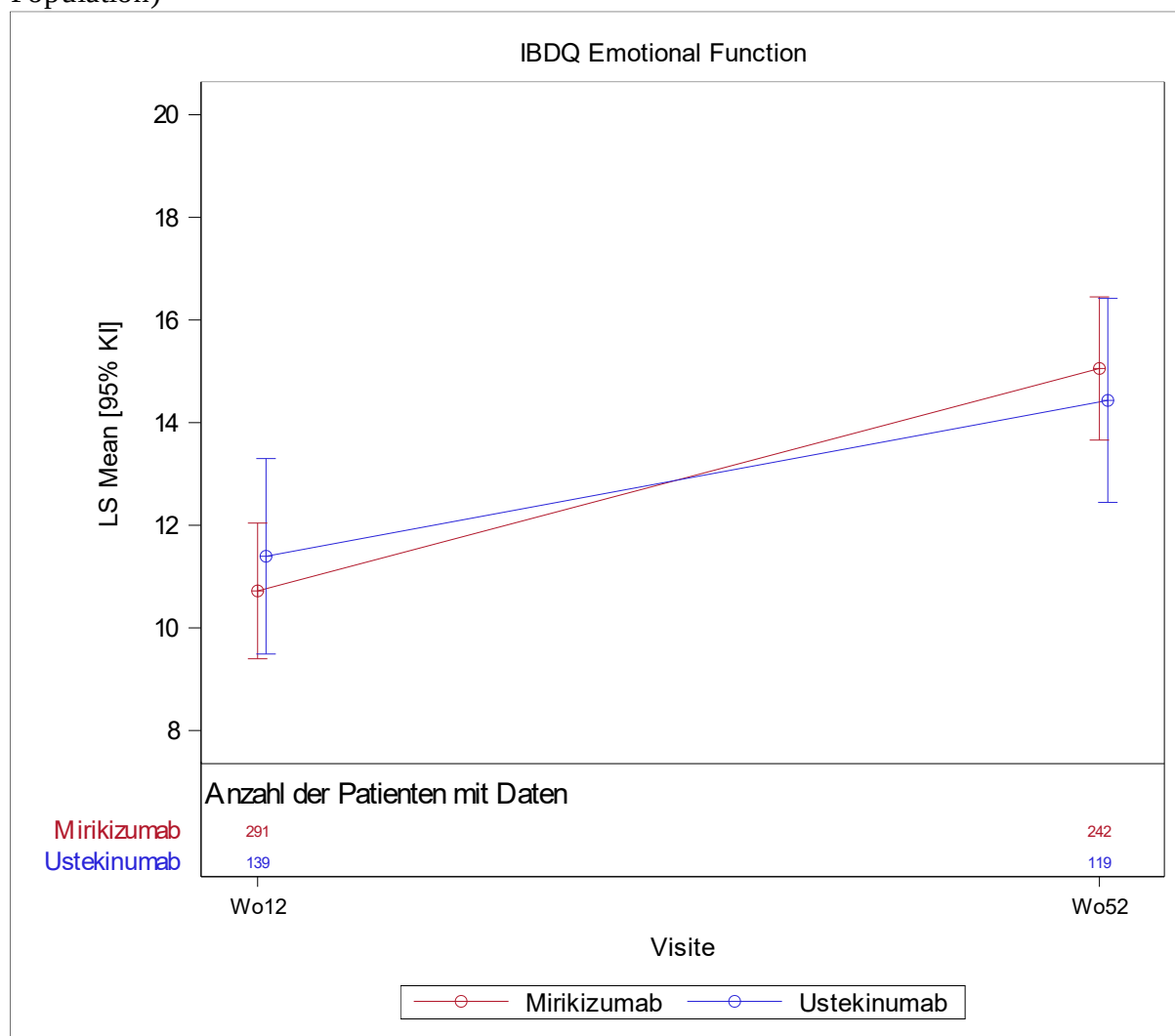
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19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des IBDQ Emotional Function bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)



Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

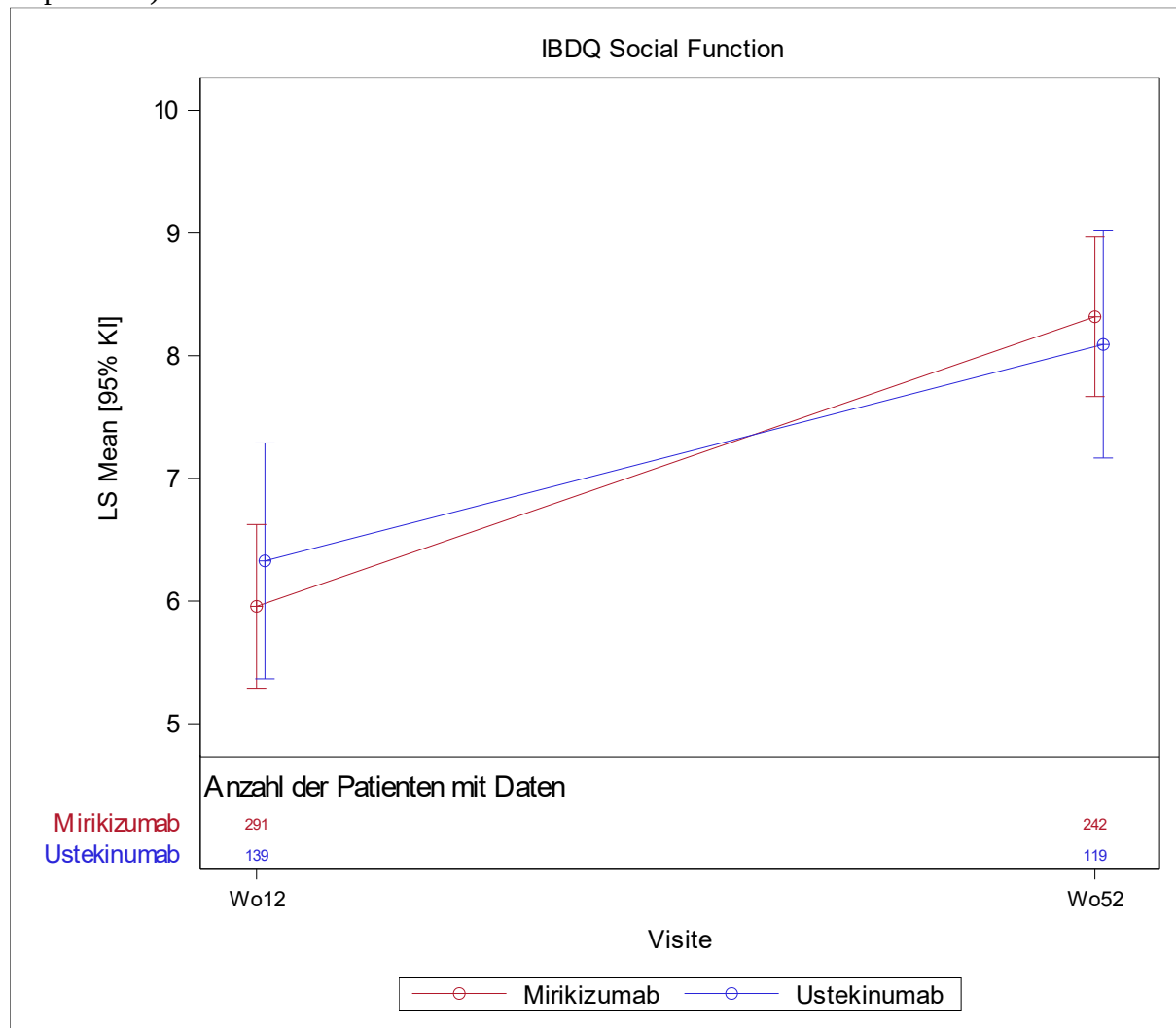
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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des IBDQ Social Function bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)



Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

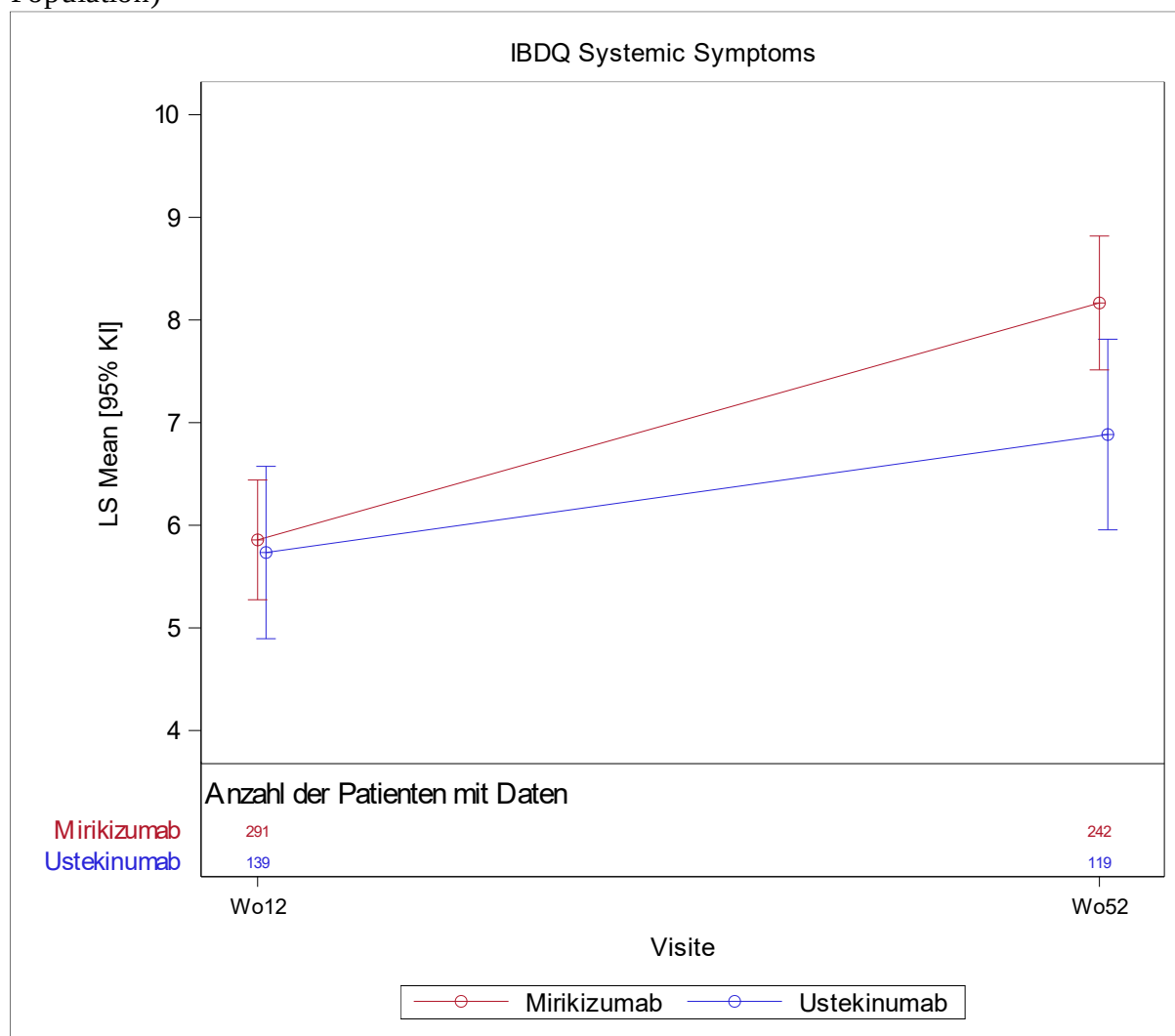
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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des IBDQ Systemic Symptoms bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)



Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; RCT: randomisierte, kontrollierte Studie; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/f_ibdqssrm_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Gesundheitsbezogene Lebensqualität

Ergebnisse für die Veränderung des SF-36 von Baseline bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab		Ustekinumab		Mirikizumab vs. Ustekinumab
	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	Baseline N MW (SD)	Veränderung ggü. Baseline N LS Mean (SE) ^a	MWD [95 % KI] p-Wert ^a Hedges'g [95 % KI]
SF-36 MCS Score					
Woche 12	299 44,41 (10,69)	291 4,03 (0,50)	145 44,98 (10,52)	139 4,62 (0,72)	-0,58 [-2,30;1,13] 0,503 -0,07 [-0,27;0,13]
Woche 52	299 44,41 (10,69)	242 5,58 (0,53)	145 44,98 (10,52)	119 5,72 (0,75)	-0,13 [-1,94;1,67] 0,884 -0,02 [-0,24;0,20]
SF-36 PCS Score					
Woche 12	299 39,15 (7,95)	291 7,80 (0,40)	145 38,75 (7,85)	139 7,92 (0,58)	-0,12 [-1,50;1,27] 0,870 -0,02 [-0,22;0,19]
Woche 52	299 39,15 (7,95)	242 10,99 (0,42)	145 38,75 (7,85)	119 9,80 (0,60)	1,19 [-0,26;2,63] 0,107 0,18 [-0,04;0,40]
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn's Disease; ggü: gegenüber; ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MCS: Mental Health Component Summary Score; MMRM: Gemischtes Modell mit Messwiederholungen; MW: Mittelwert; MWD: Mittelwertdifferenz; N: Anzahl der Patienten in der Analyse; PCS: Physical Health Component Summary Score; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SE: Standardfehler; SES: Simple Endoscopy Score; SF-36: 36-Item Short Form Health Survey; SF: Stool Frequency; vs.: versus. a: das MMRM Modell umfasst Behandlung, Baseline SES-CD Total Score (<12, ≥12), entweder Baseline SF ≥ 7 und/oder Baseline AP ≥ 2.5 (ja oder nein/unbekannt), Visite, Interaktion Behandlung und Visite, Baselinewert, Interaktion Baselinewert und Visite als fixe Faktoren (unstrukturierte Varianz-Kovarianz-Struktur).					

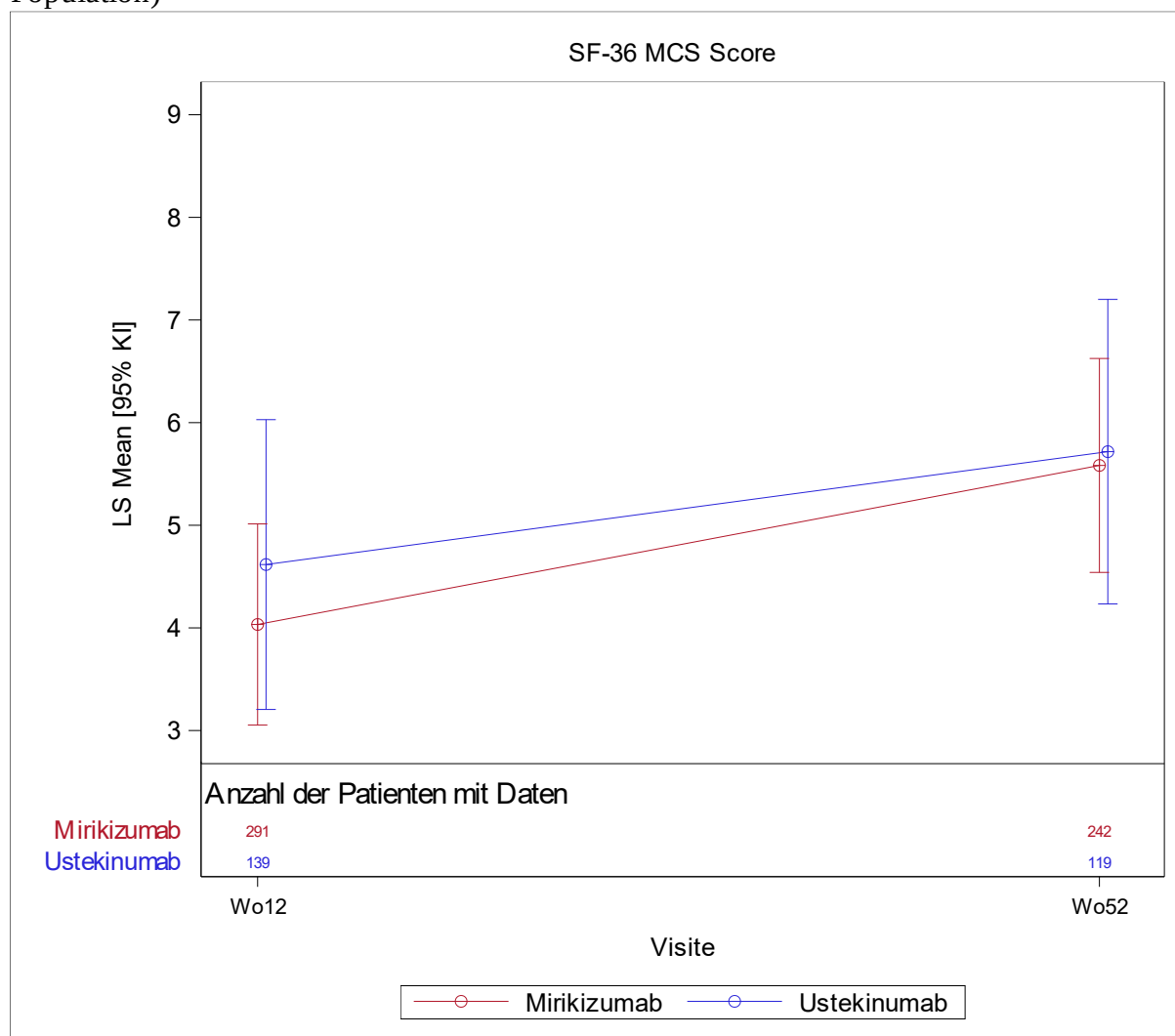
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19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des SF-36 MCS Score bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)



Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; MCS: Mental Health Component Summary Score; RCT: randomisierte, kontrollierte Studie; SF-36: 36-Item Short Form Health Survey; Wo: Woche.

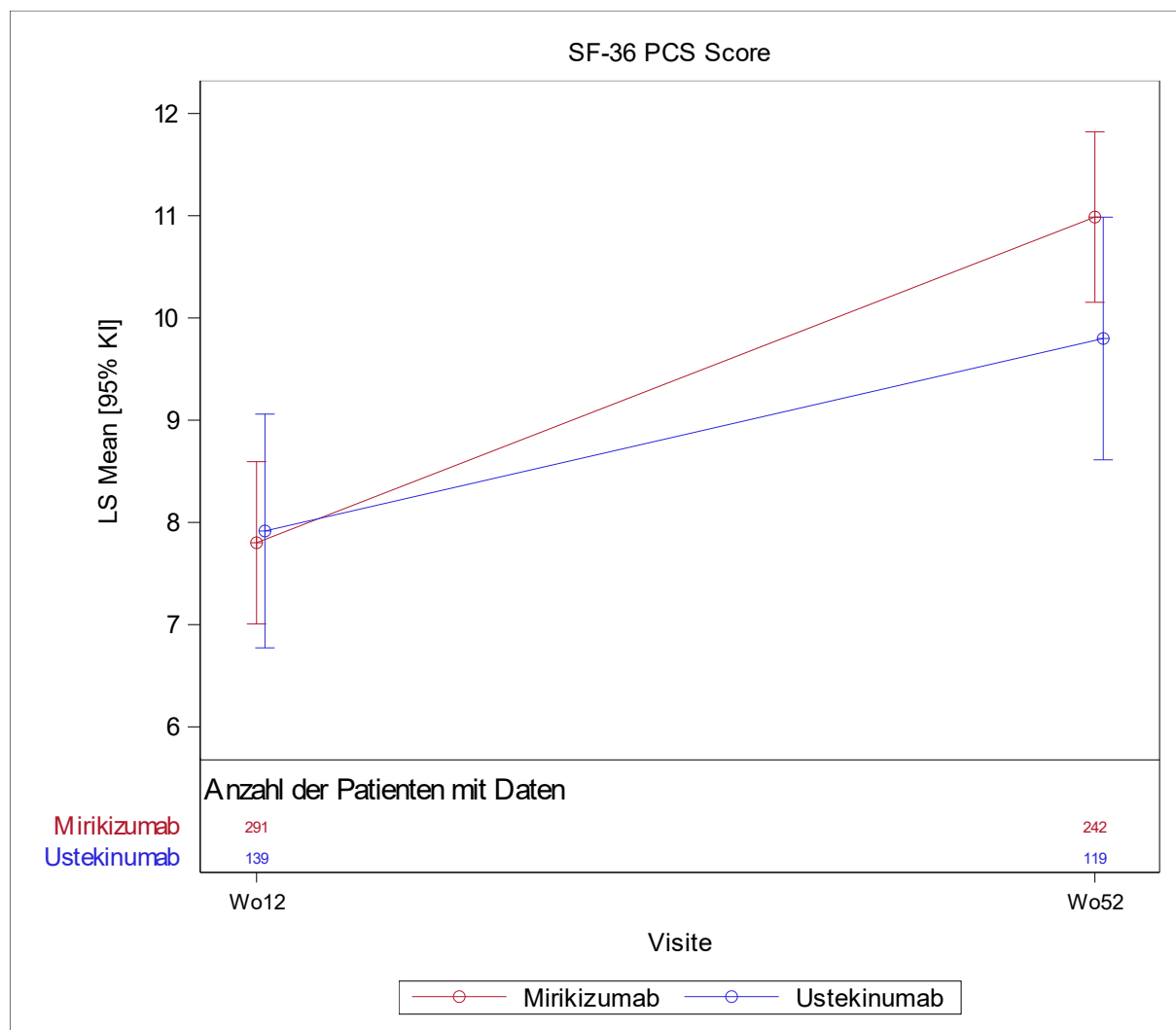
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Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/f_sf36mcsrm_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Grafische Darstellung der Ergebnisse für die Veränderung des SF-36 PCS Score bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)



Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: ITT: Intention-to-treat Population; KI: Konfidenzintervall; LS: Least Squares; PCS: Physical Health Component Summary Score; RCT: randomisierte, kontrollierte Studie; SF-36: 36-Item Short Form Health Survey; Wo: Woche.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/f_effrm_lp.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/f_sf36pcsrn_ittb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 13:38

Anhang 4-G.4.4.4 Verlaufsbeobachtungen der kontinuierlichen Endpunkte in RCT VIVID-1 in Teilpopulation B

Anhang 4-G.4.4.4.1 Klinische Remission

Zusammenfassende Statistik für PRO (AP+SF) in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)			Ustekinumab (N=145)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
PRO (AP+SF)						
Baseline	295	22,5 (7,6) 21,1 8; 75	NB	145	22,0 (7,5) 21,3 10; 57	NB
Woche 2	294	18,3 (7,9) 17,9 1; 69	-4,3 (5,0) -3,1 -25; 7	145	16,3 (7,5) 15,7 0; 48	-5,7 (6,0) -4,4 -36; 8
Woche 4	292	16,5 (8,5) 16,2 0; 69	-6,1 (6,1) -5,0 -34; 9	143	14,8 (7,9) 13,6 0; 54	-7,2 (6,9) -5,9 -32; 6
Woche 6	290	14,1 (8,4) 13,4 0; 73	-8,3 (6,6) -7,3 -36; 7	142	13,3 (7,7) 12,4 0; 44	-8,7 (7,5) -7,7 -33; 9
Woche 8	290	13,5 (8,8) 12,1 0; 63	-9,1 (7,2) -8,1 -37; 31	142	13,0 (7,4) 11,4 0; 40	-9,0 (8,0) -7,7 -44; 4
Woche 12	291	12,3 (9,2) 11,0 0; 66	-10,2 (7,8) -9,6 -37; 34	139	11,5 (7,8) 10,7 0; 51	-10,4 (8,5) -8,7 -49; 6
Woche 16	284	10,9 (9,0) 9,7 0; 78	-11,4 (7,6) -11,0 -37; 6	138	10,6 (7,3) 9,4 0; 43	-11,2 (8,7) -9,9 -53; 7
Woche 20	273	10,5 (8,6) 9,0 0; 58	-11,8 (7,4) -11,3 -37; 6	138	10,5 (8,4) 8,2 0; 54	-11,4 (9,2) -11,2 -48; 26
Woche 24	268	9,9 (8,3) 8,0 0; 53	-12,3 (7,7) -12,1 -37; 4	134	10,2 (7,5) 8,7 0; 56	-11,4 (9,2) -11,0 -50; 27
Woche 28	263	9,4 (7,7) 7,7 0; 56	-12,7 (7,7) -12,4 -37; 4	128	9,8 (6,9) 9,0 0; 38	-11,8 (9,0) -11,0 -54; 8

Endpunkt Zeitpunkt	Mirikizumab (N=300)			Ustekinumab (N=145)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
Woche 32	263	9,0 (7,6) 7,4 0; 52	-13,0 (7,6) -12,4 -37; 6	125	9,5 (6,4) 8,7 0; 37	-12,3 (8,7) -11,6 -53; 8
Woche 36	258	8,5 (7,4) 7,1 0; 48	-13,6 (7,6) -13,1 -38; 6	122	9,3 (5,9) 8,3 0; 30	-12,5 (8,7) -12,1 -51; 8
Woche 40	259	8,4 (7,6) 7,3 0; 54	-13,6 (7,7) -13,4 -37; 10	121	9,2 (6,3) 8,3 0; 34	-12,5 (8,9) -12,0 -51; 9
Woche 44	251	8,5 (7,7) 7,0 0; 56	-13,7 (7,6) -13,4 -37; 5	117	8,5 (6,2) 7,3 0; 32	-13,4 (8,7) -12,1 -48; 7
Woche 48	255	8,3 (7,5) 7,0 0; 52	-13,8 (7,6) -13,4 -36; 5	119	9,1 (6,8) 7,9 0; 39	-12,8 (9,0) -11,0 -49; 10
Woche 52	251	7,9 (7,4) 6,6 0; 60	-14,2 (7,5) -14,0 -40; 2	116	8,7 (6,9) 7,3 0; 38	-13,3 (9,0) -12,7 -51; 7
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; PRO: Patient Reported Outcome, defined as 2 of the patient-reported items of the CDAI (SF and AP); RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

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Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba
19DEC2024 / 12:36

Anhang 4-G.4.4.4.2 Symptomatik**Darm- und systemische Symptome IBDQ**

Die Ergebnisse sind Anhang 4-G.3.4.4.4 zu entnehmen.

Stuhlfrequenz – CDAI-SF

Zusammenfassende Statistik für Stool frequency in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)			Ustekinumab (N=145)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
Stool frequency						
Baseline	296	6,0 (3,4) 5,7 0; 31	NB	145	5,9 (3,2) 5,6 0; 24	NB
Woche 2	294	4,8 (3,3) 4,6 0; 28	-1,2 (1,7) -0,8 -7; 2	145	4,3 (2,9) 4,1 0; 20	-1,7 (2,1) -1,3 -13; 3
Woche 4	292	4,3 (3,4) 4,0 0; 29	-1,7 (2,0) -1,1 -11; 3	143	3,8 (3,1) 3,7 0; 22	-2,1 (2,4) -1,4 -13; 3
Woche 6	290	3,7 (3,2) 3,3 0; 29	-2,2 (2,3) -1,7 -12; 4	142	3,4 (3,0) 3,1 0; 19	-2,5 (2,5) -2,1 -12; 3
Woche 8	290	3,6 (3,4) 2,9 0; 26	-2,4 (2,6) -2,1 -13; 17	142	3,3 (2,8) 3,1 0; 17	-2,6 (2,7) -2,1 -16; 2
Woche 12	291	3,2 (3,5) 2,3 0; 26	-2,7 (2,7) -2,6 -14; 16	139	2,9 (2,9) 2,6 0; 18	-3,0 (2,9) -2,9 -18; 4
Woche 16	284	2,8 (3,3) 2,0 0; 32	-3,1 (2,5) -2,9 -12; 4	138	2,6 (2,7) 1,9 0; 18	-3,3 (3,0) -2,9 -19; 2
Woche 20	273	2,7 (3,1) 2,0 0; 21	-3,2 (2,5) -2,9 -12; 3	138	2,7 (3,1) 1,9 0; 20	-3,3 (3,2) -3,1 -19; 10
Woche 24	268	2,5 (2,9) 1,7 0; 20	-3,3 (2,6) -3,1 -13; 2	134	2,5 (2,7) 1,9 0; 20	-3,3 (3,2) -3,1 -20; 11

Endpunkt Zeitpunkt	Mirikizumab (N=300)			Ustekinumab (N=145)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
Woche 28	263	2,4 (2,7) 1,9 0; 21	-3,4 (2,7) -3,2 -16; 2	128	2,4 (2,3) 1,9 0; 12	-3,5 (3,1) -3,4 -20; 4
Woche 32	263	2,4 (2,7) 1,6 0; 19	-3,4 (2,6) -3,1 -13; 3	125	2,3 (2,2) 1,7 0; 11	-3,6 (3,0) -3,3 -20; 2
Woche 36	258	2,2 (2,6) 1,4 0; 19	-3,5 (2,7) -3,1 -13; 2	122	2,3 (2,1) 1,9 0; 8	-3,6 (3,1) -3,6 -20; 2
Woche 40	259	2,2 (2,6) 1,4 0; 20	-3,5 (2,6) -3,3 -13; 3	121	2,3 (2,2) 1,7 0; 10	-3,6 (3,2) -3,7 -20; 4
Woche 44	251	2,2 (2,7) 1,4 0; 21	-3,6 (2,6) -3,4 -13; 1	117	2,1 (2,1) 1,3 0; 12	-3,8 (3,1) -3,7 -19; 3
Woche 48	255	2,1 (2,6) 1,6 0; 20	-3,6 (2,7) -3,3 -13; 2	119	2,3 (2,4) 1,8 0; 12	-3,6 (3,2) -3,6 -19; 4
Woche 52	251	2,1 (2,6) 1,3 0; 24	-3,7 (2,7) -3,4 -14; 1	116	2,2 (2,4) 1,4 0; 12	-3,8 (3,2) -3,6 -20; 3
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_sfs_m_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba
19DEC2024 / 12:36

Imperativer Stuhldrang - Urgency NRS

Zusammenfassende Statistik für Urgency NRS in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)			Ustekinumab (N=145)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
Urgency NRS						
Baseline	299	6,7 (2,2) 7,0 0; 10	NB	145	6,5 (2,2) 6,6 0; 10	NB
Woche 2	295	5,8 (2,4) 6,0 0; 10	-0,9 (1,5) -0,6 -9; 2	145	5,4 (2,5) 5,6 0; 10	-1,2 (1,6) -1,0 -9; 3
Woche 4	294	5,4 (2,6) 5,7 0; 10	-1,3 (1,9) -0,9 -8; 6	143	4,9 (2,7) 4,9 0; 10	-1,7 (2,0) -1,4 -9; 2
Woche 6	291	4,9 (2,6) 5,0 0; 10	-1,8 (2,0) -1,4 -8; 3	142	4,6 (2,7) 4,8 0; 10	-2,0 (2,1) -1,6 -9; 2
Woche 8	291	4,6 (2,7) 4,6 0; 10	-2,1 (2,1) -1,7 -9; 3	142	4,5 (2,7) 4,5 0; 10	-2,1 (2,2) -1,8 -9; 2
Woche 12	291	4,2 (2,8) 4,0 0; 10	-2,5 (2,5) -2,3 -10; 4	139	4,1 (2,7) 4,0 0; 10	-2,5 (2,4) -2,3 -9; 4
Woche 16	284	3,8 (2,8) 3,3 0; 10	-2,9 (2,5) -2,7 -10; 2	138	3,8 (2,6) 3,6 0; 10	-2,8 (2,5) -2,4 -10; 3
Woche 20	273	3,6 (2,7) 3,0 0; 10	-3,1 (2,5) -3,0 -10; 2	138	3,7 (2,7) 3,1 0; 10	-2,9 (2,5) -2,6 -10; 4
Woche 24	268	3,5 (2,7) 3,0 0; 10	-3,2 (2,5) -3,0 -10; 2	134	3,6 (2,6) 3,2 0; 10	-2,9 (2,5) -2,9 -10; 4
Woche 28	263	3,4 (2,7) 3,0 0; 10	-3,3 (2,6) -3,3 -10; 3	128	3,5 (2,5) 2,9 0; 10	-3,0 (2,5) -2,9 -10; 3
Woche 32	263	3,2 (2,7) 2,9 0; 10	-3,4 (2,6) -3,1 -10; 2	125	3,3 (2,5) 2,9 0; 10	-3,2 (2,5) -2,9 -10; 3

Endpunkt Zeitpunkt	Mirikizumab (N=300)			Ustekinumab (N=145)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
Woche 36	258	3,1 (2,6) 2,7 0; 10	-3,6 (2,6) -3,3 -10; 2	122	3,2 (2,4) 3,0 0; 9	-3,3 (2,4) -3,3 -10; 4
Woche 40	259	3,0 (2,6) 2,7 0; 10	-3,6 (2,8) -3,6 -10; 3	121	3,2 (2,5) 2,9 0; 9	-3,3 (2,5) -3,3 -10; 4
Woche 44	251	3,0 (2,6) 2,7 0; 10	-3,6 (2,7) -3,4 -10; 3	117	3,0 (2,4) 2,7 0; 9	-3,5 (2,5) -3,3 -10; 4
Woche 48	255	3,0 (2,6) 2,6 0; 10	-3,6 (2,7) -3,6 -10; 3	119	3,0 (2,4) 2,7 0; 9	-3,5 (2,7) -3,4 -10; 5
Woche 52	251	2,8 (2,6) 2,3 0; 10	-3,7 (2,7) -3,7 -10; 4	116	3,1 (2,5) 2,5 0; 10	-3,4 (2,7) -3,5 -10; 4
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; NRS: Numeric Rating Scale; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_urghsm_ittb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 12:36

Abdominelle Schmerzen – CDAI-AP

Zusammenfassende Statistik für Abdominal pain in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)			Ustekinumab (N=145)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
Abdominal pain						
Baseline	298	2,1 (0,6) 2,0 0; 3	NB	145	2,0 (0,7) 2,0 0; 3	NB
Woche 2	296	1,7 (0,7) 1,9 0; 3	-0,4 (0,5) -0,3 -2; 1	145	1,5 (0,7) 1,6 0; 3	-0,5 (0,5) -0,3 -2; 1
Woche 4	294	1,6 (0,7) 1,7 0; 3	-0,5 (0,7) -0,4 -3; 1	143	1,4 (0,7) 1,4 0; 3	-0,6 (0,6) -0,4 -3; 0
Woche 6	291	1,4 (0,7) 1,3 0; 3	-0,8 (0,7) -0,7 -3; 1	142	1,3 (0,7) 1,1 0; 3	-0,7 (0,7) -0,7 -3; 1
Woche 8	291	1,3 (0,7) 1,1 0; 3	-0,8 (0,8) -0,9 -3; 1	142	1,3 (0,7) 1,1 0; 3	-0,7 (0,7) -0,7 -3; 1
Woche 12	291	1,2 (0,8) 1,0 0; 3	-0,9 (0,8) -1,0 -3; 1	139	1,1 (0,7) 1,0 0; 3	-0,9 (0,8) -0,9 -3; 1
Woche 16	284	1,1 (0,8) 1,0 0; 3	-1,0 (0,8) -1,0 -3; 1	138	1,1 (0,7) 1,0 0; 3	-0,9 (0,8) -0,9 -3; 1
Woche 20	273	1,0 (0,8) 1,0 0; 3	-1,1 (0,8) -1,0 -3; 1	138	1,0 (0,7) 1,0 0; 3	-1,0 (0,8) -1,0 -3; 1
Woche 24	268	1,0 (0,8) 1,0 0; 3	-1,1 (0,8) -1,0 -3; 1	134	1,0 (0,7) 1,0 0; 3	-1,0 (0,8) -1,0 -3; 1
Woche 28	263	0,9 (0,8) 1,0 0; 3	-1,2 (0,8) -1,0 -3; 1	128	1,0 (0,7) 1,0 0; 3	-1,0 (0,8) -1,0 -3; 1
Woche 32	263	0,9 (0,7) 1,0 0; 3	-1,2 (0,8) -1,1 -3; 1	125	1,0 (0,6) 1,0 0; 3	-1,0 (0,8) -1,0 -3; 1

Endpunkt Zeitpunkt	Mirikizumab (N=300)			Ustekinumab (N=145)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
Woche 36	258	0,8 (0,7) 1,0 0; 3	-1,3 (0,8) -1,1 -3; 1	122	0,9 (0,6) 1,0 0; 3	-1,0 (0,8) -1,0 -3; 1
Woche 40	259	0,8 (0,7) 1,0 0; 3	-1,3 (0,8) -1,1 -3; 1	121	0,9 (0,7) 1,0 0; 3	-1,1 (0,8) -1,0 -3; 1
Woche 44	251	0,8 (0,7) 1,0 0; 3	-1,3 (0,8) -1,1 -3; 1	117	0,9 (0,6) 1,0 0; 3	-1,1 (0,8) -1,1 -3; 1
Woche 48	255	0,8 (0,7) 1,0 0; 3	-1,3 (0,8) -1,3 -3; 1	119	0,9 (0,6) 1,0 0; 3	-1,1 (0,8) -1,0 -3; 1
Woche 52	251	0,8 (0,7) 0,8 0; 3	-1,3 (0,8) -1,3 -3; 1	116	0,9 (0,7) 1,0 0; 3	-1,1 (0,8) -1,0 -3; 1
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_apsm_ittb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 12:36

Fatigue – FACIT Fatigue

Zusammenfassende Statistik für FACIT-Fatigue in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)			Ustekinumab (N=145)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
FACIT-Fatigue						
Baseline	298	31,5 (11,9) 33,0 2; 52	NB	145	31,9 (12,0) 34,0 4; 52	NB
Woche 12	290	37,1 (10,7) 41,0 0; 52	5,5 (9,5) 4,0 -29; 40	139	37,4 (10,2) 40,0 5; 52	5,4 (11,1) 3,0 -24; 45
Woche 52	242	40,3 (9,3) 43,0 6; 52	8,9 (11,1) 6,0 -17; 42	117	39,3 (9,5) 42,0 10; 52	7,0 (11,5) 4,0 -11; 43
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: FACIT: Functional Assessment of Chronic Illness Therapy -Fatigue; ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_facism_ittb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 12:36

Depressionen – QIDS-SR16

Zusammenfassende Statistik für QIDS-SR16 Total Score in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)			Ustekinumab (N=145)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
QIDS-SR16 Total Score						
Baseline	296	7,2 (4,8) 6,0 0; 23	NB	144	6,7 (4,6) 6,0 0; 21	NB
Woche 12	292	5,3 (4,3) 4,0 0; 23	-1,7 (4,0) -2,0 -21; 13	139	5,3 (3,9) 4,0 0; 22	-1,4 (4,4) -1,0 -18; 14
Woche 24	267	5,0 (3,9) 4,0 0; 19	-2,0 (4,4) -2,0 -19; 12	134	4,9 (3,8) 4,0 0; 19	-1,7 (4,4) -1,0 -19; 7
Woche 36	253	4,7 (4,4) 3,0 0; 22	-2,4 (4,7) -2,0 -20; 15	124	4,6 (3,6) 4,0 0; 22	-1,9 (4,9) -1,0 -20; 17
Woche 52	243	4,4 (3,8) 3,0 0; 20	-2,7 (4,5) -2,0 -20; 15	119	4,4 (3,9) 4,0 0; 19	-2,1 (5,1) -1,0 -21; 8
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; QIDS-SR16: Quick Inventory of Depressive Symptomatology - Self Report (16 items); RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_qidssm_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adef_gba

19DEC2024 / 12:36

Anhang 4-G.4.4.3 Gesundheitszustand**Gesundheitszustand – EQ-5D VAS**

Zusammenfassende Statistik für EQ-5D VAS in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)			Ustekinumab (N=145)		
			Veränderung ggü. Baseline			Veränderung ggü. Baseline
	n	MW (SD) Median Min; Max	MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	MW (SD) Median Min; Max
EQ-5D VAS						
Baseline	299	53,6 (20,2) 55,0 0; 92	NB	145	54,0 (21,0) 51,0 10; 100	NB
Woche 12	292	71,1 (19,0) 74,0 1; 100	17,4 (20,9) 15,0 -40; 95	139	70,0 (19,2) 75,0 10; 100	15,4 (24,4) 11,0 -70; 80
Woche 52	243	78,7 (14,5) 80,0 30; 100	25,1 (22,0) 21,0 -29; 100	119	74,3 (18,1) 80,0 12; 100	19,9 (24,5) 19,0 -49; 80
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: EQ-5D: Fragebogen der EuroQol-Gruppe zur Lebensqualität auf 5 Dimensionen; ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; RCT: randomisierte kontrollierte Studie; SD: Standardabweichung; VAS: Visuelle Analogskala.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_vassm_ittb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adef_gba
19DEC2024 / 12:36

Gesundheitszustand – PGRS

Zusammenfassende Statistik für Patient Global Rating of severity (PGRS) in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)			Ustekinumab (N=145)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
PGRS						
Baseline	298	4,5 (0,8) 4,4 1; 6	NB	145	4,4 (0,8) 4,3 1; 6	NB
Woche 2	295	4,0 (0,9) 4,0 1; 6	-0,5 (0,8) -0,3 -4; 1	145	3,7 (1,0) 3,9 1; 6	-0,7 (0,8) -0,7 -4; 1
Woche 4	294	3,7 (1,0) 4,0 1; 6	-0,7 (0,9) -0,6 -4; 1	143	3,5 (1,1) 3,6 1; 6	-0,9 (1,0) -0,9 -4; 1
Woche 6	291	3,4 (1,1) 3,6 1; 6	-1,1 (1,0) -1,0 -5; 1	142	3,3 (1,1) 3,3 1; 6	-1,1 (1,1) -1,0 -4; 1
Woche 8	291	3,3 (1,2) 3,3 1; 6	-1,2 (1,1) -1,0 -5; 1	142	3,3 (1,2) 3,1 1; 6	-1,1 (1,1) -1,0 -4; 1
Woche 12	291	3,1 (1,2) 3,0 1; 6	-1,4 (1,1) -1,1 -5; 1	139	3,0 (1,2) 3,0 1; 6	-1,4 (1,2) -1,2 -5; 1
Woche 16	284	2,9 (1,2) 3,0 1; 6	-1,6 (1,2) -1,5 -5; 1	138	2,9 (1,1) 3,0 1; 6	-1,4 (1,2) -1,3 -5; 1
Woche 20	273	2,8 (1,2) 2,9 1; 6	-1,7 (1,2) -1,6 -5; 1	138	2,8 (1,1) 2,9 1; 6	-1,5 (1,2) -1,6 -5; 1
Woche 24	268	2,8 (1,2) 2,6 1; 6	-1,7 (1,3) -1,6 -5; 1	134	2,9 (1,1) 2,9 1; 6	-1,5 (1,2) -1,4 -5; 1
Woche 28	263	2,7 (1,2) 2,7 1; 6	-1,7 (1,3) -1,7 -5; 1	128	2,8 (1,1) 3,0 1; 6	-1,5 (1,2) -1,4 -5; 1
Woche 32	263	2,6 (1,2) 2,6 1; 6	-1,8 (1,3) -1,7 -5; 1	125	2,8 (1,0) 2,9 1; 5	-1,6 (1,1) -1,6 -5; 1

Endpunkt Zeitpunkt	Mirikizumab (N=300)			Ustekinumab (N=145)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
Woche 36	258	2,5 (1,2) 2,3 1; 5	-1,9 (1,3) -2,0 -5; 1	122	2,7 (0,9) 2,9 1; 6	-1,6 (1,1) -1,6 -5; 1
Woche 40	259	2,5 (1,2) 2,4 1; 6	-1,9 (1,3) -2,0 -5; 2	121	2,7 (1,0) 2,9 1; 5	-1,7 (1,2) -1,6 -5; 1
Woche 44	251	2,5 (1,2) 2,3 1; 6	-1,9 (1,3) -2,0 -5; 2	117	2,6 (1,0) 2,6 1; 5	-1,8 (1,2) -1,7 -5; 1
Woche 48	255	2,5 (1,2) 2,3 1; 6	-1,9 (1,3) -2,0 -5; 2	119	2,6 (1,0) 2,7 1; 5	-1,8 (1,2) -1,9 -5; 1
Woche 52	251	2,4 (1,2) 2,1 1; 5	-2,0 (1,3) -2,0 -5; 2	116	2,5 (1,1) 2,4 1; 5	-1,9 (1,2) -1,7 -5; 1
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; PGRS: Patient Global Rating of Severity; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_pgrssm_ittb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 12:36

Gesundheitszustand – PGIC

Zusammenfassende Statistik für Patient Reported Impression of Change (PGIC) in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)		Ustekinumab (N=145)	
	n	MW (SD) Median Min; Max	n	MW (SD) Median Min; Max
PGIC				
Woche 4	289	3,0 (0,9) 3,0 1; 7	142	3,0 (1,0) 3,0 1; 7
Woche 8	289	2,7 (1,0) 3,0 1; 7	142	2,8 (1,0) 3,0 1; 6
Woche 12	292	2,6 (1,2) 3,0 1; 7	139	2,6 (1,2) 3,0 1; 7
Woche 52	243	2,0 (0,9) 2,0 1; 7	119	2,2 (1,1) 2,0 1; 7
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; PGIC: Patient Global Impression of Change; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.				

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_pgicsm_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 12:36

Gesundheitszustand – WPAI-CD (Aktivitätsbeeinträchtigung)

Zusammenfassende Statistik für WPAI (Activity impairment) in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population, Participants with baseline employment status of Yes)

Endpunkt Zeitpunkt	Mirikizumab (N=173)			Ustekinumab (N=80)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
WPAI (Activity impairment)						
Baseline	173	50,6 (25,7) 50,0 0; 100	NB	80	50,4 (25,8) 50,0 0; 100	NB
Woche 12	170	27,9 (24,4) 20,0 0; 100	-22,7 (29,5) -20,0 -100; 40	77	26,1 (24,0) 20,0 0; 100	-23,8 (28,5) -20,0 -80; 50
Woche 52	142	18,2 (20,7) 10,0 0; 90	-33,1 (29,9) -30,0 -100; 50	67	21,5 (21,7) 20,0 0; 90	-29,1 (31,9) -30,0 -100; 40
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; WPAI: Work Productivity and Activity Impairment Questionnaire.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_wpaism_empl_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

19DEC2024 / 12:36

Allgemeinbefinden - CDAI-GWP

Zusammenfassende Statistik für General well being in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)			Ustekinumab (N=145)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
General well being						
Baseline	299	2,3 (0,9) 2,3 0; 4	NB	145	2,3 (1,0) 2,1 0; 4	NB
Woche 2	296	1,9 (0,9) 2,0 0; 4	-0,4 (0,7) -0,3 -3; 1	145	1,7 (0,9) 1,7 0; 4	-0,5 (0,7) -0,4 -3; 1
Woche 4	294	1,7 (0,9) 1,7 0; 4	-0,6 (0,8) -0,4 -4; 1	143	1,5 (0,9) 1,4 0; 4	-0,7 (0,8) -0,6 -3; 1
Woche 6	291	1,4 (0,9) 1,3 0; 4	-0,9 (0,9) -0,9 -4; 2	142	1,4 (0,9) 1,1 0; 4	-0,9 (0,9) -0,7 -4; 1
Woche 8	291	1,4 (1,0) 1,3 0; 4	-0,9 (0,9) -0,9 -4; 1	142	1,4 (1,0) 1,1 0; 4	-0,9 (0,9) -0,7 -4; 1
Woche 12	291	1,2 (0,9) 1,0 0; 4	-1,1 (0,9) -1,0 -4; 1	139	1,2 (1,0) 1,0 0; 4	-1,0 (1,1) -1,0 -4; 1
Woche 16	284	1,1 (0,9) 1,0 0; 4	-1,2 (1,0) -1,1 -4; 1	138	1,2 (0,9) 1,0 0; 4	-1,1 (1,0) -1,0 -4; 1
Woche 20	273	1,0 (0,9) 1,0 0; 4	-1,3 (1,0) -1,3 -4; 1	138	1,1 (0,9) 1,0 0; 4	-1,1 (1,0) -1,0 -4; 1
Woche 24	268	1,0 (0,9) 1,0 0; 4	-1,3 (1,1) -1,2 -4; 1	134	1,1 (0,9) 1,0 0; 4	-1,1 (1,1) -1,0 -4; 1
Woche 28	263	0,9 (0,9) 1,0 0; 4	-1,3 (1,1) -1,3 -4; 2	128	1,1 (0,8) 1,0 0; 4	-1,2 (1,0) -1,1 -4; 1
Woche 32	263	0,9 (0,8) 1,0 0; 4	-1,4 (1,1) -1,3 -4; 1	125	1,1 (0,8) 1,0 0; 3	-1,1 (0,9) -1,0 -4; 1

Endpunkt Zeitpunkt	Mirikizumab (N=300)			Ustekinumab (N=145)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
Woche 36	258	0,9 (0,8) 1,0 0; 4	-1,4 (1,0) -1,4 -4; 1	122	1,0 (0,7) 1,0 0; 4	-1,2 (0,9) -1,0 -4; 1
Woche 40	259	0,9 (0,8) 1,0 0; 4	-1,4 (1,1) -1,4 -4; 2	121	1,0 (0,7) 1,0 0; 4	-1,2 (1,0) -1,0 -4; 1
Woche 44	251	0,9 (0,8) 1,0 0; 4	-1,4 (1,1) -1,4 -4; 1	117	0,9 (0,8) 1,0 0; 4	-1,3 (1,1) -1,3 -4; 2
Woche 48	255	0,8 (0,8) 1,0 0; 3	-1,5 (1,1) -1,4 -4; 2	119	0,9 (0,7) 1,0 0; 3	-1,3 (1,0) -1,3 -4; 1
Woche 52	251	0,8 (0,8) 0,8 0; 3	-1,5 (1,0) -1,6 -4; 1	116	0,9 (0,8) 1,0 0; 3	-1,3 (1,0) -1,1 -4; 1
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_gwbsm_ittb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

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Anhang 4-G.4.4.4.4 Gesundheitsbezogene Lebensqualität**Krankheitsspezifische Lebensqualität**

Zusammenfassende Statistik für IBDQ in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)			Ustekinumab (N=145)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
IBDQ Total Score						
Baseline	299	127,5 (32,7) 129,0 37; 202	NB	145	126,5 (34,9) 129,0 46; 213	NB
Woche 12	292	163,8 (34,7) 172,5 56; 222	36,1 (32,1) 35,0 -58; 127	139	164,7 (34,0) 166,0 58; 223	38,0 (32,0) 36,0 -30; 155
Woche 52	243	178,9 (28,9) 184,0 73; 224	50,5 (35,0) 48,5 -22; 187	119	174,6 (29,8) 181,0 100; 221	46,4 (37,3) 42,0 -26; 151
IBDQ Bowel Symptoms						
Baseline	299	37,8 (9,5) 38,0 11; 61	NB	145	37,3 (9,9) 37,0 13; 65	NB
Woche 12	292	51,5 (10,9) 53,0 16; 70	13,6 (10,9) 13,0 -19; 49	139	51,6 (10,7) 52,0 20; 70	14,4 (10,7) 15,0 -13; 44
Woche 52	243	56,4 (8,9) 57,0 22; 70	18,3 (11,0) 18,0 -7; 56	119	54,4 (9,4) 56,0 24; 70	16,9 (11,4) 17,0 -16; 49
IBDQ Emotional Function						
Baseline	299	51,3 (14,3) 52,0 12; 83	NB	145	51,0 (15,2) 52,0 17; 83	NB
Woche 12	292	62,1 (14,1) 65,0 18; 84	10,7 (13,1) 10,0 -31; 48	139	62,6 (13,6) 63,0 21; 84	11,5 (13,2) 9,0 -14; 62
Woche 52	243	67,0 (12,2) 70,0 20; 84	15,4 (14,5) 13,0 -18; 72	119	66,2 (12,3) 69,0 32; 83	14,6 (15,7) 13,0 -17; 61
IBDQ Social Function						

Endpunkt Zeitpunkt	Mirikizumab (N=300)			Ustekinumab (N=145)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
Baseline	299	20,8 (7,3) 21,0 5; 35	NB	145	20,5 (7,4) 20,0 6; 35	NB
Woche 12	292	26,7 (7,0) 28,5 6; 35	6,0 (6,7) 5,0 -20; 26	139	27,0 (6,6) 29,0 8; 35	6,4 (6,9) 5,0 -8; 28
Woche 52	243	29,4 (5,9) 31,0 7; 35	8,5 (7,0) 8,0 -9; 30	119	29,1 (5,3) 30,0 13; 35	8,0 (7,4) 6,0 -8; 29
IBDQ Systemic Symptoms						
Baseline	299	17,6 (5,6) 17,0 5; 30	NB	145	17,7 (5,8) 18,0 5; 35	NB
Woche 12	292	23,5 (6,0) 25,0 5; 35	5,9 (5,5) 5,0 -10; 21	139	23,5 (6,2) 24,0 5; 35	5,7 (5,6) 5,0 -8; 24
Woche 52	243	26,1 (5,3) 27,0 10; 35	8,3 (6,3) 8,0 -5; 29	119	24,9 (5,8) 26,0 9; 35	6,8 (6,7) 6,0 -10; 24
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ggü: gegenüber; IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; Max: Maximum; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_ibdqsm_itb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba
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Gesundheitsbezogene Lebensqualität

Zusammenfassende Statistik für SF-36 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Endpunkt Zeitpunkt	Mirikizumab (N=300)			Ustekinumab (N=145)		
	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max	n	MW (SD) Median Min; Max	Veränderung ggü. Baseline MW (SD) Median Min; Max
SF-36 MCS Score						
Baseline	299	44,4 (10,7) 45,9 9; 67	NB	145	45,0 (10,5) 45,8 16; 64	NB
Woche 12	292	48,6 (10,8) 51,5 8; 66	4,1 (9,4) 3,5 -27; 33	139	49,4 (9,4) 51,3 18; 65	4,6 (10,0) 3,7 -21; 37
Woche 52	243	50,6 (9,2) 52,5 17; 65	6,0 (10,0) 4,9 -25; 34	119	50,7 (9,5) 53,6 14; 63	5,6 (11,1) 4,5 -23; 41
SF-36 PCS Score						
Baseline	299	39,2 (8,0) 39,2 15; 58	NB	145	38,8 (7,9) 39,5 16; 58	NB
Woche 12	292	47,0 (8,6) 48,2 21; 66	7,8 (7,7) 7,0 -11; 35	139	46,9 (7,5) 47,9 16; 60	8,1 (7,4) 7,6 -12; 29
Woche 52	243	50,3 (7,3) 52,4 28; 64	11,0 (7,9) 10,6 -8; 36	119	48,8 (7,9) 50,3 16; 66	10,0 (8,5) 9,5 -13; 36
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: ggü: gegenüber; ITT: Intention-to-treat Population; Max: Maximum; MCS: Mental Health Component Summary Score; Min: Minimum; MW: Mittelwert; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit Daten; NB: nicht berechnet; PCS: Physical Health Component Summary Score; RCT: randomisierte, kontrollierte Studie; SD: Standardabweichung; SF-36: 36-Item Short Form Health Survey.						

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_eff_sm.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_sf36sm_ittb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adeff_gba

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Anhang 4-G.4.5 Unerwünschte Ereignisse nach SOC/PT in RCT VIVID-1 in Teilpopulation B

Anteil der Patienten mit unerwünschten Ereignissen nach SOC/PT bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (Safety-Population)

SOC Preferred term	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
TEAEs occurred in ≥10% or in ≥10 patients and 1% in any treatment arm within analysis population					
Infections and infestations	130/299 (43,5)	79/145 (54,5)	0,80 [0,66; 0,97]	0,64 [0,43; 0,96]	-11,00 [-20,87; -1,14]
				0,033	
COVID-19	53/299 (17,7)	32/145 (22,1)	0,80 [0,54; 1,19]	0,76 [0,47; 1,24]	-4,34 [-12,36; 3,68]
				0,304	
Upper respiratory tract infection	22/299 (7,4)	11/145 (7,6)	0,97 [0,48; 1,95]	0,97 [0,46; 2,05]	-0,23 [-5,46; 5,00]
				1,000	
Nasopharyngitis	18/299 (6,0)	13/145 (9,0)	0,67 [0,34; 1,33]	0,65 [0,31; 1,37]	-2,95 [-8,32; 2,43]
				0,320	
Gastroenteritis	10/299 (3,3)	4/145 (2,8)	1,21 [0,39; 3,80]	1,22 [0,38; 3,96]	0,59 [-2,77; 3,94]
				1,000	
Gastrointestinal disorders	105/299 (35,1)	55/145 (37,9)	0,93 [0,71; 1,20]	0,89 [0,59; 1,34]	-2,81 [-12,39; 6,76]
				0,599	
Diarrhoea	20/299 (6,7)	10/145 (6,9)	0,97 [0,47; 2,02]	0,97 [0,44; 2,12]	-0,21 [-5,21; 4,80]
				1,000	
Abdominal pain	15/299 (5,0)	6/145 (4,1)	1,21 [0,48; 3,06]	1,22 [0,46; 3,22]	0,88 [-3,20; 4,96]
				0,814	

SOC Preferred term	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Vomiting	13/299 (4,3)	6/145 (4,1)	1,05 [0,41; 2,71]	1,05 [0,39; 2,83]	0,21 [-3,77; 4,19]
			1,000		
Crohn's disease	12/299 (4,0)	10/145 (6,9)	0,58 [0,26; 1,32]	0,56 [0,24; 1,34]	-2,88 [-7,57; 1,80]
			0,243		
General disorders and administration site conditions	75/299 (25,1)	24/145 (16,6)	1,52 [1,00; 2,29]	1,69 [1,01; 2,81]	8,53 [0,74; 16,33]
			0,051		
Injection site reaction	18/299 (6,0)	1/145 (0,7)	8,73 [1,18; 64,75]	9,22 [1,22; 69,79]	5,33 [2,32; 8,34]
			0,010		
Pyrexia	16/299 (5,4)	7/145 (4,8)	1,11 [0,47; 2,63]	1,11 [0,45; 2,77]	0,52 [-3,80; 4,85]
			1,000		
Fatigue	12/299 (4,0)	4/145 (2,8)	1,45 [0,48; 4,43]	1,47 [0,47; 4,65]	1,25 [-2,22; 4,73]
			0,597		
Injection site pain	10/299 (3,3)	8/145 (5,5)	0,61 [0,24; 1,50]	0,59 [0,23; 1,53]	-2,17 [-6,41; 2,07]
			0,308		
Musculoskeletal and connective tissue disorders	58/299 (19,4)	18/145 (12,4)	1,56 [0,96; 2,55]	1,70 [0,96; 3,01]	6,98 [-0,01; 13,98]
			0,080		
Arthralgia	23/299 (7,7)	7/145 (4,8)	1,59 [0,70; 3,63]	1,64 [0,69; 3,92]	2,86 [-1,75; 7,48]
			0,316		
Back pain	12/299 (4,0)	1/145 (0,7)	5,82 [0,76; 44,32]	6,02 [0,78; 46,76]	3,32 [0,72; 5,92]
			0,069		

SOC Preferred term	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Investigations	54/299 (18,1)	21/145 (14,5)	1,25 [0,78; 1,98]	1,30 [0,75; 2,25]	3,58 [-3,62; 10,78]
				0,418	
Skin and subcutaneous tissue disorders	53/299 (17,7)	20/145 (13,8)	1,29 [0,80; 2,07]	1,35 [0,77; 2,35]	3,93 [-3,16; 11,02]
				0,340	
Rash	12/299 (4,0)	0/145 (0,0)	12,17 [0,73; >100]	12,65 [0,74; >100]	4,01 [1,79; 6,24]
				0,011	
Blood and lymphatic system disorders	40/299 (13,4)	19/145 (13,1)	1,02 [0,61; 1,70]	1,02 [0,57; 1,84]	0,27 [-6,44; 6,99]
				1,000	
Anaemia	21/299 (7,0)	8/145 (5,5)	1,27 [0,58; 2,80]	1,29 [0,56; 3,00]	1,51 [-3,21; 6,22]
				0,683	
Nervous system disorders	34/299 (11,4)	14/145 (9,7)	1,18 [0,65; 2,12]	1,20 [0,62; 2,32]	1,72 [-4,29; 7,72]
				0,629	
Headache	19/299 (6,4)	6/145 (4,1)	1,54 [0,63; 3,76]	1,57 [0,61; 4,02]	2,22 [-2,04; 6,48]
				0,389	
Respiratory, thoracic and mediastinal disorders	32/299 (10,7)	11/145 (7,6)	1,41 [0,73; 2,72]	1,46 [0,71; 2,99]	3,12 [-2,44; 8,67]
				0,392	
Injury, poisoning and procedural complications	25/299 (8,4)	11/145 (7,6)	1,10 [0,56; 2,18]	1,11 [0,53; 2,33]	0,77 [-4,56; 6,11]
				0,855	
Metabolism and nutrition disorders	24/299 (8,0)	13/145 (9,0)	0,90 [0,47; 1,71]	0,89 [0,44; 1,80]	-0,94 [-6,52; 4,64]
				0,718	

SOC Preferred term	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Reproductive system and breast disorders	14/299 (4,7)	8/145 (5,5)	0,85 [0,36; 1,98]	0,84 [0,34; 2,05]	-0,83 [-5,26; 3,59]
			0,816		
Psychiatric disorders	13/299 (4,3)	4/145 (2,8)	1,58 [0,52; 4,75]	1,60 [0,51; 5,00]	1,59 [-1,94; 5,12]
			0,599		
Renal and urinary disorders	13/299 (4,3)	5/145 (3,4)	1,26 [0,46; 3,47]	1,27 [0,44; 3,64]	0,90 [-2,86; 4,66]
			0,800		
Surgical and medical procedures	10/299 (3,3)	3/145 (2,1)	1,62 [0,45; 5,78]	1,64 [0,44; 6,04]	1,28 [-1,81; 4,36]
			0,560		
Severe TEAEs occurred in ≥5% or in ≥10 patients and 1% in any treatment arm within analysis population					
Gastrointestinal disorders	15/299 (5,0)	5/145 (3,4)	1,45 [0,54; 3,93]	1,48 [0,53; 4,15]	1,57 [-2,30; 5,43]
			0,627		
Serious TEAEs occurred in ≥5% or in ≥10 patients and 1% in any treatment arm within analysis population					
Gastrointestinal disorders	21/299 (7,0)	10/145 (6,9)	1,02 [0,49; 2,11]	1,02 [0,47; 2,23]	0,13 [-4,91; 5,17]
			1,000		
Datenschnitt: 23. August 2023; Biologic-failed Safety Population. Abkürzungen: KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; n: Anzahl der Patienten mit mindestens einem Ereignis; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; SOC: System Organ Class. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_aespt.sas

Output Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_aespt_safb.rtf

Dataset Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba

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Ergebnisse für den Anteil der Patienten mit Behandlungsabbruch aufgrund unerwünschter Ereignisse nach SOC/PT bis Woche 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (Safety-Population)

SOC Preferred term	Mirikizumab Pat. mit Ereignis n/N (%)	Ustekinumab Pat. mit Ereignis n/N (%)
Gastrointestinal disorders	4/299 (1,3)	2/145 (1,4)
Crohn's disease	2/299 (0,7)	1/145 (0,7)
Abdominal pain	1/299 (0,3)	0/145 (0,0)
Large intestine perforation	1/299 (0,3)	0/145 (0,0)
Anorectal disorder	0/299 (0,0)	1/145 (0,7)
Infections and infestations	2/299 (0,7)	0/145 (0,0)
Abdominal abscess	1/299 (0,3)	0/145 (0,0)
Herpes zoster	1/299 (0,3)	0/145 (0,0)
General disorders and administration site conditions	1/299 (0,3)	0/145 (0,0)
Fatigue	1/299 (0,3)	0/145 (0,0)
Immune system disorders	1/299 (0,3)	0/145 (0,0)
Anaphylactic reaction	1/299 (0,3)	0/145 (0,0)
Investigations	1/299 (0,3)	1/145 (0,7)
Hepatitis B DNA assay positive	1/299 (0,3)	0/145 (0,0)
Alanine aminotransferase increased	0/299 (0,0)	1/145 (0,7)
Musculoskeletal and connective tissue disorders	1/299 (0,3)	0/145 (0,0)
Arthralgia	1/299 (0,3)	0/145 (0,0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1/299 (0,3)	0/145 (0,0)
Breast cancer	1/299 (0,3)	0/145 (0,0)
Respiratory, thoracic and mediastinal disorders	1/299 (0,3)	1/145 (0,7)
Dyspnoea	1/299 (0,3)	0/145 (0,0)
Interstitial lung disease	0/299 (0,0)	1/145 (0,7)
Datenschnitt: 23. August 2023; Biologic-failed Safety Population. Abkürzungen: n: Anzahl der Patienten; N: Anzahl der Patienten in der Analyse; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; SOC: System Organ Class.		

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_aeldstspt.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_aeldstspt_safb.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba

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Anhang 4-G.4.6 Ergebnisse der Subgruppenanalysen mit nicht statistisch signifikantem Interaktionsterm in der Gesamtpopulation in RCT VIVID-1 in Teilpopulation B

Anhang 4-G.4.6.1 Morbidität

Anhang 4-G.4.6.1.1 Klinische Remission

Subgruppen für Clinical remission by PRO, defined as SF $\leq$ 3 and AP $\leq$ 1 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,777)					
<65 years	147/287 (51,2)	66/141 (46,8)	1,09 [0,89; 1,35]	1,19 [0,80; 1,79]	4,41 [-5,65; 14,47]
			0,412		
≥65 years	5/13 (38,5)	1/4 (25,0)	1,54 [0,25; 9,60]	1,88 [0,15; 23,40]	13,46 [-36,54; 63,46]
			1,000		
Age 2 (p-value of the interaction test: 0,350)					
<40 years	105/202 (52,0)	40/91 (44,0)	1,18 [0,91; 1,54]	1,38 [0,84; 2,27]	8,02 [-4,28; 20,33]
			0,210		
≥40 years	47/98 (48,0)	27/54 (50,0)	0,96 [0,68; 1,34]	0,92 [0,47; 1,79]	-2,04 [-18,64; 14,56]
			0,866		
Sex (p-value of the interaction test: 0,585)					
Male	94/179 (52,5)	30/65 (46,2)	1,14 [0,85; 1,53]	1,29 [0,73; 2,28]	6,36 [-7,80; 20,52]
			0,389		
Female	58/121 (47,9)	37/80 (46,3)	1,04 [0,77; 1,40]	1,07 [0,61; 1,88]	1,68 [-12,41; 15,78]
			0,885		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Weight (p-value of the interaction test: 0,939)					
<100 kg	146/284 (51,4)	65/140 (46,4)	1,11 [0,90; 1,37]	1,22 [0,81; 1,83]	4,98 [-5,12; 15,08]
				0,354	
≥100 kg	6/15 (40,0)	2/5 (40,0)	1,00 [0,29; 3,45]	1,00 [0,13; 7,89]	0,00 [-49,58; 49,58]
				1,000	
BMI (p-value of the interaction test: 0,381)					
Underweight (<18.5 kg/m ²)	28/54 (51,9)	11/32 (34,4)	1,51 [0,88; 2,60]	2,06 [0,83; 5,08]	17,48 [-3,70; 38,65]
				0,125	
Normal (≥18.5 and <25 kg/m ²)	81/161 (50,3)	32/60 (53,3)	0,94 [0,71; 1,25]	0,89 [0,49; 1,60]	-3,02 [-17,82; 11,78]
				0,763	
Overweight (≥25 and <30 kg/m ²)	30/55 (54,5)	20/38 (52,6)	1,04 [0,70; 1,52]	1,08 [0,47; 2,47]	1,91 [-18,71; 22,53]
				1,000	
Obese and Extreme obese (≥30 kg/m ²)	13/29 (44,8)	4/15 (26,7)	1,68 [0,66; 4,27]	2,23 [0,57; 8,69]	18,16 [-10,62; 46,94]
				0,333	
Tobacco use (p-value of the interaction test: 0,486)					
Current	24/52 (46,2)	15/29 (51,7)	0,89 [0,56; 1,41]	0,80 [0,32; 1,99]	-5,57 [-28,25; 17,11]
				0,651	
Former	23/49 (46,9)	6/21 (28,6)	1,64 [0,78; 3,44]	2,21 [0,74; 6,65]	18,37 [-5,48; 42,21]
				0,191	
Never	105/199 (52,8)	46/95 (48,4)	1,09 [0,85; 1,39]	1,19 [0,73; 1,94]	4,34 [-7,87; 16,55]
				0,533	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,334)					
Ever	142/280 (50,7)	66/140 (47,1)	1,08 [0,87; 1,33]	1,15 [0,77; 1,73]	3,57 [-6,56; 13,70]
			0,535		
Never	10/20 (50,0)	1/5 (20,0)	2,50 [0,41; 15,23]	4,00 [0,38; 42,37]	30,00 [-11,35; 71,35]
			0,341		
Prior anti-TNF failure (p-value of the interaction test: 0,393)					
Ever	144/282 (51,1)	63/139 (45,3)	1,13 [0,91; 1,40]	1,26 [0,84; 1,89]	5,74 [-4,39; 15,87]
			0,300		
Never	8/18 (44,4)	4/6 (66,7)	0,67 [0,31; 1,43]	0,40 [0,06; 2,77]	-22,22 [-66,38; 21,93]
			0,640		
Prior anti-integrin failure (p-value of the interaction test: 0,180)					
Ever	35/71 (49,3)	18/31 (58,1)	0,85 [0,58; 1,24]	0,70 [0,30; 1,65]	-8,77 [-29,67; 12,14]
			0,519		
Never	117/229 (51,1)	49/114 (43,0)	1,19 [0,93; 1,52]	1,39 [0,88; 2,18]	8,11 [-3,05; 19,27]
			0,170		
Baseline corticosteroid use (p-value of the interaction test: 0,911)					
Yes	41/76 (53,9)	19/39 (48,7)	1,11 [0,75; 1,62]	1,23 [0,57; 2,67]	5,23 [-14,05; 24,51]
			0,694		
No	111/224 (49,6)	48/106 (45,3)	1,09 [0,85; 1,40]	1,19 [0,75; 1,89]	4,27 [-7,25; 15,79]
			0,481		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Duration of CD (p-value of the interaction test: 0,594)					
<1 year	9/23 (39,1)	3/9 (33,3)	1,17 [0,41; 3,37]	1,29 [0,25; 6,49]	5,80 [-30,90; 42,49]
				1,000	
≥1 to <5 years	55/104 (52,9)	17/44 (38,6)	1,37 [0,90; 2,07]	1,78 [0,87; 3,66]	14,25 [-3,04; 31,54]
				0,150	
≥5 years	88/173 (50,9)	47/92 (51,1)	1,00 [0,78; 1,28]	0,99 [0,60; 1,64]	-0,22 [-12,86; 12,42]
				1,000	
Baseline disease location (p-value of the interaction test: 0,251)					
Colonic	65/120 (54,2)	28/59 (47,5)	1,14 [0,83; 1,56]	1,31 [0,70; 2,44]	6,71 [-8,84; 22,26]
				0,429	
Ileal	10/32 (31,3)	4/6 (66,7)	0,47 [0,22; 1,01]	0,23 [0,04; 1,45]	-35,42 [-76,41; 5,58]
				0,167	
Ileal-Colonic	77/148 (52,0)	35/80 (43,8)	1,19 [0,89; 1,59]	1,39 [0,81; 2,41]	8,28 [-5,25; 21,80]
				0,268	
Baseline fecal calprotectin (p-value of the interaction test: 0,637)					
≤250	15/38 (39,5)	6/15 (40,0)	0,99 [0,47; 2,06]	0,98 [0,29; 3,32]	-0,53 [-29,79; 28,73]
				1,000	
>250	109/208 (52,4)	42/93 (45,2)	1,16 [0,90; 1,50]	1,34 [0,82; 2,18]	7,24 [-4,94; 19,42]
				0,263	
Baseline CRP (p-value of the interaction test: 0,383)					
≤10	71/145 (49,0)	28/58 (48,3)	1,01 [0,74; 1,39]	1,03 [0,56; 1,89]	0,69 [-14,53; 15,91]
				1,000	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
>10	81/154 (52,6)	39/87 (44,8)	1,17 [0,89; 1,55]	1,37 [0,81; 2,32]	7,77 [-5,32; 20,86]
0,284					
Baseline SES-CD total score (p-value of the interaction test: 0,773)					
<12	63/143 (44,1)	25/66 (37,9)	1,16 [0,81; 1,67]	1,29 [0,71; 2,35]	6,18 [-8,08; 20,43]
0,452					
≥12	89/157 (56,7)	42/79 (53,2)	1,07 [0,83; 1,37]	1,15 [0,67; 1,98]	3,52 [-9,94; 16,98]
0,677					
Baseline AP average (p-value of the interaction test: 0,601)					
<2	39/72 (54,2)	22/48 (45,8)	1,18 [0,81; 1,72]	1,40 [0,67; 2,91]	8,33 [-9,86; 26,53]
0,456					
≥2	113/226 (50,0)	45/97 (46,4)	1,08 [0,84; 1,38]	1,16 [0,72; 1,86]	3,61 [-8,27; 15,48]
0,627					
Baseline SF average (p-value of the interaction test: 0,205)					
<7	120/220 (54,5)	46/100 (46,0)	1,19 [0,93; 1,51]	1,41 [0,88; 2,26]	8,55 [-3,23; 20,32]
0,184					
≥7	32/76 (42,1)	21/45 (46,7)	0,90 [0,60; 1,36]	0,83 [0,40; 1,75]	-4,56 [-22,88; 13,76]
0,706					
Baseline CDAI 1 (p-value of the interaction test: 0,304)					
<300	66/109 (60,6)	28/59 (47,5)	1,28 [0,94; 1,74]	1,70 [0,90; 3,22]	13,09 [-2,61; 28,79]
0,107					
≥300	86/184 (46,7)	39/84 (46,4)	1,01 [0,76; 1,33]	1,01 [0,60; 1,70]	0,31 [-12,56; 13,18]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline CDAI 2 (p-value of the interaction test: 0,350)					
<220	18/29 (62,1)	5/12 (41,7)	1,49 [0,72; 3,08]	2,29 [0,58; 9,02]	20,40 [-12,61; 53,42]
				0,307	
≥220 and <450	127/244 (52,0)	56/119 (47,1)	1,11 [0,88; 1,39]	1,22 [0,79; 1,89]	4,99 [-5,95; 15,93]
				0,434	
≥450	7/20 (35,0)	6/12 (50,0)	0,70 [0,31; 1,59]	0,54 [0,13; 2,31]	-15,00 [-50,17; 20,17]
				0,473	
OECD Country (p-value of the interaction test: 0,764)					
Yes	95/178 (53,4)	42/83 (50,6)	1,05 [0,82; 1,36]	1,12 [0,66; 1,88]	2,77 [-10,25; 15,78]
				0,692	
No	57/122 (46,7)	25/62 (40,3)	1,16 [0,81; 1,66]	1,30 [0,70; 2,41]	6,40 [-8,68; 21,48]
				0,436	
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PRO: Patient Reported Outcome, defined as 2 of the patient-reported items of the CDAI (SF and AP); RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_prorem_sub_itb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Subgruppen für Corticosteroid-free from week 40 to week 52 and achieving clinical remission by PRO at week 52 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,915)					
<65 years	114/287 (39,7)	50/141 (35,5)	1,12 [0,86; 1,46]	1,20 [0,79; 1,82]	4,26 [-5,46; 13,98]
			0,459		
≥65 years	4/13 (30,8)	1/4 (25,0)	1,23 [0,19; 8,09]	1,33 [0,10; 17,10]	5,77 [-43,53; 55,07]
			1,000		
Age 2 (p-value of the interaction test: 0,443)					
<40 years	83/202 (41,1)	31/91 (34,1)	1,21 [0,87; 1,68]	1,35 [0,81; 2,26]	7,02 [-4,84; 18,89]
			0,300		
≥40 years	35/98 (35,7)	20/54 (37,0)	0,96 [0,62; 1,49]	0,94 [0,47; 1,88]	-1,32 [-17,32; 14,67]
			1,000		
Sex (p-value of the interaction test: 0,618)					
Male	68/179 (38,0)	20/65 (30,8)	1,23 [0,82; 1,86]	1,38 [0,75; 2,53]	7,22 [-6,06; 20,50]
			0,366		
Female	50/121 (41,3)	31/80 (38,8)	1,07 [0,75; 1,51]	1,11 [0,62; 1,98]	2,57 [-11,25; 16,39]
			0,770		
Weight (p-value of the interaction test: 0,495)					
<100 kg	114/284 (40,1)	49/140 (35,0)	1,15 [0,88; 1,50]	1,25 [0,82; 1,90]	5,14 [-4,60; 14,88]
			0,340		
≥100 kg	4/15 (26,7)	2/5 (40,0)	0,67 [0,17; 2,60]	0,55 [0,07; 4,56]	-13,33 [-61,76; 35,09]
			0,613		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
BMI (p-value of the interaction test: 0,104)					
Underweight ($<18.5 \text{ kg/m}^2$)	20/54 (37,0)	4/32 (12,5)	2,96 [1,11; 7,90]	4,12 [1,26; 13,46]	24,54 [7,30; 41,78]
			0,024		
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	70/161 (43,5)	25/60 (41,7)	1,04 [0,74; 1,48]	1,08 [0,59; 1,96]	1,81 [-12,83; 16,45]
			0,879		
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	19/55 (34,5)	17/38 (44,7)	0,77 [0,47; 1,28]	0,65 [0,28; 1,52]	-10,19 [-30,39; 10,00]
			0,388		
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	9/29 (31,0)	5/15 (33,3)	0,93 [0,38; 2,29]	0,90 [0,24; 3,41]	-2,30 [-31,50; 26,90]
			1,000		
Tobacco use (p-value of the interaction test: 0,604)					
Current	23/52 (44,2)	11/29 (37,9)	1,17 [0,67; 2,03]	1,30 [0,51; 3,28]	6,30 [-15,93; 28,53]
			0,643		
Former	16/49 (32,7)	4/21 (19,0)	1,71 [0,65; 4,52]	2,06 [0,60; 7,14]	13,61 [-7,71; 34,92]
			0,387		
Never	79/199 (39,7)	36/95 (37,9)	1,05 [0,77; 1,43]	1,08 [0,65; 1,78]	1,80 [-10,09; 13,69]
			0,799		
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,921)					
Ever	117/280 (41,8)	51/140 (36,4)	1,15 [0,89; 1,49]	1,25 [0,82; 1,90]	5,36 [-4,49; 15,20]
			0,342		
Never	1/20 (5,0)	0/5 (0,0)	0,86 [0,04; 18,45]	0,85 [0,03; 23,82]	5,00 [-4,55; 14,55]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Prior anti-TNF failure (p-value of the interaction test: 0,896)					
Ever	112/282 (39,7)	49/139 (35,3)	1,13 [0,86; 1,47]	1,21 [0,79; 1,85]	4,46 [-5,32; 14,25]
				0,395	
Never	6/18 (33,3)	2/6 (33,3)	1,00 [0,27; 3,69]	1,00 [0,14; 7,10]	0,00 [-43,55; 43,55]
				1,000	
Prior anti-integrin failure (p-value of the interaction test: 0,631)					
Ever	28/71 (39,4)	12/31 (38,7)	1,02 [0,60; 1,73]	1,03 [0,43; 2,45]	0,73 [-19,85; 21,30]
				1,000	
Never	90/229 (39,3)	39/114 (34,2)	1,15 [0,85; 1,55]	1,25 [0,78; 1,99]	5,09 [-5,67; 15,85]
				0,408	
Baseline corticosteroid use (p-value of the interaction test: 0,881)					
Yes	27/76 (35,5)	13/39 (33,3)	1,07 [0,62; 1,82]	1,10 [0,49; 2,49]	2,19 [-16,10; 20,49]
				0,840	
No	91/224 (40,6)	38/106 (35,8)	1,13 [0,84; 1,53]	1,22 [0,76; 1,98]	4,78 [-6,39; 15,94]
				0,469	
Duration of CD (p-value of the interaction test: 0,387)					
<1 year	6/23 (26,1)	1/9 (11,1)	2,35 [0,33; 16,87]	2,82 [0,29; 27,54]	14,98 [-12,29; 42,24]
				0,640	
≥1 to <5 years	50/104 (48,1)	15/44 (34,1)	1,41 [0,89; 2,23]	1,79 [0,86; 3,72]	13,99 [-3,00; 30,97]
				0,148	
≥5 years	62/173 (35,8)	35/92 (38,0)	0,94 [0,68; 1,31]	0,91 [0,54; 1,53]	-2,21 [-14,43; 10,02]
				0,789	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Baseline disease location (p-value of the interaction test: 0,104)					
Colonic	44/120 (36,7)	21/59 (35,6)	1,03 [0,68; 1,56]	1,05 [0,55; 2,01]	1,07 [-13,88; 16,03]
				1,000	
Ileal	9/32 (28,1)	4/6 (66,7)	0,42 [0,19; 0,93]	0,20 [0,03; 1,26]	-38,54 [-79,35; 2,27]
				0,154	
Ileal-Colonic	65/148 (43,9)	26/80 (32,5)	1,35 [0,94; 1,95]	1,63 [0,92; 2,87]	11,42 [-1,59; 24,43]
				0,119	
Baseline AP average (p-value of the interaction test: 0,738)					
<2	33/72 (45,8)	18/48 (37,5)	1,22 [0,78; 1,90]	1,41 [0,67; 2,97]	8,33 [-9,56; 26,22]
				0,452	
≥2	85/226 (37,6)	33/97 (34,0)	1,11 [0,80; 1,53]	1,17 [0,71; 1,93]	3,59 [-7,76; 14,94]
				0,614	
Baseline SF average (p-value of the interaction test: 0,348)					
<7	89/220 (40,5)	33/100 (33,0)	1,23 [0,89; 1,69]	1,38 [0,84; 2,27]	7,45 [-3,81; 18,72]
				0,216	
≥7	29/76 (38,2)	18/45 (40,0)	0,95 [0,60; 1,51]	0,93 [0,44; 1,97]	-1,84 [-19,85; 16,16]
				0,849	
Baseline CDAI 1 (p-value of the interaction test: 0,523)					
<300	50/109 (45,9)	25/59 (42,4)	1,08 [0,75; 1,55]	1,15 [0,61; 2,18]	3,50 [-12,20; 19,20]
				0,746	
≥300	68/184 (37,0)	26/84 (31,0)	1,19 [0,82; 1,73]	1,31 [0,75; 2,27]	6,00 [-6,09; 18,10]
				0,408	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline CDAI 2 (p-value of the interaction test: 0,616)					
<220	15/29 (51,7)	4/12 (33,3)	1,55 [0,65; 3,72]	2,14 [0,53; 8,72]	18,39 [-13,89; 50,67]
				0,325	
≥220 and <450	97/244 (39,8)	45/119 (37,8)	1,05 [0,80; 1,39]	1,09 [0,69; 1,70]	1,94 [-8,72; 12,60]
				0,733	
≥450	6/20 (30,0)	2/12 (16,7)	1,80 [0,43; 7,53]	2,14 [0,36; 12,89]	13,33 [-15,79; 42,45]
				0,676	
OECD Country (p-value of the interaction test: 0,313)					
Yes	75/178 (42,1)	35/83 (42,2)	1,00 [0,74; 1,36]	1,00 [0,59; 1,69]	-0,03 [-12,90; 12,83]
				1,000	
No	43/122 (35,2)	16/62 (25,8)	1,37 [0,84; 2,22]	1,56 [0,79; 3,09]	9,44 [-4,36; 23,24]
				0,243	
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PRO: Patient Reported Outcome, defined as 2 of the patient-reported items of the CDAI (SF and AP); RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; RR: relatives Risiko; SF: Stool Frequency; TNF: Tumor Necrosis Factor. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_csfprespro_sub_ittb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Anhang 4-G.4.6.1.2 Symptomatik**Darm- und systemische Symptome IBDQ**

Subgruppen für Increase in IBDQ Bowel Symptoms by at least 9 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,227)					
<65 years	190/287 (66,2)	90/141 (63,8)	1,04 [0,89; 1,20]	1,11 [0,73; 1,69]	2,37 [-7,26; 12,01]
			0,666		
≥65 years	7/13 (53,8)	0/4 (0,0)	5,36 [0,37; 77,70]	10,38 [0,47; >100]	53,85 [26,75; 80,95]
			0,103		
Age 2 (p-value of the interaction test: 0,534)					
<40 years	138/202 (68,3)	57/91 (62,6)	1,09 [0,91; 1,31]	1,29 [0,77; 2,16]	5,68 [-6,15; 17,51]
			0,352		
≥40 years	59/98 (60,2)	33/54 (61,1)	0,99 [0,75; 1,29]	0,96 [0,49; 1,90]	-0,91 [-17,12; 15,31]
			1,000		
Sex (p-value of the interaction test: 0,478)					
Male	114/179 (63,7)	41/65 (63,1)	1,01 [0,81; 1,25]	1,03 [0,57; 1,85]	0,61 [-13,07; 14,30]
			1,000		
Female	83/121 (68,6)	49/80 (61,3)	1,12 [0,91; 1,38]	1,38 [0,76; 2,50]	7,35 [-6,16; 20,85]
			0,292		
Weight (p-value of the interaction test: 0,426)					
<100 kg	187/284 (65,8)	88/140 (62,9)	1,05 [0,90; 1,22]	1,14 [0,75; 1,74]	2,99 [-6,73; 12,71]
			0,589		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
≥100 kg	10/15 (66,7)	2/5 (40,0)	1,67 [0,54; 5,17]	3,00 [0,37; 24,17]	26,67 [-22,46; 75,79]
0,347					
BMI (p-value of the interaction test: 0,711)					
Underweight ($<18.5 \text{ kg/m}^2$)	36/54 (66,7)	17/32 (53,1)	1,25 [0,86; 1,83]	1,76 [0,72; 4,32]	13,54 [-7,84; 34,92]
0,255					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	108/161 (67,1)	38/60 (63,3)	1,06 [0,85; 1,32]	1,18 [0,63; 2,19]	3,75 [-10,44; 17,94]
0,634					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	35/55 (63,6)	26/38 (68,4)	0,93 [0,69; 1,25]	0,81 [0,34; 1,94]	-4,78 [-24,28; 14,71]
0,664					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	18/29 (62,1)	9/15 (60,0)	1,03 [0,63; 1,71]	1,09 [0,30; 3,91]	2,07 [-28,37; 32,51]
1,000					
Tobacco use (p-value of the interaction test: 0,231)					
Current	33/52 (63,5)	21/29 (72,4)	0,88 [0,65; 1,19]	0,66 [0,25; 1,78]	-8,95 [-29,83; 11,93]
0,469					
Former	32/49 (65,3)	9/21 (42,9)	1,52 [0,89; 2,60]	2,51 [0,88; 7,14]	22,45 [-2,56; 47,46]
0,113					
Never	132/199 (66,3)	60/95 (63,2)	1,05 [0,87; 1,26]	1,15 [0,69; 1,91]	3,17 [-8,54; 14,89]
0,603					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,116)					
Ever	186/280 (66,4)	90/140 (64,3)	1,03 [0,89; 1,20]	1,10 [0,72; 1,68]	2,14 [-7,53; 11,82]
0,664					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Never	11/20 (55,0)	0/5 (0,0)	6,57 [0,45; 96,05]	13,32 [0,65; >100]	55,00 [33,20; 76,80]
0,046					
Prior anti-TNF failure (p-value of the interaction test: 0,210)					
Ever	185/282 (65,6)	84/139 (60,4)	1,09 [0,93; 1,27]	1,25 [0,82; 1,90]	5,17 [-4,67; 15,01]
0,332					
Never	12/18 (66,7)	6/6 (100)	0,71 [0,48; 1,04]	0,15 [0,01; 3,06]	-33,33 [-55,11; -11,56]
0,277					
Prior anti-integrin failure (p-value of the interaction test: 0,264)					
Ever	46/71 (64,8)	22/31 (71,0)	0,91 [0,69; 1,21]	0,75 [0,30; 1,88]	-6,18 [-25,64; 13,28]
0,650					
Never	151/229 (65,9)	68/114 (59,6)	1,11 [0,93; 1,32]	1,31 [0,82; 2,08]	6,29 [-4,61; 17,19]
0,283					
Baseline corticosteroid use (p-value of the interaction test: 0,432)					
Yes	48/76 (63,2)	26/39 (66,7)	0,95 [0,72; 1,25]	0,86 [0,38; 1,93]	-3,51 [-21,85; 14,84]
0,838					
No	149/224 (66,5)	64/106 (60,4)	1,10 [0,92; 1,32]	1,30 [0,81; 2,10]	6,14 [-5,04; 17,32]
0,324					
Baseline immunomodulator use (p-value of the interaction test: 0,293)					
Yes	44/66 (66,7)	21/39 (53,8)	1,24 [0,88; 1,73]	1,71 [0,76; 3,86]	12,82 [-6,52; 32,16]
0,216					
No	153/234 (65,4)	69/106 (65,1)	1,00 [0,85; 1,19]	1,01 [0,63; 1,64]	0,29 [-10,64; 11,22]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Duration of CD (p-value of the interaction test: 0,356)					
<1 year	12/23 (52,2)	2/9 (22,2)	2,35 [0,65; 8,47]	3,82 [0,65; 22,45]	29,95 [-4,03; 63,93]
				0,235	
≥1 to <5 years	78/104 (75,0)	30/44 (68,2)	1,10 [0,87; 1,38]	1,40 [0,65; 3,04]	6,82 [-9,26; 22,90]
				0,422	
≥5 years	107/173 (61,8)	58/92 (63,0)	0,98 [0,81; 1,19]	0,95 [0,56; 1,60]	-1,19 [-13,43; 11,04]
				0,895	
Baseline disease location (p-value of the interaction test: 0,076)					
Colonic	84/120 (70,0)	31/59 (52,5)	1,33 [1,02; 1,74]	2,11 [1,11; 4,01]	17,46 [2,31; 32,61]
				0,031	
Ileal	14/32 (43,8)	4/6 (66,7)	0,66 [0,33; 1,31]	0,39 [0,06; 2,44]	-22,92 [-64,37; 18,53]
				0,395	
Ileal-Colonic	99/148 (66,9)	55/80 (68,8)	0,97 [0,81; 1,17]	0,92 [0,51; 1,65]	-1,86 [-14,53; 10,82]
				0,882	
Baseline fecal calprotectin (p-value of the interaction test: 0,414)					
≤250	19/38 (50,0)	9/15 (60,0)	0,83 [0,49; 1,40]	0,67 [0,20; 2,24]	-10,00 [-39,45; 19,45]
				0,556	
>250	140/208 (67,3)	58/93 (62,4)	1,08 [0,90; 1,30]	1,24 [0,75; 2,07]	4,94 [-6,79; 16,67]
				0,432	
Baseline SES-CD total score (p-value of the interaction test: 0,761)					
<12	88/143 (61,5)	39/66 (59,1)	1,04 [0,82; 1,32]	1,11 [0,61; 2,01]	2,45 [-11,85; 16,74]
				0,762	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
≥12	109/157 (69,4)	51/79 (64,6)	1,08 [0,89; 1,31]	1,25 [0,70; 2,21]	4,87 [-7,91; 17,64]
0,464					
Baseline AP average (p-value of the interaction test: 0,777)					
<2	45/72 (62,5)	27/48 (56,3)	1,11 [0,82; 1,51]	1,30 [0,62; 2,73]	6,25 [-11,69; 24,19]
0,569					
≥2	152/226 (67,3)	63/97 (64,9)	1,04 [0,87; 1,23]	1,11 [0,67; 1,83]	2,31 [-8,99; 13,60]
0,701					
Baseline SF average (p-value of the interaction test: 0,313)					
<7	148/220 (67,3)	60/100 (60,0)	1,12 [0,93; 1,35]	1,37 [0,84; 2,24]	7,27 [-4,16; 18,70]
0,209					
≥7	48/76 (63,2)	30/45 (66,7)	0,95 [0,72; 1,24]	0,86 [0,39; 1,86]	-3,51 [-21,04; 14,02]
0,844					
Baseline CDAI 1 (p-value of the interaction test: 0,227)					
<300	63/109 (57,8)	36/59 (61,0)	0,95 [0,73; 1,23]	0,88 [0,46; 1,67]	-3,22 [-18,74; 12,30]
0,744					
≥300	132/184 (71,7)	54/84 (64,3)	1,12 [0,93; 1,34]	1,41 [0,81; 2,44]	7,45 [-4,68; 19,59]
0,253					
Baseline CDAI 2 (p-value of the interaction test: 0,670)					
<220	15/29 (51,7)	5/12 (41,7)	1,24 [0,58; 2,64]	1,50 [0,39; 5,84]	10,06 [-23,24; 43,36]
0,734					
≥220 and <450	169/244 (69,3)	77/119 (64,7)	1,07 [0,92; 1,25]	1,23 [0,77; 1,95]	4,56 [-5,80; 14,91]
0,404					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
≥450	11/20 (55,0)	8/12 (66,7)	0,83 [0,47; 1,45]	0,61 [0,14; 2,71]	-11,67 [-46,12; 22,78]
			0,713		

Datenschnitt: 23. August 2023; Biologic-failed ITT Population.

Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor.

RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm.

a: Exakter Test nach Fisher.

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_ibdqbsi9_sub_ittb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Subgruppen für Increase in IBDQ Systemic Symptoms by at least 4.5 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,159)					
<65 years	156/287 (54,4)	67/141 (47,5)	1,14 [0,93; 1,40]	1,32 [0,88; 1,97]	6,84 [-3,22; 16,90]
			0,217		
≥65 years	9/13 (69,2)	0/4 (0,0)	6,79 [0,48; 96,45]	19,00 [0,83; >100]	69,23 [44,14; 94,32]
			0,029		
Age 2 (p-value of the interaction test: 0,989)					
<40 years	115/202 (56,9)	44/91 (48,4)	1,18 [0,92; 1,50]	1,41 [0,86; 2,32]	8,58 [-3,75; 20,91]
			0,205		
≥40 years	50/98 (51,0)	23/54 (42,6)	1,20 [0,83; 1,73]	1,40 [0,72; 2,74]	8,43 [-8,06; 24,92]
			0,397		
Sex (p-value of the interaction test: 0,282)					
Male	95/179 (53,1)	32/65 (49,2)	1,08 [0,81; 1,43]	1,17 [0,66; 2,06]	3,84 [-10,34; 18,03]
			0,664		
Female	70/121 (57,9)	35/80 (43,8)	1,32 [0,99; 1,77]	1,76 [1,00; 3,12]	14,10 [0,12; 28,09]
			0,061		
Race (p-value of the interaction test: 0,109)					
Asian	60/100 (60,0)	21/56 (37,5)	1,60 [1,10; 2,33]	2,50 [1,28; 4,90]	22,50 [6,59; 38,41]
			0,008		
White	92/180 (51,1)	41/82 (50,0)	1,02 [0,79; 1,32]	1,05 [0,62; 1,76]	1,11 [-11,94; 14,17]
			0,895		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Other	8/13 (61,5)	5/7 (71,4)	0,86 [0,46; 1,63]	0,64 [0,09; 4,66]	-9,89 [-52,54; 32,76]
1,000					
Geographic region 1 (p-value of the interaction test: 0,121)					
Europe	61/114 (53,5)	27/50 (54,0)	0,99 [0,73; 1,35]	0,98 [0,50; 1,91]	-0,49 [-17,06; 16,08]
1,000					
North America	28/54 (51,9)	14/26 (53,8)	0,96 [0,62; 1,49]	0,92 [0,36; 2,36]	-1,99 [-25,33; 21,35]
1,000					
Other	76/132 (57,6)	26/69 (37,7)	1,53 [1,09; 2,14]	2,24 [1,24; 4,08]	19,89 [5,69; 34,10]
0,008					
Geographic region 2 (p-value of the interaction test: 0,217)					
Asia	61/105 (58,1)	20/56 (35,7)	1,63 [1,10; 2,40]	2,50 [1,28; 4,88]	22,38 [6,68; 38,08]
0,008					
Central America/South America	13/24 (54,2)	6/13 (46,2)	1,17 [0,59; 2,35]	1,38 [0,36; 5,34]	8,01 [-25,63; 41,65]
0,737					
Europe and ROW	63/117 (53,8)	27/50 (54,0)	1,00 [0,73; 1,35]	0,99 [0,51; 1,93]	-0,15 [-16,66; 16,35]
1,000					
North America	28/54 (51,9)	14/26 (53,8)	0,96 [0,62; 1,49]	0,92 [0,36; 2,36]	-1,99 [-25,33; 21,35]
1,000					
Weight (p-value of the interaction test: 0,630)					
<100 kg	158/284 (55,6)	66/140 (47,1)	1,18 [0,96; 1,45]	1,41 [0,94; 2,11]	8,49 [-1,60; 18,58]
0,121					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
≥100 kg	7/15 (46,7)	1/5 (20,0)	2,33 [0,37; 14,61]	3,50 [0,31; 39,15]	26,67 [-16,54; 69,87]
0,603					
BMI (p-value of the interaction test: 0,395)					
Underweight ($<18.5 \text{ kg/m}^2$)	30/54 (55,6)	13/32 (40,6)	1,37 [0,84; 2,21]	1,83 [0,75; 4,43]	14,93 [-6,64; 36,50]
0,265					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	91/161 (56,5)	30/60 (50,0)	1,13 [0,85; 1,51]	1,30 [0,72; 2,36]	6,52 [-8,27; 21,31]
0,448					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	29/55 (52,7)	21/38 (55,3)	0,95 [0,65; 1,40]	0,90 [0,39; 2,07]	-2,54 [-23,13; 18,06]
0,835					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	15/29 (51,7)	3/15 (20,0)	2,59 [0,89; 7,55]	4,29 [1,00; 18,45]	31,72 [4,51; 58,94]
0,057					
Tobacco use (p-value of the interaction test: 0,785)					
Current	27/52 (51,9)	11/29 (37,9)	1,37 [0,80; 2,33]	1,77 [0,70; 4,46]	13,99 [-8,29; 36,27]
0,254					
Former	24/49 (49,0)	10/21 (47,6)	1,03 [0,60; 1,75]	1,06 [0,38; 2,94]	1,36 [-24,18; 26,90]
1,000					
Never	114/199 (57,3)	46/95 (48,4)	1,18 [0,93; 1,50]	1,43 [0,87; 2,33]	8,87 [-3,31; 21,04]
0,169					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,678)					
Ever	157/280 (56,1)	66/140 (47,1)	1,19 [0,97; 1,46]	1,43 [0,95; 2,15]	8,93 [-1,18; 19,04]
0,097					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Never	8/20 (40,0)	1/5 (20,0)	2,00 [0,32; 12,51]	2,67 [0,25; 28,44]	20,00 [-21,11; 61,11]
0,621					
Prior anti-TNF failure (p-value of the interaction test: 0,065)					
Ever	156/282 (55,3)	61/139 (43,9)	1,26 [1,02; 1,56]	1,58 [1,05; 2,38]	11,43 [1,35; 21,52]
0,030					
Never	9/18 (50,0)	6/6 (100)	0,54 [0,33; 0,88]	0,08 [0,00; 1,57]	-50,00 [-73,10; -26,90]
0,052					
Prior anti-integrin failure (p-value of the interaction test: 0,914)					
Ever	40/71 (56,3)	14/31 (45,2)	1,25 [0,80; 1,93]	1,57 [0,67; 3,66]	11,18 [-9,80; 32,15]
0,389					
Never	125/229 (54,6)	53/114 (46,5)	1,17 [0,93; 1,48]	1,38 [0,88; 2,17]	8,09 [-3,10; 19,29]
0,170					
Baseline corticosteroid use (p-value of the interaction test: 0,119)					
Yes	39/76 (51,3)	22/39 (56,4)	0,91 [0,64; 1,29]	0,81 [0,37; 1,77]	-5,09 [-24,29; 14,10]
0,694					
No	126/224 (56,3)	45/106 (42,5)	1,33 [1,03; 1,70]	1,74 [1,09; 2,78]	13,80 [2,36; 25,23]
0,025					
Baseline immunomodulator use (p-value of the interaction test: 0,154)					
Yes	39/66 (59,1)	15/39 (38,5)	1,54 [0,98; 2,40]	2,31 [1,03; 5,20]	20,63 [1,29; 39,96]
0,046					
No	126/234 (53,8)	52/106 (49,1)	1,10 [0,87; 1,38]	1,21 [0,77; 1,92]	4,79 [-6,67; 16,25]
0,415					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Duration of CD (p-value of the interaction test: 0,329)					
<1 year	9/23 (39,1)	1/9 (11,1)	3,52 [0,52; 23,95]	5,14 [0,55; 48,37]	28,02 [-0,61; 56,64]
			0,210		
≥1 to <5 years	60/104 (57,7)	18/44 (40,9)	1,41 [0,95; 2,09]	1,97 [0,96; 4,03]	16,78 [-0,57; 34,14]
			0,073		
≥5 years	96/173 (55,5)	48/92 (52,2)	1,06 [0,84; 1,35]	1,14 [0,69; 1,90]	3,32 [-9,29; 15,93]
			0,607		
Baseline disease location (p-value of the interaction test: 0,174)					
Colonic	70/120 (58,3)	24/59 (40,7)	1,43 [1,02; 2,02]	2,04 [1,08; 3,85]	17,66 [2,33; 32,98]
			0,038		
Ileal	14/32 (43,8)	4/6 (66,7)	0,66 [0,33; 1,31]	0,39 [0,06; 2,44]	-22,92 [-64,37; 18,53]
			0,395		
Ileal-Colonic	81/148 (54,7)	39/80 (48,8)	1,12 [0,86; 1,47]	1,27 [0,74; 2,19]	5,98 [-7,60; 19,55]
			0,407		
Baseline fecal calprotectin (p-value of the interaction test: 0,275)					
≤250	15/38 (39,5)	7/15 (46,7)	0,85 [0,43; 1,65]	0,75 [0,22; 2,49]	-7,19 [-36,84; 22,45]
			0,759		
>250	120/208 (57,7)	42/93 (45,2)	1,28 [0,99; 1,64]	1,66 [1,01; 2,71]	12,53 [0,39; 24,67]
			0,046		
Baseline CRP (p-value of the interaction test: 0,223)					
≤10	70/145 (48,3)	27/58 (46,6)	1,04 [0,75; 1,43]	1,07 [0,58; 1,97]	1,72 [-13,47; 16,92]
			0,877		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
>10	95/154 (61,7)	40/87 (46,0)	1,34 [1,03; 1,74]	1,89 [1,11; 3,22]	15,71 [2,73; 28,70]
0,022					
Baseline SES-CD total score (p-value of the interaction test: 0,340)					
<12	79/143 (55,2)	27/66 (40,9)	1,35 [0,98; 1,87]	1,78 [0,99; 3,22]	14,34 [-0,06; 28,73]
0,074					
≥12	86/157 (54,8)	40/79 (50,6)	1,08 [0,83; 1,40]	1,18 [0,69; 2,03]	4,14 [-9,35; 17,64]
0,582					
Baseline AP average (p-value of the interaction test: 0,309)					
<2	38/72 (52,8)	17/48 (35,4)	1,49 [0,96; 2,31]	2,04 [0,96; 4,32]	17,36 [-0,42; 35,14]
0,066					
≥2	127/226 (56,2)	50/97 (51,5)	1,09 [0,87; 1,36]	1,21 [0,75; 1,94]	4,65 [-7,22; 16,51]
0,466					
Baseline SF average (p-value of the interaction test: 0,227)					
<7	122/220 (55,5)	42/100 (42,0)	1,32 [1,02; 1,71]	1,72 [1,07; 2,77]	13,45 [1,76; 25,15]
0,030					
≥7	42/76 (55,3)	25/45 (55,6)	0,99 [0,71; 1,38]	0,99 [0,47; 2,07]	-0,29 [-18,62; 18,03]
1,000					
Baseline CDAI 2 (p-value of the interaction test: 0,301)					
<220	14/29 (48,3)	2/12 (16,7)	2,90 [0,77; 10,84]	4,67 [0,87; 25,14]	31,61 [3,76; 59,45]
0,084					
≥220 and <450	141/244 (57,8)	59/119 (49,6)	1,17 [0,94; 1,44]	1,39 [0,90; 2,16]	8,21 [-2,71; 19,12]
0,146					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
≥450	8/20 (40,0)	6/12 (50,0)	0,80 [0,37; 1,74]	0,67 [0,16; 2,82]	-10,00 [-45,51; 25,51]
0,718					
OECD Country (p-value of the interaction test: 0,534)					
Yes	97/178 (54,5)	40/83 (48,2)	1,13 [0,87; 1,47]	1,29 [0,76; 2,17]	6,30 [-6,70; 19,30]
0,355					
No	68/122 (55,7)	27/62 (43,5)	1,28 [0,93; 1,77]	1,63 [0,88; 3,02]	12,19 [-2,98; 27,36]
0,123					
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_ibdqssi4_5_sub_ittb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

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Stuhlfrequenz – CDAI-SF

Subgruppen für Reduction in Stool Frequency by at least 15 percent-points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,467)					
<65 years	215/287 (74,9)	93/141 (66,0)	1,14 [0,99; 1,30]	1,54 [0,99; 2,39]	8,96 [-0,34; 18,25]
			0,067		
≥65 years	8/13 (61,5)	3/4 (75,0)	0,82 [0,40; 1,67]	0,53 [0,04; 6,65]	-13,46 [-63,46; 36,54]
			1,000		
Sex (p-value of the interaction test: 0,620)					
Male	135/179 (75,4)	46/65 (70,8)	1,07 [0,89; 1,27]	1,27 [0,67; 2,39]	4,65 [-8,08; 17,38]
			0,509		
Female	88/121 (72,7)	50/80 (62,5)	1,16 [0,95; 1,42]	1,60 [0,87; 2,93]	10,23 [-3,02; 23,48]
			0,162		
Weight (p-value of the interaction test: 0,129)					
<100 kg	210/284 (73,9)	94/140 (67,1)	1,10 [0,96; 1,26]	1,39 [0,89; 2,16]	6,80 [-2,50; 16,11]
			0,169		
≥100 kg	13/15 (86,7)	2/5 (40,0)	2,17 [0,73; 6,46]	9,75 [0,95; 99,96]	46,67 [0,41; 92,93]
			0,073		
BMI (p-value of the interaction test: 0,455)					
Underweight (<18.5 kg/m ²)	38/54 (70,4)	17/32 (53,1)	1,32 [0,92; 1,92]	2,10 [0,85; 5,19]	17,25 [-3,90; 38,39]
			0,163		
Normal (≥18.5 and <25 kg/m ²)	122/161 (75,8)	44/60 (73,3)	1,03 [0,87; 1,23]	1,14 [0,58; 2,24]	2,44 [-10,56; 15,44]
			0,728		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Overweight (≥25 and <30 kg/m ²)	40/55 (72,7)	27/38 (71,1)	1,02 [0,79; 1,33]	1,09 [0,43; 2,72]	1,67 [-16,94; 20,29]
			1,000		
Obese and Extreme obese (≥30 kg/m ²)	23/29 (79,3)	8/15 (53,3)	1,49 [0,89; 2,47]	3,35 [0,87; 13,00]	25,98 [-3,26; 55,21]
			0,092		
Tobacco use (p-value of the interaction test: 0,050)					
Current	34/52 (65,4)	23/29 (79,3)	0,82 [0,63; 1,08]	0,49 [0,17; 1,43]	-13,93 [-33,54; 5,68]
			0,215		
Former	38/49 (77,6)	10/21 (47,6)	1,63 [1,01; 2,61]	3,80 [1,28; 11,28]	29,93 [5,59; 54,28]
			0,023		
Never	151/199 (75,9)	63/95 (66,3)	1,14 [0,97; 1,35]	1,60 [0,94; 2,73]	9,56 [-1,65; 20,77]
			0,094		
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,333)					
Ever	212/280 (75,7)	95/140 (67,9)	1,12 [0,98; 1,27]	1,48 [0,94; 2,31]	7,86 [-1,37; 17,08]
			0,102		
Never	11/20 (55,0)	1/5 (20,0)	2,75 [0,46; 16,59]	4,89 [0,46; 51,87]	35,00 [-6,29; 76,29]
			0,322		
Prior anti-TNF failure (p-value of the interaction test: 0,535)					
Ever	210/282 (74,5)	91/139 (65,5)	1,14 [0,99; 1,31]	1,54 [0,99; 2,39]	9,00 [-0,40; 18,40]
			0,066		
Never	13/18 (72,2)	5/6 (83,3)	0,87 [0,55; 1,37]	0,52 [0,05; 5,63]	-11,11 [-47,41; 25,18]
			1,000		
Prior anti-integrin failure (p-value of the interaction test: 0,849)					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Ever	53/71 (74,6)	21/31 (67,7)	1,10 [0,83; 1,46]	1,40 [0,56; 3,53]	6,91 [-12,41; 26,22]
			0,479		
Never	170/229 (74,2)	75/114 (65,8)	1,13 [0,97; 1,31]	1,50 [0,92; 2,44]	8,45 [-1,94; 18,84]
			0,128		
Baseline corticosteroid use (p-value of the interaction test: 0,437)					
Yes	52/76 (68,4)	26/39 (66,7)	1,03 [0,78; 1,34]	1,08 [0,48; 2,47]	1,75 [-16,36; 19,87]
			0,837		
No	171/224 (76,3)	70/106 (66,0)	1,16 [0,99; 1,35]	1,66 [1,00; 2,75]	10,30 [-0,29; 20,90]
			0,063		
Baseline immunomodulator use (p-value of the interaction test: 0,480)					
Yes	52/66 (78,8)	25/39 (64,1)	1,23 [0,94; 1,60]	2,08 [0,86; 5,02]	14,69 [-3,31; 32,68]
			0,114		
No	171/234 (73,1)	71/106 (67,0)	1,09 [0,93; 1,27]	1,34 [0,81; 2,20]	6,10 [-4,51; 16,70]
			0,301		
Baseline disease location (p-value of the interaction test: 0,748)					
Colonic	96/120 (80,0)	41/59 (69,5)	1,15 [0,95; 1,39]	1,76 [0,86; 3,58]	10,51 [-3,25; 24,27]
			0,135		
Ileal	20/32 (62,5)	4/6 (66,7)	0,94 [0,50; 1,75]	0,83 [0,13; 5,26]	-4,17 [-45,45; 37,11]
			1,000		
Ileal-Colonic	107/148 (72,3)	51/80 (63,8)	1,13 [0,94; 1,38]	1,48 [0,83; 2,65]	8,55 [-4,22; 21,31]
			0,229		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline SES-CD total score (p-value of the interaction test: 0,465)					
<12	97/143 (67,8)	41/66 (62,1)	1,09 [0,88; 1,36]	1,29 [0,70; 2,36]	5,71 [-8,27; 19,70]
			0,435		
≥12	126/157 (80,3)	55/79 (69,6)	1,15 [0,98; 1,36]	1,77 [0,95; 3,30]	10,63 [-1,27; 22,53]
			0,075		
Baseline AP average (p-value of the interaction test: 0,871)					
<2	52/72 (72,2)	31/48 (64,6)	1,12 [0,87; 1,44]	1,43 [0,65; 3,13]	7,64 [-9,39; 24,67]
			0,423		
≥2	171/226 (75,7)	65/97 (67,0)	1,13 [0,96; 1,32]	1,53 [0,91; 2,58]	8,65 [-2,25; 19,56]
			0,132		
Baseline SF average (p-value of the interaction test: 0,240)					
<7	165/220 (75,0)	62/100 (62,0)	1,21 [1,02; 1,44]	1,84 [1,11; 3,05]	13,00 [1,90; 24,10]
			0,024		
≥7	58/76 (76,3)	34/45 (75,6)	1,01 [0,82; 1,24]	1,04 [0,44; 2,47]	0,76 [-15,02; 16,54]
			1,000		
Baseline CDAI 1 (p-value of the interaction test: 0,836)					
<300	79/109 (72,5)	37/59 (62,7)	1,16 [0,92; 1,45]	1,57 [0,80; 3,07]	9,77 [-5,15; 24,68]
			0,222		
≥300	144/184 (78,3)	58/84 (69,0)	1,13 [0,96; 1,33]	1,61 [0,90; 2,88]	9,21 [-2,33; 20,76]
			0,126		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline CDAI 2 (p-value of the interaction test: 0,822)					
<220	18/29 (62,1)	6/12 (50,0)	1,24 [0,66; 2,34]	1,64 [0,42; 6,36]	12,07 [-21,28; 45,42]
				0,507	
≥220 and <450	193/244 (79,1)	82/119 (68,9)	1,15 [1,00; 1,32]	1,71 [1,04; 2,80]	10,19 [0,43; 19,95]
				0,037	
≥450	12/20 (60,0)	7/12 (58,3)	1,03 [0,57; 1,87]	1,07 [0,25; 4,59]	1,67 [-33,53; 36,87]
				1,000	
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_sfi15p_sub_itb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

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Imperativer Stuhldrang - Urgency NRS

Subgruppen für Urgency NRS Score ≤ 2 in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,470)					
<65 years	114/287 (39,7)	40/141 (28,4)	1,40 [1,04; 1,89]	1,66 [1,08; 2,57]	11,35 [2,00; 20,70]
			0,024		
≥65 years	5/13 (38,5)	2/4 (50,0)	0,77 [0,23; 2,55]	0,63 [0,07; 5,97]	-11,54 [-67,22; 44,14]
			1,000		
Age 2 (p-value of the interaction test: 0,401)					
<40 years	81/202 (40,1)	24/91 (26,4)	1,52 [1,04; 2,23]	1,87 [1,08; 3,22]	13,73 [2,43; 25,02]
			0,026		
≥40 years	38/98 (38,8)	18/54 (33,3)	1,16 [0,74; 1,83]	1,27 [0,63; 2,54]	5,44 [-10,41; 21,29]
			0,599		
Sex (p-value of the interaction test: 0,403)					
Male	75/179 (41,9)	18/65 (27,7)	1,51 [0,99; 2,32]	1,88 [1,01; 3,50]	14,21 [1,15; 27,27]
			0,053		
Female	44/121 (36,4)	24/80 (30,0)	1,21 [0,80; 1,83]	1,33 [0,73; 2,44]	6,36 [-6,84; 19,57]
			0,366		
Geographic region 2 (p-value of the interaction test: 0,078)					
Asia	55/105 (52,4)	14/56 (25,0)	2,10 [1,28; 3,42]	3,30 [1,61; 6,75]	27,38 [12,55; 42,21]
			<0,001		
Central America/South America	9/24 (37,5)	4/13 (30,8)	1,22 [0,46; 3,20]	1,35 [0,32; 5,69]	6,73 [-24,96; 38,43]
			0,734		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Europe and ROW	41/117 (35,0)	16/50 (32,0)	1,10 [0,68; 1,76]	1,15 [0,57; 2,32]	3,04 [-12,51; 18,60]
			0,726		
North America	14/54 (25,9)	8/26 (30,8)	0,84 [0,41; 1,75]	0,79 [0,28; 2,21]	-4,84 [-26,09; 16,40]
			0,790		
Weight (p-value of the interaction test: 0,309)					
<100 kg	113/284 (39,8)	42/140 (30,0)	1,33 [0,99; 1,77]	1,54 [1,00; 2,38]	9,79 [0,30; 19,28]
			0,054		
≥100 kg	6/15 (40,0)	0/5 (0,0)	4,88 [0,32; 73,94]	7,53 [0,35; >100]	40,00 [15,21; 64,79]
			0,260		
BMI (p-value of the interaction test: 0,532)					
Underweight (<18.5 kg/m ²)	25/54 (46,3)	9/32 (28,1)	1,65 [0,88; 3,07]	2,20 [0,86; 5,63]	18,17 [-2,31; 38,65]
			0,114		
Normal (≥18.5 and <25 kg/m ²)	63/161 (39,1)	16/60 (26,7)	1,47 [0,92; 2,33]	1,77 [0,92; 3,40]	12,46 [-1,03; 25,96]
			0,114		
Overweight (≥25 and <30 kg/m ²)	20/55 (36,4)	14/38 (36,8)	0,99 [0,57; 1,70]	0,98 [0,42; 2,31]	-0,48 [-20,40; 19,44]
			1,000		
Obese and Extreme obese (≥30 kg/m ²)	11/29 (37,9)	3/15 (20,0)	1,90 [0,62; 5,78]	2,44 [0,56; 10,64]	17,93 [-8,93; 44,79]
			0,314		
Tobacco use (p-value of the interaction test: 0,228)					
Current	20/52 (38,5)	7/29 (24,1)	1,59 [0,77; 3,31]	1,96 [0,71; 5,43]	14,32 [-6,11; 34,75]
			0,226		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Former	20/49 (40,8)	3/21 (14,3)	2,86 [0,95; 8,59]	4,14 [1,07; 15,94]	26,53 [6,20; 46,86]
			0,050		
Never	79/199 (39,7)	32/95 (33,7)	1,18 [0,85; 1,64]	1,30 [0,78; 2,16]	6,01 [-5,67; 17,70]
			0,368		
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,663)					
Ever	115/280 (41,1)	42/140 (30,0)	1,37 [1,03; 1,83]	1,63 [1,05; 2,51]	11,07 [1,54; 20,60]
			0,032		
Never	4/20 (20,0)	0/5 (0,0)	2,57 [0,16; 41,34]	3,00 [0,14; 65,08]	20,00 [2,47; 37,53]
			0,549		
Prior anti-TNF failure (p-value of the interaction test: 0,765)					
Ever	110/282 (39,0)	40/139 (28,8)	1,36 [1,00; 1,83]	1,58 [1,02; 2,45]	10,23 [0,79; 19,67]
			0,041		
Never	9/18 (50,0)	2/6 (33,3)	1,50 [0,44; 5,09]	2,00 [0,29; 13,81]	16,67 [-27,56; 60,90]
			0,649		
Prior anti-integrin failure (p-value of the interaction test: 0,330)					
Ever	30/71 (42,3)	7/31 (22,6)	1,87 [0,92; 3,79]	2,51 [0,96; 6,58]	19,67 [1,00; 38,34]
			0,074		
Never	89/229 (38,9)	35/114 (30,7)	1,27 [0,92; 1,74]	1,43 [0,89; 2,32]	8,16 [-2,40; 18,72]
			0,153		
Baseline corticosteroid use (p-value of the interaction test: 0,689)					
Yes	29/76 (38,2)	12/39 (30,8)	1,24 [0,71; 2,15]	1,39 [0,61; 3,16]	7,39 [-10,75; 25,53]
			0,538		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
No	90/224 (40,2)	30/106 (28,3)	1,42 [1,01; 2,00]	1,70 [1,03; 2,81]	11,88 [1,16; 22,59]
0,038					
Baseline immunomodulator use (p-value of the interaction test: 0,081)					
Yes	34/66 (51,5)	9/39 (23,1)	2,23 [1,20; 4,15]	3,54 [1,46; 8,60]	28,44 [10,54; 46,33]
0,004					
No	85/234 (36,3)	33/106 (31,1)	1,17 [0,84; 1,62]	1,26 [0,77; 2,06]	5,19 [-5,56; 15,95]
0,390					
Duration of CD (p-value of the interaction test: 0,143)					
<1 year	7/23 (30,4)	1/9 (11,1)	2,74 [0,39; 19,22]	3,50 [0,36; 33,56]	19,32 [-8,52; 47,17]
0,386					
≥1 to <5 years	50/104 (48,1)	10/44 (22,7)	2,12 [1,18; 3,78]	3,15 [1,41; 7,03]	25,35 [9,68; 41,02]
0,006					
≥5 years	62/173 (35,8)	31/92 (33,7)	1,06 [0,75; 1,51]	1,10 [0,65; 1,87]	2,14 [-9,87; 14,16]
0,787					
Baseline disease location (p-value of the interaction test: 0,221)					
Colonic	53/120 (44,2)	15/59 (25,4)	1,74 [1,07; 2,81]	2,32 [1,17; 4,62]	18,74 [4,52; 32,97]
0,021					
Ileal	10/32 (31,3)	3/6 (50,0)	0,63 [0,24; 1,62]	0,45 [0,08; 2,66]	-18,75 [-61,86; 24,36]
0,392					
Ileal-Colonic	56/148 (37,8)	24/80 (30,0)	1,26 [0,85; 1,87]	1,42 [0,79; 2,54]	7,84 [-4,89; 20,56]
0,249					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline fecal calprotectin (p-value of the interaction test: 0,091)					
≤250	9/38 (23,7)	5/15 (33,3)	0,71 [0,28; 1,77]	0,62 [0,17; 2,30]	-9,65 [-37,07; 17,77]
				0,504	
>250	91/208 (43,8)	25/93 (26,9)	1,63 [1,13; 2,35]	2,12 [1,24; 3,61]	16,87 [5,61; 28,12]
				0,007	
Baseline SES-CD total score (p-value of the interaction test: 0,253)					
<12	45/143 (31,5)	18/66 (27,3)	1,15 [0,73; 1,83]	1,22 [0,64; 2,34]	4,20 [-8,97; 17,36]
				0,627	
≥12	74/157 (47,1)	24/79 (30,4)	1,55 [1,07; 2,25]	2,04 [1,15; 3,62]	16,75 [3,95; 29,55]
				0,017	
Baseline AP average (p-value of the interaction test: 0,384)					
<2	30/72 (41,7)	12/48 (25,0)	1,67 [0,95; 2,92]	2,14 [0,96; 4,79]	16,67 [-0,06; 33,39]
				0,079	
≥2	89/226 (39,4)	30/97 (30,9)	1,27 [0,91; 1,79]	1,45 [0,87; 2,41]	8,45 [-2,74; 19,64]
				0,167	
Baseline SF average (p-value of the interaction test: 0,120)					
<7	93/220 (42,3)	27/100 (27,0)	1,57 [1,10; 2,24]	1,98 [1,18; 3,32]	15,27 [4,39; 26,15]
				0,009	
≥7	25/76 (32,9)	15/45 (33,3)	0,99 [0,58; 1,67]	0,98 [0,45; 2,15]	-0,44 [-17,80; 16,92]
				1,000	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Baseline CDAI 1 (p-value of the interaction test: 0,120)					
<300	54/109 (49,5)	16/59 (27,1)	1,83 [1,15; 2,89]	2,64 [1,33; 5,24]	22,42 [7,70; 37,15]
				0,005	
≥300	64/184 (34,8)	26/84 (31,0)	1,12 [0,77; 1,64]	1,19 [0,68; 2,07]	3,83 [-8,22; 15,88]
				0,579	
Baseline CDAI 2 (p-value of the interaction test: 0,129)					
<220	15/29 (51,7)	1/12 (8,3)	6,21 [0,92; 41,88]	11,79 [1,34; >100]	43,39 [19,41; 67,38]
				0,013	
≥220 and <450	95/244 (38,9)	39/119 (32,8)	1,19 [0,88; 1,61]	1,31 [0,82; 2,07]	6,16 [-4,26; 16,58]
				0,297	
≥450	8/20 (40,0)	2/12 (16,7)	2,40 [0,61; 9,49]	3,33 [0,57; 19,42]	23,33 [-6,76; 53,43]
				0,248	
OECD Country (p-value of the interaction test: 0,496)					
Yes	72/178 (40,4)	27/83 (32,5)	1,24 [0,87; 1,78]	1,41 [0,81; 2,44]	7,92 [-4,47; 20,31]
				0,273	
No	47/122 (38,5)	15/62 (24,2)	1,59 [0,97; 2,61]	1,96 [0,99; 3,90]	14,33 [0,61; 28,05]
				0,069	
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NRS: Numeric Rating Scale; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_urgle2_sub_ittb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Subgruppen für Reduction in Urgency NRS Score by at least 3 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,986)					
<65 years	149/287 (51,9)	67/141 (47,5)	1,09 [0,89; 1,34]	1,19 [0,80; 1,79]	4,40 [-5,67; 14,47]
			0,412		
≥65 years	5/13 (38,5)	1/4 (25,0)	1,54 [0,25; 9,60]	1,88 [0,15; 23,40]	13,46 [-36,54; 63,46]
			1,000		
Age 2 (p-value of the interaction test: 0,193)					
<40 years	108/202 (53,5)	40/91 (44,0)	1,22 [0,93; 1,59]	1,46 [0,89; 2,41]	9,51 [-2,79; 21,81]
			0,165		
≥40 years	46/98 (46,9)	28/54 (51,9)	0,91 [0,65; 1,26]	0,82 [0,42; 1,60]	-4,91 [-21,50; 11,68]
			0,613		
Sex (p-value of the interaction test: 0,735)					
Male	89/179 (49,7)	30/65 (46,2)	1,08 [0,80; 1,46]	1,15 [0,65; 2,04]	3,57 [-10,59; 17,73]
			0,665		
Female	65/121 (53,7)	38/80 (47,5)	1,13 [0,85; 1,50]	1,28 [0,73; 2,26]	6,22 [-7,88; 20,31]
			0,471		
Weight (p-value of the interaction test: 0,668)					
<100 kg	148/284 (52,1)	67/140 (47,9)	1,09 [0,89; 1,34]	1,19 [0,79; 1,78]	4,26 [-5,86; 14,37]
			0,470		
≥100 kg	6/15 (40,0)	1/5 (20,0)	2,00 [0,31; 12,84]	2,67 [0,24; 30,07]	20,00 [-22,94; 62,94]
			0,613		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
BMI (p-value of the interaction test: 0,238)					
Underweight ($<18.5 \text{ kg/m}^2$)	29/54 (53,7)	11/32 (34,4)	1,56 [0,91; 2,68]	2,21 [0,90; 5,47]	19,33 [-1,83; 40,49]
				0,117	
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	86/161 (53,4)	29/60 (48,3)	1,11 [0,82; 1,49]	1,23 [0,68; 2,22]	5,08 [-9,72; 19,89]
				0,546	
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	29/55 (52,7)	25/38 (65,8)	0,80 [0,57; 1,13]	0,58 [0,25; 1,36]	-13,06 [-33,10; 6,98]
				0,285	
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	10/29 (34,5)	3/15 (20,0)	1,72 [0,56; 5,34]	2,11 [0,48; 9,24]	14,48 [-12,14; 41,11]
				0,488	
Tobacco use (p-value of the interaction test: 0,056)					
Current	24/52 (46,2)	16/29 (55,2)	0,84 [0,54; 1,30]	0,70 [0,28; 1,73]	-9,02 [-31,63; 13,59]
				0,492	
Former	28/49 (57,1)	5/21 (23,8)	2,40 [1,08; 5,36]	4,27 [1,35; 13,51]	33,33 [10,45; 56,22]
				0,018	
Never	102/199 (51,3)	47/95 (49,5)	1,04 [0,81; 1,32]	1,07 [0,66; 1,75]	1,78 [-10,44; 14,00]
				0,804	
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,175)					
Ever	145/280 (51,8)	68/140 (48,6)	1,07 [0,87; 1,31]	1,14 [0,76; 1,71]	3,21 [-6,92; 13,35]
				0,537	
Never	9/20 (45,0)	0/5 (0,0)	5,43 [0,37; 80,39]	9,09 [0,44; >100]	45,00 [23,20; 66,80]
				0,123	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Prior anti-TNF failure (p-value of the interaction test: 0,774)					
Ever	143/282 (50,7)	65/139 (46,8)	1,08 [0,88; 1,34]	1,17 [0,78; 1,76]	3,95 [-6,19; 14,09]
				0,469	
Never	11/18 (61,1)	3/6 (50,0)	1,22 [0,51; 2,95]	1,57 [0,24; 10,09]	11,11 [-34,80; 57,02]
				0,665	
Prior anti-integrin failure (p-value of the interaction test: 0,583)					
Ever	35/71 (49,3)	15/31 (48,4)	1,02 [0,66; 1,57]	1,04 [0,45; 2,41]	0,91 [-20,18; 22,00]
				1,000	
Never	119/229 (52,0)	53/114 (46,5)	1,12 [0,89; 1,41]	1,25 [0,79; 1,95]	5,47 [-5,74; 16,69]
				0,361	
Baseline corticosteroid use (p-value of the interaction test: 0,140)					
Yes	38/76 (50,0)	23/39 (59,0)	0,85 [0,60; 1,20]	0,70 [0,32; 1,52]	-8,97 [-28,07; 10,12]
				0,431	
No	116/224 (51,8)	45/106 (42,5)	1,22 [0,95; 1,57]	1,46 [0,91; 2,32]	9,33 [-2,13; 20,79]
				0,126	
Baseline immunomodulator use (p-value of the interaction test: 0,556)					
Yes	33/66 (50,0)	16/39 (41,0)	1,22 [0,78; 1,91]	1,44 [0,65; 3,20]	8,97 [-10,62; 28,57]
				0,422	
No	121/234 (51,7)	52/106 (49,1)	1,05 [0,84; 1,33]	1,11 [0,70; 1,76]	2,65 [-8,82; 14,12]
				0,725	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Baseline disease location (p-value of the interaction test: 0,237)					
Colonic	63/120 (52,5)	29/59 (49,2)	1,07 [0,78; 1,46]	1,14 [0,61; 2,13]	3,35 [-12,23; 18,92]
				0,751	
Ileal	12/32 (37,5)	4/6 (66,7)	0,56 [0,27; 1,16]	0,30 [0,05; 1,89]	-29,17 [-70,45; 12,11]
				0,217	
Ileal-Colonic	79/148 (53,4)	35/80 (43,8)	1,22 [0,91; 1,63]	1,47 [0,85; 2,54]	9,63 [-3,89; 23,15]
				0,212	
Baseline fecal calprotectin (p-value of the interaction test: 0,441)					
≤250	17/38 (44,7)	8/15 (53,3)	0,84 [0,46; 1,51]	0,71 [0,21; 2,35]	-8,60 [-38,38; 21,19]
				0,761	
>250	108/208 (51,9)	42/93 (45,2)	1,15 [0,89; 1,49]	1,31 [0,80; 2,14]	6,76 [-5,42; 18,94]
				0,319	
Baseline CRP (p-value of the interaction test: 0,074)					
≤10	70/145 (48,3)	32/58 (55,2)	0,88 [0,66; 1,17]	0,76 [0,41; 1,40]	-6,90 [-22,06; 8,27]
				0,438	
>10	84/154 (54,5)	36/87 (41,4)	1,32 [0,99; 1,76]	1,70 [1,00; 2,89]	13,17 [0,17; 26,16]
				0,060	
Baseline SES-CD total score (p-value of the interaction test: 0,719)					
<12	67/143 (46,9)	29/66 (43,9)	1,07 [0,77; 1,47]	1,12 [0,63; 2,02]	2,91 [-11,59; 17,41]
				0,766	
≥12	87/157 (55,4)	39/79 (49,4)	1,12 [0,86; 1,46]	1,27 [0,74; 2,19]	6,05 [-7,44; 19,54]
				0,409	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline AP average (p-value of the interaction test: 0,154)					
<2	25/72 (34,7)	20/48 (41,7)	0,83 [0,53; 1,32]	0,74 [0,35; 1,58]	-6,94 [-24,71; 10,82]
			0,449		
≥2	129/226 (57,1)	48/97 (49,5)	1,15 [0,92; 1,45]	1,36 [0,84; 2,19]	7,60 [-4,26; 19,45]
			0,224		
Baseline SF average (p-value of the interaction test: 0,057)					
<7	114/220 (51,8)	40/100 (40,0)	1,30 [0,99; 1,70]	1,61 [1,00; 2,61]	11,82 [0,17; 23,47]
			0,054		
≥7	40/76 (52,6)	28/45 (62,2)	0,85 [0,62; 1,16]	0,67 [0,32; 1,43]	-9,59 [-27,66; 8,48]
			0,346		
Baseline CDAI 1 (p-value of the interaction test: 0,969)					
<300	46/109 (42,2)	22/59 (37,3)	1,13 [0,76; 1,68]	1,23 [0,64; 2,35]	4,91 [-10,52; 20,35]
			0,622		
≥300	108/184 (58,7)	46/84 (54,8)	1,07 [0,85; 1,35]	1,17 [0,70; 1,98]	3,93 [-8,87; 16,74]
			0,595		
Baseline CDAI 2 (p-value of the interaction test: 0,863)					
<220	9/29 (31,0)	3/12 (25,0)	1,24 [0,40; 3,81]	1,35 [0,29; 6,20]	6,03 [-23,69; 35,76]
			1,000		
≥220 and <450	137/244 (56,1)	62/119 (52,1)	1,08 [0,88; 1,32]	1,18 [0,76; 1,83]	4,05 [-6,88; 14,97]
			0,501		
≥450	8/20 (40,0)	3/12 (25,0)	1,60 [0,52; 4,89]	2,00 [0,41; 9,74]	15,00 [-17,58; 47,58]
			0,465		

	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Subgruppe			p-Wert ^a		
Datenschnitt: 23. August 2023; Biologic-failed ITT Population.					
Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NRS: Numeric Rating Scale; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor.					
RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald.					
Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm.					
a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_urg3_sub_ittb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Abdominelle Schmerzen – CDAI-AP

Subgruppen für Clinical Remission by PRO (AP=0) in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,095)					
<65 years	72/287 (25,1)	20/141 (14,2)	1,77 [1,12; 2,78]	2,03 [1,18; 3,49]	10,90 [3,27; 18,54]
			0,012		
≥65 years	4/13 (30,8)	3/4 (75,0)	0,41 [0,15; 1,11]	0,15 [0,01; 1,90]	-44,23 [-93,53; 5,07]
			0,250		
Age 2 (p-value of the interaction test: 0,353)					
<40 years	51/202 (25,2)	12/91 (13,2)	1,91 [1,07; 3,41]	2,22 [1,12; 4,41]	12,06 [2,88; 21,24]
			0,021		
≥40 years	25/98 (25,5)	11/54 (20,4)	1,25 [0,67; 2,34]	1,34 [0,60; 2,99]	5,14 [-8,64; 18,92]
			0,553		
Sex (p-value of the interaction test: 0,936)					
Male	49/179 (27,4)	12/65 (18,5)	1,48 [0,84; 2,61]	1,66 [0,82; 3,38]	8,91 [-2,56; 20,39]
			0,182		
Female	27/121 (22,3)	11/80 (13,8)	1,62 [0,85; 3,08]	1,80 [0,84; 3,88]	8,56 [-2,02; 19,15]
			0,144		
Weight (p-value of the interaction test: 0,820)					
<100 kg	72/284 (25,4)	22/140 (15,7)	1,61 [1,05; 2,49]	1,82 [1,07; 3,09]	9,64 [1,77; 17,51]
			0,026		
≥100 kg	4/15 (26,7)	1/5 (20,0)	1,33 [0,19; 9,31]	1,45 [0,12; 17,23]	6,67 [-34,93; 48,26]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
BMI (p-value of the interaction test: 0,184)					
Underweight (<18.5 kg/m ²)	16/54 (29,6)	3/32 (9,4)	3,16 [1,00; 10,01]	4,07 [1,08; 15,30]	20,25 [4,43; 36,08]
				0,033	
Normal (≥18.5 and <25 kg/m ²)	38/161 (23,6)	9/60 (15,0)	1,57 [0,81; 3,05]	1,75 [0,79; 3,88]	8,60 [-2,56; 19,77]
				0,198	
Overweight (≥25 and <30 kg/m ²)	13/55 (23,6)	10/38 (26,3)	0,90 [0,44; 1,83]	0,87 [0,33; 2,25]	-2,68 [-20,63; 15,27]
				0,810	
Obese and Extreme obese (≥30 kg/m ²)	9/29 (31,0)	1/15 (6,7)	4,66 [0,65; 33,37]	6,30 [0,72; 55,51]	24,37 [3,32; 45,41]
				0,127	
Tobacco use (p-value of the interaction test: 0,670)					
Current	11/52 (21,2)	5/29 (17,2)	1,23 [0,47; 3,19]	1,29 [0,40; 4,15]	3,91 [-13,76; 21,58]
				0,776	
Former	10/49 (20,4)	1/21 (4,8)	4,29 [0,59; 31,39]	5,13 [0,61; 42,94]	15,65 [1,14; 30,15]
				0,154	
Never	55/199 (27,6)	17/95 (17,9)	1,54 [0,95; 2,51]	1,75 [0,95; 3,22]	9,74 [-0,16; 19,64]
				0,082	
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,245)					
Ever	74/280 (26,4)	22/140 (15,7)	1,68 [1,09; 2,59]	1,93 [1,14; 3,26]	10,71 [2,78; 18,65]
				0,014	
Never	2/20 (10,0)	1/5 (20,0)	0,50 [0,06; 4,47]	0,44 [0,03; 6,19]	-10,00 [-47,45; 27,45]
				0,504	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Prior anti-TNF failure (p-value of the interaction test: 0,658)					
Ever	69/282 (24,5)	22/139 (15,8)	1,55 [1,00; 2,39]	1,72 [1,01; 2,93]	8,64 [0,77; 16,51]
			0,045		
Never	7/18 (38,9)	1/6 (16,7)	2,33 [0,36; 15,30]	3,18 [0,30; 33,26]	22,22 [-15,15; 59,59]
			0,621		
Prior anti-integrin failure (p-value of the interaction test: 0,505)					
Ever	17/71 (23,9)	6/31 (19,4)	1,24 [0,54; 2,84]	1,31 [0,46; 3,73]	4,59 [-12,50; 21,68]
			0,797		
Never	59/229 (25,8)	17/114 (14,9)	1,73 [1,06; 2,82]	1,98 [1,09; 3,59]	10,85 [2,20; 19,50]
			0,027		
Baseline corticosteroid use (p-value of the interaction test: 0,361)					
Yes	16/76 (21,1)	7/39 (17,9)	1,17 [0,53; 2,61]	1,22 [0,45; 3,27]	3,10 [-12,03; 18,24]
			0,808		
No	60/224 (26,8)	16/106 (15,1)	1,77 [1,08; 2,93]	2,06 [1,12; 3,78]	11,69 [2,74; 20,64]
			0,025		
Baseline immunomodulator use (p-value of the interaction test: 0,159)					
Yes	24/66 (36,4)	5/39 (12,8)	2,84 [1,18; 6,83]	3,89 [1,34; 11,26]	23,54 [7,90; 39,19]
			0,012		
No	52/234 (22,2)	18/106 (17,0)	1,31 [0,81; 2,12]	1,40 [0,77; 2,53]	5,24 [-3,67; 14,16]
			0,312		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Duration of CD (p-value of the interaction test: 0,106)					
<1 year	4/23 (17,4)	0/9 (0,0)	3,75 [0,22; 63,36]	4,38 [0,21; 90,11]	17,39 [1,90; 32,88]
			0,303		
≥1 to <5 years	30/104 (28,8)	3/44 (6,8)	4,23 [1,36; 13,14]	5,54 [1,59; 19,27]	22,03 [10,57; 33,49]
			0,002		
≥5 years	42/173 (24,3)	20/92 (21,7)	1,12 [0,70; 1,78]	1,15 [0,63; 2,11]	2,54 [-8,04; 13,11]
			0,761		
Baseline disease location (p-value of the interaction test: 0,318)					
Colonic	32/120 (26,7)	10/59 (16,9)	1,57 [0,83; 2,98]	1,78 [0,81; 3,93]	9,72 [-2,70; 22,14]
			0,190		
Ileal	2/32 (6,3)	1/6 (16,7)	0,38 [0,04; 3,51]	0,33 [0,03; 4,40]	-10,42 [-41,39; 20,56]
			0,412		
Ileal-Colonic	42/148 (28,4)	12/80 (15,0)	1,89 [1,06; 3,38]	2,25 [1,10; 4,57]	13,38 [2,70; 24,05]
			0,023		
Baseline fecal calprotectin (p-value of the interaction test: 0,201)					
≤250	7/38 (18,4)	3/15 (20,0)	0,92 [0,27; 3,10]	0,90 [0,20; 4,08]	-1,58 [-25,28; 22,12]
			1,000		
>250	54/208 (26,0)	11/93 (11,8)	2,19 [1,20; 4,00]	2,61 [1,30; 5,27]	14,13 [5,27; 23,00]
			0,006		
Baseline SES-CD total score (p-value of the interaction test: 0,193)					
<12	28/143 (19,6)	11/66 (16,7)	1,17 [0,62; 2,21]	1,22 [0,56; 2,62]	2,91 [-8,18; 14,01]
			0,705		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
≥12	48/157 (30,6)	12/79 (15,2)	2,01 [1,14; 3,57]	2,46 [1,22; 4,96]	15,38 [4,68; 26,09]
0,011					
Baseline AP average (p-value of the interaction test: 0,779)					
<2	23/72 (31,9)	9/48 (18,8)	1,70 [0,86; 3,36]	2,03 [0,85; 4,89]	13,19 [-2,23; 28,62]
0,141					
≥2	53/226 (23,5)	14/97 (14,4)	1,62 [0,95; 2,78]	1,82 [0,95; 3,46]	9,02 [0,11; 17,93]
0,073					
Baseline SF average (p-value of the interaction test: 0,746)					
<7	56/220 (25,5)	17/100 (17,0)	1,50 [0,92; 2,44]	1,67 [0,91; 3,05]	8,45 [-0,89; 17,80]
0,114					
≥7	19/76 (25,0)	6/45 (13,3)	1,88 [0,81; 4,35]	2,17 [0,79; 5,91]	11,67 [-2,24; 25,57]
0,165					
Baseline CDAI 1 (p-value of the interaction test: 0,233)					
<300	36/109 (33,0)	9/59 (15,3)	2,17 [1,12; 4,18]	2,74 [1,21; 6,18]	17,77 [5,04; 30,51]
0,017					
≥300	39/184 (21,2)	14/84 (16,7)	1,27 [0,73; 2,21]	1,34 [0,69; 2,64]	4,53 [-5,39; 14,45]
0,414					
Baseline CDAI 2 (p-value of the interaction test: 0,736)					
<220	10/29 (34,5)	4/12 (33,3)	1,03 [0,40; 2,66]	1,05 [0,25; 4,37]	1,15 [-30,64; 32,94]
1,000					
≥220 and <450	60/244 (24,6)	17/119 (14,3)	1,72 [1,05; 2,82]	1,96 [1,08; 3,53]	10,30 [2,01; 18,59]
0,028					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
≥450	5/20 (25,0)	2/12 (16,7)	1,50 [0,34; 6,56]	1,67 [0,27; 10,33]	8,33 [-20,03; 36,70]
0,683					
OECD Country (p-value of the interaction test: 0,426)					
Yes	44/178 (24,7)	15/83 (18,1)	1,37 [0,81; 2,31]	1,49 [0,77; 2,86]	6,65 [-3,78; 17,07]
0,268					
No	32/122 (26,2)	8/62 (12,9)	2,03 [1,00; 4,14]	2,40 [1,03; 5,59]	13,33 [1,90; 24,75]
0,040					
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PRO: Patient Reported Outcome, defined as 2 of the patient-reported items of the CDAI (SF and AP); RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_prorap3_sub_ittb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba
20DEC2024 / 04:00

Subgruppen für Reduction in Abdominal pain by at least 0.45 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,706)					
<65 years	206/287 (71,8)	83/141 (58,9)	1,22 [1,04; 1,43]	1,78 [1,16; 2,71]	12,91 [3,26; 22,56]
			0,008		
≥65 years	8/13 (61,5)	1/4 (25,0)	2,46 [0,43; 14,18]	4,80 [0,38; 59,89]	36,54 [-13,46; 86,54]
			0,294		
Age 2 (p-value of the interaction test: 0,727)					
<40 years	142/202 (70,3)	50/91 (54,9)	1,28 [1,04; 1,57]	1,94 [1,16; 3,24]	15,35 [3,34; 27,36]
			0,012		
≥40 years	72/98 (73,5)	34/54 (63,0)	1,17 [0,92; 1,48]	1,63 [0,80; 3,32]	10,51 [-5,06; 26,07]
			0,199		
Sex (p-value of the interaction test: 0,613)					
Male	127/179 (70,9)	35/65 (53,8)	1,32 [1,03; 1,68]	2,09 [1,17; 3,76]	17,10 [3,28; 30,93]
			0,015		
Female	87/121 (71,9)	49/80 (61,3)	1,17 [0,95; 1,44]	1,62 [0,89; 2,95]	10,65 [-2,69; 24,00]
			0,125		
Race (p-value of the interaction test: 0,121)					
Asian	78/100 (78,0)	29/56 (51,8)	1,51 [1,15; 1,98]	3,30 [1,63; 6,69]	26,21 [10,81; 41,62]
			0,001		
White	122/180 (67,8)	51/82 (62,2)	1,09 [0,90; 1,33]	1,28 [0,74; 2,20]	5,58 [-6,94; 18,10]
			0,401		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Other	9/13 (69,2)	4/7 (57,1)	1,21 [0,58; 2,53]	1,69 [0,25; 11,34]	12,09 [-32,34; 56,51]
0,651					
Geographic region 1 (p-value of the interaction test: 0,082)					
Europe	83/114 (72,8)	35/50 (70,0)	1,04 [0,84; 1,29]	1,15 [0,55; 2,39]	2,81 [-12,29; 17,91]
0,710					
North America	31/54 (57,4)	14/26 (53,8)	1,07 [0,70; 1,63]	1,16 [0,45; 2,96]	3,56 [-19,70; 26,82]
0,813					
Other	100/132 (75,8)	35/69 (50,7)	1,49 [1,16; 1,92]	3,04 [1,64; 5,63]	25,03 [11,15; 38,91]
<0,001					
Geographic region 2 (p-value of the interaction test: 0,166)					
Asia	80/105 (76,2)	28/56 (50,0)	1,52 [1,15; 2,02]	3,20 [1,61; 6,38]	26,19 [10,77; 41,61]
0,001					
Central America/South America	18/24 (75,0)	7/13 (53,8)	1,39 [0,80; 2,42]	2,57 [0,62; 10,74]	21,15 [-11,01; 53,32]
0,274					
Europe and ROW	85/117 (72,6)	35/50 (70,0)	1,04 [0,84; 1,28]	1,14 [0,55; 2,36]	2,65 [-12,40; 17,70]
0,712					
North America	31/54 (57,4)	14/26 (53,8)	1,07 [0,70; 1,63]	1,16 [0,45; 2,96]	3,56 [-19,70; 26,82]
0,813					
Weight (p-value of the interaction test: 0,497)					
<100 kg	205/284 (72,2)	83/140 (59,3)	1,22 [1,04; 1,42]	1,78 [1,16; 2,73]	12,90 [3,23; 22,56]
0,008					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
≥100 kg	9/15 (60,0)	1/5 (20,0)	3,00 [0,50; 18,17]	6,00 [0,53; 67,65]	40,00 [-2,94; 82,94]
0,303					
BMI (p-value of the interaction test: 0,494)					
Underweight ($<18.5 \text{ kg/m}^2$)	36/54 (66,7)	14/32 (43,8)	1,52 [0,99; 2,36]	2,57 [1,05; 6,32]	22,92 [1,62; 44,21]
0,044					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	117/161 (72,7)	40/60 (66,7)	1,09 [0,89; 1,33]	1,33 [0,70; 2,52]	6,00 [-7,77; 19,78]
0,407					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	43/55 (78,2)	22/38 (57,9)	1,35 [1,00; 1,83]	2,61 [1,05; 6,46]	20,29 [1,17; 39,41]
0,042					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	18/29 (62,1)	8/15 (53,3)	1,16 [0,67; 2,02]	1,43 [0,41; 5,06]	8,74 [-22,07; 39,55]
0,748					
Tobacco use (p-value of the interaction test: 0,633)					
Current	39/52 (75,0)	18/29 (62,1)	1,21 [0,87; 1,67]	1,83 [0,69; 4,88]	12,93 [-8,29; 34,15]
0,310					
Former	36/49 (73,5)	10/21 (47,6)	1,54 [0,96; 2,49]	3,05 [1,05; 8,84]	25,85 [1,17; 50,53]
0,054					
Never	139/199 (69,8)	56/95 (58,9)	1,18 [0,98; 1,43]	1,61 [0,97; 2,68]	10,90 [-0,87; 22,67]
0,067					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,658)					
Ever	201/280 (71,8)	82/140 (58,6)	1,23 [1,05; 1,43]	1,80 [1,18; 2,75]	13,21 [3,50; 22,93]
0,008					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Never	13/20 (65,0)	2/5 (40,0)	1,63 [0,53; 4,98]	2,79 [0,37; 20,82]	25,00 [-22,76; 72,76]
0,358					
Prior anti-TNF failure (p-value of the interaction test: 0,999)					
Ever	202/282 (71,6)	81/139 (58,3)	1,23 [1,05; 1,44]	1,81 [1,18; 2,77]	13,36 [3,62; 23,10]
0,008					
Never	12/18 (66,7)	3/6 (50,0)	1,33 [0,56; 3,16]	2,00 [0,31; 13,06]	16,67 [-28,88; 62,22]
0,635					
Prior anti-integrin failure (p-value of the interaction test: 0,202)					
Ever	48/71 (67,6)	20/31 (64,5)	1,05 [0,77; 1,42]	1,15 [0,47; 2,79]	3,09 [-16,96; 23,14]
0,821					
Never	166/229 (72,5)	64/114 (56,1)	1,29 [1,08; 1,55]	2,06 [1,29; 3,29]	16,35 [5,56; 27,14]
0,003					
Baseline corticosteroid use (p-value of the interaction test: 0,226)					
Yes	51/76 (67,1)	25/39 (64,1)	1,05 [0,79; 1,39]	1,14 [0,51; 2,57]	3,00 [-15,39; 21,39]
0,836					
No	163/224 (72,8)	59/106 (55,7)	1,31 [1,08; 1,58]	2,13 [1,31; 3,45]	17,11 [6,00; 28,22]
0,003					
Baseline immunomodulator use (p-value of the interaction test: 0,084)					
Yes	50/66 (75,8)	19/39 (48,7)	1,56 [1,10; 2,21]	3,29 [1,42; 7,64]	27,04 [8,25; 45,83]
0,006					
No	164/234 (70,1)	65/106 (61,3)	1,14 [0,96; 1,36]	1,48 [0,91; 2,39]	8,76 [-2,21; 19,74]
0,134					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Duration of CD (p-value of the interaction test: 0,247)					
<1 year	13/23 (56,5)	0/9 (0,0)	11,25 [0,74; >100]	24,43 [1,27; >100]	56,52 [36,26; 76,78]
			0,004		
≥1 to <5 years	75/104 (72,1)	27/44 (61,4)	1,18 [0,90; 1,53]	1,63 [0,77; 3,42]	10,75 [-6,02; 27,52]
			0,244		
≥5 years	126/173 (72,8)	57/92 (62,0)	1,18 [0,98; 1,41]	1,65 [0,96; 2,82]	10,88 [-1,06; 22,81]
			0,072		
Baseline disease location (p-value of the interaction test: 0,099)					
Colonic	91/120 (75,8)	31/59 (52,5)	1,44 [1,11; 1,88]	2,83 [1,46; 5,48]	23,29 [8,42; 38,16]
			0,002		
Ileal	19/32 (59,4)	5/6 (83,3)	0,71 [0,45; 1,13]	0,29 [0,03; 2,80]	-23,96 [-58,29; 10,38]
			0,383		
Ileal-Colonic	104/148 (70,3)	48/80 (60,0)	1,17 [0,95; 1,44]	1,58 [0,89; 2,78]	10,27 [-2,75; 23,29]
			0,141		
Baseline fecal calprotectin (p-value of the interaction test: 0,083)					
≤250	22/38 (57,9)	10/15 (66,7)	0,87 [0,55; 1,36]	0,69 [0,20; 2,40]	-8,77 [-37,33; 19,79]
			0,756		
>250	154/208 (74,0)	50/93 (53,8)	1,38 [1,12; 1,69]	2,45 [1,47; 4,09]	20,28 [8,52; 32,03]
			<0,001		
Baseline CRP (p-value of the interaction test: 0,302)					
≤10	100/145 (69,0)	36/58 (62,1)	1,11 [0,88; 1,40]	1,36 [0,72; 2,57]	6,90 [-7,69; 21,48]
			0,409		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
>10	114/154 (74,0)	48/87 (55,2)	1,34 [1,09; 1,66]	2,32 [1,33; 4,03]	18,85 [6,32; 31,39]
0,004					
Baseline SES-CD total score (p-value of the interaction test: 0,161)					
<12	98/143 (68,5)	41/66 (62,1)	1,10 [0,89; 1,37]	1,33 [0,72; 2,44]	6,41 [-7,55; 20,37]
0,431					
≥12	116/157 (73,9)	43/79 (54,4)	1,36 [1,09; 1,70]	2,37 [1,34; 4,18]	19,45 [6,50; 32,41]
0,003					
Baseline SF average (p-value of the interaction test: 0,258)					
<7	157/220 (71,4)	54/100 (54,0)	1,32 [1,08; 1,61]	2,12 [1,30; 3,47]	17,36 [5,91; 28,81]
0,003					
≥7	54/76 (71,1)	30/45 (66,7)	1,07 [0,83; 1,37]	1,23 [0,55; 2,71]	4,39 [-12,75; 21,52]
0,685					
Baseline CDAI 1 (p-value of the interaction test: 0,244)					
<300	73/109 (67,0)	27/59 (45,8)	1,46 [1,08; 1,99]	2,40 [1,26; 4,60]	21,21 [5,73; 36,69]
0,009					
≥300	137/184 (74,5)	57/84 (67,9)	1,10 [0,93; 1,30]	1,38 [0,78; 2,43]	6,60 [-5,21; 18,41]
0,303					
Baseline CDAI 2 (p-value of the interaction test: 0,104)					
<220	20/29 (69,0)	2/12 (16,7)	4,14 [1,14; 15,01]	11,11 [2,01; 61,43]	52,30 [25,32; 79,28]
0,005					
≥220 and <450	179/244 (73,4)	75/119 (63,0)	1,16 [0,99; 1,36]	1,62 [1,01; 2,58]	10,34 [0,04; 20,63]
0,051					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
≥450	11/20 (55,0)	7/12 (58,3)	0,94 [0,51; 1,75]	0,87 [0,21; 3,71]	-3,33 [-38,74; 32,07]
1,000					
OECD Country (p-value of the interaction test: 0,677)					
Yes	128/178 (71,9)	50/83 (60,2)	1,19 [0,98; 1,45]	1,69 [0,98; 2,92]	11,67 [-0,76; 24,10]
0,065					
No	86/122 (70,5)	34/62 (54,8)	1,29 [1,00; 1,66]	1,97 [1,04; 3,71]	15,65 [0,86; 30,45]
0,049					
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_api0_45_sub_ittb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Fatigue – FACIT Fatigue

Subgruppen für Increase in FACIT-Fatigue Score by at least 8 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,368)					
<65 years	103/287 (35,9)	44/141 (31,2)	1,15 [0,86; 1,54]	1,23 [0,80; 1,90]	4,68 [-4,77; 14,13]
			0,386		
≥65 years	6/13 (46,2)	0/4 (0,0)	4,64 [0,32; 68,34]	7,80 [0,35; >100]	46,15 [19,05; 73,25]
			0,237		
Age 2 (p-value of the interaction test: 0,686)					
<40 years	76/202 (37,6)	30/91 (33,0)	1,14 [0,81; 1,61]	1,23 [0,73; 2,07]	4,66 [-7,09; 16,40]
			0,512		
≥40 years	33/98 (33,7)	14/54 (25,9)	1,30 [0,76; 2,21]	1,45 [0,69; 3,04]	7,75 [-7,22; 22,72]
			0,363		
Sex (p-value of the interaction test: 0,744)					
Male	60/179 (33,5)	16/65 (24,6)	1,36 [0,85; 2,18]	1,54 [0,81; 2,94]	8,90 [-3,65; 21,45]
			0,213		
Female	49/121 (40,5)	28/80 (35,0)	1,16 [0,80; 1,67]	1,26 [0,70; 2,27]	5,50 [-8,13; 19,12]
			0,462		
Race (p-value of the interaction test: 0,367)					
Asian	34/100 (34,0)	13/56 (23,2)	1,46 [0,85; 2,54]	1,70 [0,81; 3,59]	10,79 [-3,65; 25,22]
			0,203		
White	67/180 (37,2)	27/82 (32,9)	1,13 [0,79; 1,62]	1,21 [0,70; 2,10]	4,30 [-8,09; 16,68]
			0,579		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Other	4/13 (30,8)	4/7 (57,1)	0,54 [0,19; 1,52]	0,33 [0,05; 2,24]	-26,37 [-70,80; 18,05]
0,356					
Geographic region 1 (p-value of the interaction test: 0,505)					
Europe	45/114 (39,5)	14/50 (28,0)	1,41 [0,86; 2,32]	1,68 [0,81; 3,45]	11,47 [-3,87; 26,82]
0,216					
North America	23/54 (42,6)	12/26 (46,2)	0,92 [0,55; 1,55]	0,87 [0,34; 2,22]	-3,56 [-26,82; 19,70]
0,813					
Other	41/132 (31,1)	18/69 (26,1)	1,19 [0,74; 1,91]	1,28 [0,67; 2,45]	4,97 [-8,05; 18,00]
0,516					
Geographic region 2 (p-value of the interaction test: 0,244)					
Asia	35/105 (33,3)	12/56 (21,4)	1,56 [0,88; 2,75]	1,83 [0,86; 3,91]	11,90 [-2,12; 25,93]
0,146					
Central America/South America	6/24 (25,0)	6/13 (46,2)	0,54 [0,22; 1,34]	0,39 [0,09; 1,62]	-21,15 [-53,32; 11,01]
0,274					
Europe and ROW	45/117 (38,5)	14/50 (28,0)	1,37 [0,83; 2,26]	1,61 [0,78; 3,31]	10,46 [-4,79; 25,71]
0,220					
North America	23/54 (42,6)	12/26 (46,2)	0,92 [0,55; 1,55]	0,87 [0,34; 2,22]	-3,56 [-26,82; 19,70]
0,813					
Weight (p-value of the interaction test: 0,846)					
<100 kg	107/284 (37,7)	44/140 (31,4)	1,20 [0,90; 1,60]	1,32 [0,86; 2,03]	6,25 [-3,29; 15,78]
0,236					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
≥100 kg	2/15 (13,3)	0/5 (0,0)	1,88 [0,10; 33,66]	2,04 [0,08; 49,68]	13,33 [-3,87; 30,54]
1,000					
BMI (p-value of the interaction test: 0,942)					
Underweight ($<18.5 \text{ kg/m}^2$)	20/54 (37,0)	11/32 (34,4)	1,08 [0,60; 1,95]	1,12 [0,45; 2,80]	2,66 [-18,24; 23,56]
1,000					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	61/161 (37,9)	17/60 (28,3)	1,34 [0,85; 2,09]	1,54 [0,81; 2,94]	9,55 [-4,09; 23,20]
0,208					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	19/55 (34,5)	12/38 (31,6)	1,09 [0,60; 1,98]	1,14 [0,47; 2,76]	2,97 [-16,43; 22,37]
0,825					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	9/29 (31,0)	4/15 (26,7)	1,16 [0,43; 3,16]	1,24 [0,31; 4,96]	4,37 [-23,64; 32,37]
1,000					
Tobacco use (p-value of the interaction test: 0,603)					
Current	20/52 (38,5)	7/29 (24,1)	1,59 [0,77; 3,31]	1,96 [0,71; 5,43]	14,32 [-6,11; 34,75]
0,226					
Former	15/49 (30,6)	7/21 (33,3)	0,92 [0,44; 1,92]	0,88 [0,30; 2,63]	-2,72 [-26,66; 21,22]
1,000					
Never	74/199 (37,2)	30/95 (31,6)	1,18 [0,83; 1,67]	1,28 [0,76; 2,16]	5,61 [-5,90; 17,12]
0,364					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,681)					
Ever	102/280 (36,4)	43/140 (30,7)	1,19 [0,88; 1,59]	1,29 [0,84; 1,99]	5,71 [-3,78; 15,21]
0,277					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Never	7/20 (35,0)	1/5 (20,0)	1,75 [0,27; 11,15]	2,15 [0,20; 23,18]	15,00 [-25,82; 55,82]
1,000					
Prior anti-TNF failure (p-value of the interaction test: 0,240)					
Ever	101/282 (35,8)	40/139 (28,8)	1,24 [0,92; 1,69]	1,38 [0,89; 2,15]	7,04 [-2,34; 16,42]
0,155					
Never	8/18 (44,4)	4/6 (66,7)	0,67 [0,31; 1,43]	0,40 [0,06; 2,77]	-22,22 [-66,38; 21,93]
0,640					
Prior anti-integrin failure (p-value of the interaction test: 0,747)					
Ever	29/71 (40,8)	11/31 (35,5)	1,15 [0,66; 2,00]	1,26 [0,52; 3,01]	5,36 [-15,00; 25,72]
0,664					
Never	80/229 (34,9)	33/114 (28,9)	1,21 [0,86; 1,69]	1,32 [0,81; 2,15]	5,99 [-4,38; 16,35]
0,276					
Baseline corticosteroid use (p-value of the interaction test: 0,689)					
Yes	30/76 (39,5)	12/39 (30,8)	1,28 [0,74; 2,22]	1,47 [0,65; 3,33]	8,70 [-9,48; 26,89]
0,417					
No	79/224 (35,3)	32/106 (30,2)	1,17 [0,83; 1,64]	1,26 [0,77; 2,07]	5,08 [-5,67; 15,83]
0,385					
Baseline immunomodulator use (p-value of the interaction test: 0,379)					
Yes	23/66 (34,8)	9/39 (23,1)	1,51 [0,78; 2,93]	1,78 [0,72; 4,39]	11,77 [-5,75; 29,29]
0,273					
No	86/234 (36,8)	35/106 (33,0)	1,11 [0,81; 1,53]	1,18 [0,73; 1,91]	3,73 [-7,14; 14,61]
0,542					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Duration of CD (p-value of the interaction test: 0,316)					
<1 year	6/23 (26,1)	0/9 (0,0)	5,42 [0,34; 87,33]	7,06 [0,36; >100]	26,09 [8,14; 44,03]
			0,150		
≥1 to <5 years	44/104 (42,3)	13/44 (29,5)	1,43 [0,86; 2,38]	1,75 [0,82; 3,72]	12,76 [-3,73; 29,25]
			0,196		
≥5 years	59/173 (34,1)	31/92 (33,7)	1,01 [0,71; 1,44]	1,02 [0,60; 1,74]	0,41 [-11,56; 12,37]
			1,000		
Baseline disease location (p-value of the interaction test: 0,170)					
Colonic	48/120 (40,0)	15/59 (25,4)	1,57 [0,96; 2,57]	1,96 [0,98; 3,90]	14,58 [0,42; 28,73]
			0,067		
Ileal	11/32 (34,4)	3/6 (50,0)	0,69 [0,27; 1,75]	0,52 [0,09; 3,04]	-15,63 [-58,88; 27,63]
			0,650		
Ileal-Colonic	50/148 (33,8)	26/80 (32,5)	1,04 [0,71; 1,53]	1,06 [0,59; 1,89]	1,28 [-11,50; 14,07]
			0,884		
Baseline fecal calprotectin (p-value of the interaction test: 0,084)					
≤250	16/38 (42,1)	2/15 (13,3)	3,16 [0,82; 12,10]	4,73 [0,93; 23,94]	28,77 [5,48; 52,06]
			0,059		
>250	71/208 (34,1)	29/93 (31,2)	1,09 [0,77; 1,56]	1,14 [0,68; 1,93]	2,95 [-8,46; 14,36]
			0,692		
Baseline CRP (p-value of the interaction test: 0,920)					
≤10	49/145 (33,8)	17/58 (29,3)	1,15 [0,73; 1,83]	1,23 [0,64; 2,39]	4,48 [-9,54; 18,50]
			0,620		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
>10	60/154 (39,0)	27/87 (31,0)	1,26 [0,87; 1,82]	1,42 [0,81; 2,48]	7,93 [-4,48; 20,33]
0,264					
Baseline SES-CD total score (p-value of the interaction test: 0,375)					
<12	50/143 (35,0)	16/66 (24,2)	1,44 [0,89; 2,33]	1,68 [0,87; 3,25]	10,72 [-2,24; 23,68]
0,150					
≥12	59/157 (37,6)	28/79 (35,4)	1,06 [0,74; 1,52]	1,10 [0,62; 1,93]	2,14 [-10,85; 15,12]
0,777					
Baseline AP average (p-value of the interaction test: 0,186)					
<2	25/72 (34,7)	9/48 (18,8)	1,85 [0,95; 3,61]	2,30 [0,96; 5,51]	15,97 [0,39; 31,56]
0,065					
≥2	84/226 (37,2)	35/97 (36,1)	1,03 [0,75; 1,41]	1,05 [0,64; 1,72]	1,09 [-10,36; 12,53]
0,900					
Baseline SF average (p-value of the interaction test: 0,494)					
<7	76/220 (34,5)	26/100 (26,0)	1,33 [0,91; 1,94]	1,50 [0,89; 2,54]	8,55 [-2,10; 19,19]
0,155					
≥7	32/76 (42,1)	18/45 (40,0)	1,05 [0,67; 1,64]	1,09 [0,52; 2,31]	2,11 [-16,01; 20,22]
0,851					
Baseline CDAI 1 (p-value of the interaction test: 0,366)					
<300	32/109 (29,4)	11/59 (18,6)	1,57 [0,86; 2,89]	1,81 [0,84; 3,93]	10,71 [-2,40; 23,82]
0,143					
≥300	75/184 (40,8)	33/84 (39,3)	1,04 [0,76; 1,43]	1,06 [0,63; 1,80]	1,48 [-11,15; 14,10]
0,893					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline CDAI 2 (p-value of the interaction test: 0,380)					
<220	7/29 (24,1)	0/12 (0,0)	6,50 [0,40; >100]	8,33 [0,44; >100]	24,14 [8,56; 39,71]
				0,085	
≥220 and <450	90/244 (36,9)	37/119 (31,1)	1,19 [0,87; 1,62]	1,30 [0,81; 2,07]	5,79 [-4,49; 16,08]
				0,293	
≥450	10/20 (50,0)	7/12 (58,3)	0,86 [0,45; 1,64]	0,71 [0,17; 3,03]	-8,33 [-43,81; 27,14]
				0,726	
OECD Country (p-value of the interaction test: 0,604)					
Yes	73/178 (41,0)	27/83 (32,5)	1,26 [0,88; 1,80]	1,44 [0,83; 2,49]	8,48 [-3,92; 20,88]
				0,219	
No	36/122 (29,5)	17/62 (27,4)	1,08 [0,66; 1,76]	1,11 [0,56; 2,19]	2,09 [-11,65; 15,83]
				0,864	
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; FACIT: Functional Assessment of Chronic Illness Therapy-Fatigue; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_faciti8_sub_itb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Subgruppen für Increase in FACIT-Fatigue Score by at least 9 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,484)					
<65 years	95/287 (33,1)	37/141 (26,2)	1,26 [0,91; 1,74]	1,39 [0,89; 2,18]	6,86 [-2,22; 15,94]
			0,181		
≥65 years	5/13 (38,5)	0/4 (0,0)	3,93 [0,26; 58,98]	5,82 [0,26; >100]	38,46 [12,02; 64,91]
			0,261		
Age 2 (p-value of the interaction test: 0,950)					
<40 years	72/202 (35,6)	25/91 (27,5)	1,30 [0,89; 1,90]	1,46 [0,85; 2,52]	8,17 [-3,13; 19,47]
			0,182		
≥40 years	28/98 (28,6)	12/54 (22,2)	1,29 [0,71; 2,32]	1,40 [0,64; 3,04]	6,35 [-7,90; 20,60]
			0,446		
Sex (p-value of the interaction test: 0,941)					
Male	56/179 (31,3)	15/65 (23,1)	1,36 [0,83; 2,22]	1,52 [0,79; 2,93]	8,21 [-4,08; 20,50]
			0,265		
Female	44/121 (36,4)	22/80 (27,5)	1,32 [0,86; 2,03]	1,51 [0,81; 2,79]	8,86 [-4,14; 21,87]
			0,221		
Race (p-value of the interaction test: 0,378)					
Asian	31/100 (31,0)	11/56 (19,6)	1,58 [0,86; 2,89]	1,84 [0,84; 4,02]	11,36 [-2,44; 25,16]
			0,137		
White	61/180 (33,9)	22/82 (26,8)	1,26 [0,84; 1,91]	1,40 [0,78; 2,49]	7,06 [-4,76; 18,88]
			0,316		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Other	4/13 (30,8)	4/7 (57,1)	0,54 [0,19; 1,52]	0,33 [0,05; 2,24]	-26,37 [-70,80; 18,05]
0,356					
Geographic region 1 (p-value of the interaction test: 0,148)					
Europe	42/114 (36,8)	10/50 (20,0)	1,84 [1,01; 3,37]	2,33 [1,06; 5,14]	16,84 [2,65; 31,03]
0,044					
North America	20/54 (37,0)	12/26 (46,2)	0,80 [0,47; 1,38]	0,69 [0,27; 1,77]	-9,12 [-32,21; 13,97]
0,472					
Other	38/132 (28,8)	15/69 (21,7)	1,32 [0,79; 2,23]	1,46 [0,73; 2,89]	7,05 [-5,38; 19,47]
0,315					
Geographic region 2 (p-value of the interaction test: 0,127)					
Asia	32/105 (30,5)	10/56 (17,9)	1,71 [0,91; 3,21]	2,02 [0,91; 4,49]	12,62 [-0,73; 25,97]
0,093					
Central America/South America	6/24 (25,0)	5/13 (38,5)	0,65 [0,24; 1,73]	0,53 [0,13; 2,27]	-13,46 [-45,08; 18,15]
0,465					
Europe and ROW	42/117 (35,9)	10/50 (20,0)	1,79 [0,98; 3,29]	2,24 [1,02; 4,93]	15,90 [1,81; 29,99]
0,046					
North America	20/54 (37,0)	12/26 (46,2)	0,80 [0,47; 1,38]	0,69 [0,27; 1,77]	-9,12 [-32,21; 13,97]
0,472					
Weight (p-value of the interaction test: 0,870)					
<100 kg	98/284 (34,5)	37/140 (26,4)	1,31 [0,95; 1,80]	1,47 [0,94; 2,30]	8,08 [-1,08; 17,24]
0,098					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
≥100 kg	2/15 (13,3)	0/5 (0,0)	1,88 [0,10; 33,66]	2,04 [0,08; 49,68]	13,33 [-3,87; 30,54]
1,000					
BMI (p-value of the interaction test: 0,856)					
Underweight ($<18.5 \text{ kg/m}^2$)	17/54 (31,5)	9/32 (28,1)	1,12 [0,57; 2,21]	1,17 [0,45; 3,07]	3,36 [-16,55; 23,26]
0,811					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	56/161 (34,8)	14/60 (23,3)	1,49 [0,90; 2,47]	1,75 [0,89; 3,46]	11,45 [-1,54; 24,44]
0,143					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	19/55 (34,5)	12/38 (31,6)	1,09 [0,60; 1,98]	1,14 [0,47; 2,76]	2,97 [-16,43; 22,37]
0,825					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	8/29 (27,6)	2/15 (13,3)	2,07 [0,50; 8,55]	2,48 [0,45; 13,51]	14,25 [-9,42; 37,93]
0,452					
Tobacco use (p-value of the interaction test: 0,889)					
Current	17/52 (32,7)	6/29 (20,7)	1,58 [0,70; 3,56]	1,86 [0,64; 5,42]	12,00 [-7,49; 31,49]
0,310					
Former	14/49 (28,6)	5/21 (23,8)	1,20 [0,50; 2,90]	1,28 [0,39; 4,17]	4,76 [-17,42; 26,94]
0,776					
Never	69/199 (34,7)	26/95 (27,4)	1,27 [0,87; 1,85]	1,41 [0,82; 2,41]	7,30 [-3,84; 18,45]
0,232					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,314)					
Ever	93/280 (33,2)	37/140 (26,4)	1,26 [0,91; 1,73]	1,38 [0,88; 2,17]	6,79 [-2,37; 15,94]
0,179					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Never	7/20 (35,0)	0/5 (0,0)	4,29 [0,28; 64,74]	6,11 [0,30; >100]	35,00 [14,10; 55,90]
0,274					
Prior anti-TNF failure (p-value of the interaction test: 0,141)					
Ever	93/282 (33,0)	33/139 (23,7)	1,39 [0,99; 1,95]	1,58 [0,99; 2,51]	9,24 [0,29; 18,19]
0,055					
Never	7/18 (38,9)	4/6 (66,7)	0,58 [0,26; 1,31]	0,32 [0,05; 2,22]	-27,78 [-71,71; 16,15]
0,357					
Prior anti-integrin failure (p-value of the interaction test: 0,969)					
Ever	25/71 (35,2)	8/31 (25,8)	1,36 [0,69; 2,68]	1,56 [0,61; 4,00]	9,40 [-9,59; 28,40]
0,490					
Never	75/229 (32,8)	29/114 (25,4)	1,29 [0,89; 1,85]	1,43 [0,86; 2,36]	7,31 [-2,73; 17,36]
0,173					
Baseline corticosteroid use (p-value of the interaction test: 0,968)					
Yes	27/76 (35,5)	11/39 (28,2)	1,26 [0,70; 2,26]	1,40 [0,60; 3,25]	7,32 [-10,43; 25,08]
0,531					
No	73/224 (32,6)	26/106 (24,5)	1,33 [0,91; 1,95]	1,49 [0,88; 2,51]	8,06 [-2,17; 18,30]
0,157					
Baseline immunomodulator use (p-value of the interaction test: 0,587)					
Yes	21/66 (31,8)	8/39 (20,5)	1,55 [0,76; 3,16]	1,81 [0,71; 4,60]	11,31 [-5,63; 28,24]
0,262					
No	79/234 (33,8)	29/106 (27,4)	1,23 [0,86; 1,77]	1,35 [0,82; 2,24]	6,40 [-4,03; 16,83]
0,260					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Duration of CD (p-value of the interaction test: 0,306)					
<1 year	6/23 (26,1)	0/9 (0,0)	5,42 [0,34; 87,33]	7,06 [0,36; >100]	26,09 [8,14; 44,03]
			0,150		
≥1 to <5 years	42/104 (40,4)	11/44 (25,0)	1,62 [0,92; 2,84]	2,03 [0,93; 4,46]	15,38 [-0,51; 31,28]
			0,092		
≥5 years	52/173 (30,1)	26/92 (28,3)	1,06 [0,72; 1,58]	1,09 [0,62; 1,91]	1,80 [-9,66; 13,26]
			0,779		
Baseline disease location (p-value of the interaction test: 0,242)					
Colonic	44/120 (36,7)	15/59 (25,4)	1,44 [0,88; 2,37]	1,70 [0,85; 3,40]	11,24 [-2,82; 25,31]
			0,176		
Ileal	9/32 (28,1)	3/6 (50,0)	0,56 [0,21; 1,49]	0,39 [0,07; 2,31]	-21,88 [-64,81; 21,06]
			0,357		
Ileal-Colonic	47/148 (31,8)	19/80 (23,8)	1,34 [0,85; 2,11]	1,49 [0,80; 2,78]	8,01 [-3,96; 19,97]
			0,224		
Baseline fecal calprotectin (p-value of the interaction test: 0,085)					
≤250	14/38 (36,8)	1/15 (6,7)	5,53 [0,80; 38,41]	8,17 [0,97; 68,94]	30,18 [10,31; 50,04]
			0,041		
>250	66/208 (31,7)	25/93 (26,9)	1,18 [0,80; 1,74]	1,26 [0,73; 2,18]	4,85 [-6,16; 15,86]
			0,419		
Baseline CRP (p-value of the interaction test: 0,613)					
≤10	44/145 (30,3)	15/58 (25,9)	1,17 [0,71; 1,94]	1,25 [0,63; 2,48]	4,48 [-9,04; 18,01]
			0,609		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
>10	56/154 (36,4)	22/87 (25,3)	1,44 [0,95; 2,18]	1,69 [0,94; 3,03]	11,08 [-0,80; 22,96]
0,087					
Baseline SES-CD total score (p-value of the interaction test: 0,111)					
<12	46/143 (32,2)	11/66 (16,7)	1,93 [1,07; 3,48]	2,37 [1,14; 4,95]	15,50 [3,69; 27,31]
0,020					
≥12	54/157 (34,4)	26/79 (32,9)	1,05 [0,71; 1,53]	1,07 [0,60; 1,90]	1,48 [-11,27; 14,23]
0,885					
Baseline AP average (p-value of the interaction test: 0,470)					
<2	23/72 (31,9)	9/48 (18,8)	1,70 [0,86; 3,36]	2,03 [0,85; 4,89]	13,19 [-2,23; 28,62]
0,141					
≥2	77/226 (34,1)	28/97 (28,9)	1,18 [0,82; 1,69]	1,27 [0,76; 2,14]	5,20 [-5,73; 16,14]
0,437					
Baseline SF average (p-value of the interaction test: 0,881)					
<7	69/220 (31,4)	23/100 (23,0)	1,36 [0,91; 2,05]	1,53 [0,89; 2,64]	8,36 [-1,91; 18,64]
0,143					
≥7	30/76 (39,5)	14/45 (31,1)	1,27 [0,76; 2,13]	1,44 [0,66; 3,15]	8,36 [-9,06; 25,79]
0,435					
Baseline CDAI 1 (p-value of the interaction test: 0,846)					
<300	27/109 (24,8)	10/59 (16,9)	1,46 [0,76; 2,81]	1,61 [0,72; 3,62]	7,82 [-4,72; 20,36]
0,330					
≥300	71/184 (38,6)	27/84 (32,1)	1,20 [0,84; 1,72]	1,33 [0,77; 2,29]	6,44 [-5,77; 18,66]
0,340					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline CDAI 2 (p-value of the interaction test: 0,576)					
<220	4/29 (13,8)	0/12 (0,0)	3,90 [0,23; 67,31]	4,41 [0,22; 88,53]	13,79 [1,24; 26,34]
			0,302		
≥220 and <450	85/244 (34,8)	31/119 (26,1)	1,34 [0,94; 1,89]	1,52 [0,93; 2,47]	8,79 [-1,11; 18,68]
			0,095		
≥450	9/20 (45,0)	6/12 (50,0)	0,90 [0,43; 1,90]	0,82 [0,20; 3,43]	-5,00 [-40,72; 30,72]
			1,000		
OECD Country (p-value of the interaction test: 0,680)					
Yes	67/178 (37,6)	23/83 (27,7)	1,36 [0,91; 2,02]	1,57 [0,89; 2,78]	9,93 [-2,04; 21,90]
			0,126		
No	33/122 (27,0)	14/62 (22,6)	1,20 [0,69; 2,07]	1,27 [0,62; 2,60]	4,47 [-8,59; 17,52]
			0,593		
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; FACIT: Functional Assessment of Chronic Illness Therapy-Fatigue; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_faciti9_sub_itb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

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Depressionen – QIDS-SR16

Subgruppen für Reduction in QIDS-SR16 Total Score by at least 4.05 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,594)					
<65 years	65/287 (22,6)	24/141 (17,0)	1,33 [0,87; 2,03]	1,43 [0,85; 2,40]	5,63 [-2,24; 13,50]
			0,206		
≥65 years	4/13 (30,8)	0/4 (0,0)	3,21 [0,21; 49,66]	4,26 [0,19; 97,48]	30,77 [5,68; 55,86]
			0,519		
Age 2 (p-value of the interaction test: 0,698)					
<40 years	44/202 (21,8)	15/91 (16,5)	1,32 [0,78; 2,25]	1,41 [0,74; 2,69]	5,30 [-4,22; 14,81]
			0,346		
≥40 years	25/98 (25,5)	9/54 (16,7)	1,53 [0,77; 3,04]	1,71 [0,73; 4,00]	8,84 [-4,32; 22,01]
			0,230		
Sex (p-value of the interaction test: 0,363)					
Male	38/179 (21,2)	7/65 (10,8)	1,97 [0,93; 4,19]	2,23 [0,94; 5,29]	10,46 [0,83; 20,09]
			0,065		
Female	31/121 (25,6)	17/80 (21,3)	1,21 [0,72; 2,03]	1,28 [0,65; 2,50]	4,37 [-7,50; 16,24]
			0,504		
Race (p-value of the interaction test: 0,448)					
Asian	25/100 (25,0)	7/56 (12,5)	2,00 [0,92; 4,33]	2,33 [0,94; 5,81]	12,50 [0,37; 24,63]
			0,097		
White	38/180 (21,1)	15/82 (18,3)	1,15 [0,67; 1,98]	1,20 [0,62; 2,32]	2,82 [-7,46; 13,09]
			0,740		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Other	3/13 (23,1)	2/7 (28,6)	0,81 [0,17; 3,75]	0,75 [0,09; 6,04]	-5,49 [-46,05; 35,06]
1,000					
Geographic region 1 (p-value of the interaction test: 0,139)					
Europe	29/114 (25,4)	7/50 (14,0)	1,82 [0,85; 3,87]	2,10 [0,85; 5,17]	11,44 [-1,07; 23,95]
0,150					
North America	7/54 (13,0)	6/26 (23,1)	0,56 [0,21; 1,50]	0,50 [0,15; 1,66]	-10,11 [-28,62; 8,39]
0,333					
Other	33/132 (25,0)	11/69 (15,9)	1,57 [0,85; 2,91]	1,76 [0,83; 3,74]	9,06 [-2,31; 20,42]
0,155					
Geographic region 2 (p-value of the interaction test: 0,079)					
Asia	26/105 (24,8)	6/56 (10,7)	2,31 [1,01; 5,28]	2,74 [1,05; 7,13]	14,05 [2,48; 25,61]
0,039					
Central America/South America	6/24 (25,0)	5/13 (38,5)	0,65 [0,24; 1,73]	0,53 [0,13; 2,27]	-13,46 [-45,08; 18,15]
0,465					
Europe and ROW	30/117 (25,6)	7/50 (14,0)	1,83 [0,86; 3,89]	2,12 [0,86; 5,21]	11,64 [-0,81; 24,10]
0,108					
North America	7/54 (13,0)	6/26 (23,1)	0,56 [0,21; 1,50]	0,50 [0,15; 1,66]	-10,11 [-28,62; 8,39]
0,333					
Weight (p-value of the interaction test: 0,881)					
<100 kg	68/284 (23,9)	24/140 (17,1)	1,40 [0,92; 2,12]	1,52 [0,91; 2,55]	6,80 [-1,17; 14,78]
0,133					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
≥100 kg	1/15 (6,7)	0/5 (0,0)	1,13 [0,05; 23,99]	1,14 [0,04; 32,36]	6,67 [-5,96; 19,29]
1,000					
BMI (p-value of the interaction test: 0,278)					
Underweight ($<18.5 \text{ kg/m}^2$)	12/54 (22,2)	9/32 (28,1)	0,79 [0,37; 1,67]	0,73 [0,27; 1,99]	-5,90 [-25,02; 13,22]
0,607					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	38/161 (23,6)	8/60 (13,3)	1,77 [0,88; 3,57]	2,01 [0,88; 4,60]	10,27 [-0,55; 21,09]
0,135					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	12/55 (21,8)	7/38 (18,4)	1,18 [0,51; 2,73]	1,24 [0,44; 3,50]	3,40 [-13,07; 19,86]
0,796					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	7/29 (24,1)	0/15 (0,0)	8,00 [0,49; >100]	10,33 [0,55; >100]	24,14 [8,56; 39,71]
0,077					
Tobacco use (p-value of the interaction test: 0,280)					
Current	11/52 (21,2)	1/29 (3,4)	6,13 [0,83; 45,15]	7,51 [0,92; 61,51]	17,71 [4,77; 30,64]
0,048					
Former	8/49 (16,3)	2/21 (9,5)	1,71 [0,40; 7,40]	1,85 [0,36; 9,58]	6,80 [-9,47; 23,07]
0,712					
Never	50/199 (25,1)	21/95 (22,1)	1,14 [0,73; 1,78]	1,18 [0,66; 2,11]	3,02 [-7,27; 13,31]
0,662					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,466)					
Ever	64/280 (22,9)	24/140 (17,1)	1,33 [0,87; 2,04]	1,43 [0,85; 2,41]	5,71 [-2,23; 13,66]
0,204					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Never	5/20 (25,0)	0/5 (0,0)	3,14 [0,20; 49,12]	3,90 [0,18; 82,76]	25,00 [6,02; 43,98]
0,544					
Prior anti-TNF failure (p-value of the interaction test: 0,634)					
Ever	66/282 (23,4)	23/139 (16,5)	1,41 [0,92; 2,17]	1,54 [0,91; 2,61]	6,86 [-1,05; 14,77]
0,128					
Never	3/18 (16,7)	1/6 (16,7)	1,00 [0,13; 7,89]	1,00 [0,08; 11,93]	0,00 [-34,43; 34,43]
1,000					
Prior anti-integrin failure (p-value of the interaction test: 0,976)					
Ever	17/71 (23,9)	5/31 (16,1)	1,48 [0,60; 3,66]	1,64 [0,54; 4,92]	7,81 [-8,50; 24,13]
0,443					
Never	52/229 (22,7)	19/114 (16,7)	1,36 [0,85; 2,19]	1,47 [0,82; 2,63]	6,04 [-2,69; 14,77]
0,206					
Baseline corticosteroid use (p-value of the interaction test: 0,312)					
Yes	15/76 (19,7)	8/39 (20,5)	0,96 [0,45; 2,07]	0,95 [0,36; 2,49]	-0,78 [-16,29; 14,74]
1,000					
No	54/224 (24,1)	16/106 (15,1)	1,60 [0,96; 2,65]	1,79 [0,97; 3,30]	9,01 [0,19; 17,83]
0,063					
Duration of CD (p-value of the interaction test: 0,305)					
<1 year	8/23 (34,8)	0/9 (0,0)	7,08 [0,45; >100]	10,42 [0,54; >100]	34,78 [15,32; 54,25]
0,070					
≥1 to <5 years	22/104 (21,2)	5/44 (11,4)	1,86 [0,75; 4,60]	2,09 [0,74; 5,94]	9,79 [-2,44; 22,02]
0,243					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
≥5 years	39/173 (22,5)	19/92 (20,7)	1,09 [0,67; 1,78]	1,12 [0,60; 2,07]	1,89 [-8,46; 12,24]
0,757					
Baseline disease location (p-value of the interaction test: 0,093)					
Colonic	35/120 (29,2)	7/59 (11,9)	2,46 [1,16; 5,20]	3,06 [1,27; 7,39]	17,30 [5,72; 28,89]
0,014					
Ileal	5/32 (15,6)	1/6 (16,7)	0,94 [0,13; 6,67]	0,93 [0,09; 9,70]	-1,04 [-33,41; 31,32]
1,000					
Ileal-Colonic	29/148 (19,6)	16/80 (20,0)	0,98 [0,57; 1,69]	0,97 [0,49; 1,93]	-0,41 [-11,26; 10,44]
1,000					
Baseline fecal calprotectin (p-value of the interaction test: 0,429)					
≤250	5/38 (13,2)	2/15 (13,3)	0,99 [0,21; 4,54]	0,98 [0,17; 5,73]	-0,18 [-20,46; 20,11]
1,000					
>250	49/208 (23,6)	12/93 (12,9)	1,83 [1,02; 3,27]	2,08 [1,05; 4,13]	10,65 [1,73; 19,58]
0,043					
Baseline CRP (p-value of the interaction test: 0,071)					
≤10	19/145 (13,1)	9/58 (15,5)	0,84 [0,41; 1,76]	0,82 [0,35; 1,94]	-2,41 [-13,23; 8,40]
0,657					
>10	50/154 (32,5)	15/87 (17,2)	1,88 [1,13; 3,15]	2,31 [1,20; 4,42]	15,23 [4,38; 26,07]
0,011					
Baseline SES-CD total score (p-value of the interaction test: 0,868)					
<12	27/143 (18,9)	9/66 (13,6)	1,38 [0,69; 2,78]	1,47 [0,65; 3,34]	5,24 [-5,23; 15,72]
0,432					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
≥12	42/157 (26,8)	15/79 (19,0)	1,41 [0,83; 2,38]	1,56 [0,80; 3,03]	7,76 [-3,31; 18,84]
0,202					
Baseline AP average (p-value of the interaction test: 0,878)					
<2	14/72 (19,4)	6/48 (12,5)	1,56 [0,64; 3,76]	1,69 [0,60; 4,76]	6,94 [-6,14; 20,03]
0,454					
≥2	55/226 (24,3)	18/97 (18,6)	1,31 [0,81; 2,11]	1,41 [0,78; 2,56]	5,78 [-3,77; 15,33]
0,310					
Baseline SF average (p-value of the interaction test: 0,318)					
<7	51/220 (23,2)	14/100 (14,0)	1,66 [0,96; 2,85]	1,85 [0,97; 3,54]	9,18 [0,39; 17,98]
0,072					
≥7	18/76 (23,7)	10/45 (22,2)	1,07 [0,54; 2,10]	1,09 [0,45; 2,62]	1,46 [-13,99; 16,92]
1,000					
Baseline CDAI 1 (p-value of the interaction test: 0,961)					
<300	17/109 (15,6)	6/59 (10,2)	1,53 [0,64; 3,68]	1,63 [0,61; 4,39]	5,43 [-4,86; 15,72]
0,481					
≥300	51/184 (27,7)	18/84 (21,4)	1,29 [0,81; 2,07]	1,41 [0,76; 2,60]	6,29 [-4,61; 17,19]
0,296					
Baseline CDAI 2 (p-value of the interaction test: 0,720)					
<220	1/29 (3,4)	0/12 (0,0)	1,30 [0,06; 29,85]	1,32 [0,05; 34,58]	3,45 [-3,19; 10,09]
1,000					
≥220 and <450	61/244 (25,0)	20/119 (16,8)	1,49 [0,94; 2,34]	1,65 [0,94; 2,89]	8,19 [-0,45; 16,83]
0,082					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
≥450	6/20 (30,0)	4/12 (33,3)	0,90 [0,32; 2,55]	0,86 [0,18; 3,98]	-3,33 [-36,72; 30,05]
1,000					
OECD Country (p-value of the interaction test: 0,444)					
Yes	42/178 (23,6)	12/83 (14,5)	1,63 [0,91; 2,93]	1,83 [0,90; 3,69]	9,14 [-0,67; 18,94]
0,102					
No	27/122 (22,1)	12/62 (19,4)	1,14 [0,62; 2,10]	1,18 [0,55; 2,54]	2,78 [-9,51; 15,06]
0,707					
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; QIDS-SR16: Quick Inventory of Depressive Symptomatology - Self Report (16 items); RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_qidsi4_05_sub_ittb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba
20DEC2024 / 04:00

Extraintestinale Manifestationen (EIM)

Subgruppen für Resolution of extra-intestinal manifestations in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population, Participants with EIMs at baseline)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 2 (p-value of the interaction test: 0,651)					
<40 years	34/49 (69,4)	11/19 (57,9)	1,20 [0,78; 1,84]	1,65 [0,55; 4,93]	11,49 [-14,19; 37,17]
			0,402		
≥40 years	9/24 (37,5)	6/18 (33,3)	1,13 [0,49; 2,59]	1,20 [0,33; 4,32]	4,17 [-24,98; 33,31]
			1,000		
Geographic region 1 (p-value of the interaction test: 0,404)					
Europe	21/31 (67,7)	9/17 (52,9)	1,28 [0,77; 2,13]	1,87 [0,55; 6,29]	14,80 [-14,07; 43,68]
			0,361		
North America	8/22 (36,4)	5/12 (41,7)	0,87 [0,37; 2,08]	0,80 [0,19; 3,37]	-5,30 [-39,69; 29,08]
			1,000		
Other	14/20 (70,0)	3/8 (37,5)	1,87 [0,73; 4,78]	3,89 [0,70; 21,75]	32,50 [-6,60; 71,60]
			0,200		
Geographic region 2 (p-value of the interaction test: 0,651)					
Asia	6/8 (75,0)	1/4 (25,0)	3,00 [0,52; 17,16]	9,00 [0,56; >100]	50,00 [-1,97; 100,00]
			0,222		
Central America/South America	7/10 (70,0)	2/4 (50,0)	1,40 [0,48; 4,04]	2,33 [0,22; 25,24]	20,00 [-36,64; 76,64]
			0,580		
Europe and ROW	22/33 (66,7)	9/17 (52,9)	1,26 [0,76; 2,09]	1,78 [0,54; 5,88]	13,73 [-14,94; 42,39]
			0,373		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
North America	8/22 (36,4)	5/12 (41,7)	0,87 [0,37; 2,08]	0,80 [0,19; 3,37]	-5,30 [-39,69; 29,08]
1,000					
BMI (p-value of the interaction test: 0,413)					
Underweight ($<18.5 \text{ kg/m}^2$)	7/9 (77,8)	1/5 (20,0)	3,89 [0,65; 23,23]	14,00 [0,94; >100]	57,78 [13,43; 100,00]
0,091					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	24/38 (63,2)	7/12 (58,3)	1,08 [0,63; 1,85]	1,22 [0,33; 4,60]	4,82 [-27,01; 36,66]
1,000					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	9/17 (52,9)	8/14 (57,1)	0,93 [0,49; 1,75]	0,84 [0,20; 3,50]	-4,20 [-39,34; 30,94]
1,000					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	3/8 (37,5)	1/6 (16,7)	2,25 [0,30; 16,63]	3,00 [0,23; 39,61]	20,83 [-24,05; 65,72]
0,580					
Tobacco use (p-value of the interaction test: 0,319)					
Current	9/13 (69,2)	6/11 (54,5)	1,27 [0,66; 2,43]	1,88 [0,35; 9,98]	14,69 [-23,98; 53,35]
0,675					
Former	7/15 (46,7)	4/6 (66,7)	0,70 [0,32; 1,53]	0,44 [0,06; 3,16]	-20,00 [-65,39; 25,39]
0,635					
Never	27/45 (60,0)	7/20 (35,0)	1,71 [0,90; 3,26]	2,79 [0,93; 8,33]	25,00 [-0,33; 50,33]
0,105					
Prior anti-integrin failure (p-value of the interaction test: 0,490)					
Ever	13/22 (59,1)	4/12 (33,3)	1,77 [0,74; 4,24]	2,89 [0,66; 12,57]	25,76 [-7,91; 59,42]
0,282					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Never	30/51 (58,8)	13/25 (52,0)	1,13 [0,73; 1,76]	1,32 [0,50; 3,45]	6,82 [-16,97; 30,61]
0,627					
Baseline corticosteroid use (p-value of the interaction test: 0,580)					
Yes	12/24 (50,0)	5/11 (45,5)	1,10 [0,51; 2,35]	1,20 [0,29; 5,02]	4,55 [-31,04; 40,13]
1,000					
No	31/49 (63,3)	12/26 (46,2)	1,37 [0,86; 2,19]	2,01 [0,77; 5,28]	17,11 [-6,33; 40,55]
0,220					
Baseline immunomodulator use (p-value of the interaction test: 0,343)					
Yes	9/16 (56,3)	6/11 (54,5)	1,03 [0,52; 2,06]	1,07 [0,23; 5,02]	1,70 [-36,46; 39,87]
1,000					
No	34/57 (59,6)	11/26 (42,3)	1,41 [0,86; 2,32]	2,02 [0,79; 5,17]	17,34 [-5,52; 40,21]
0,161					
Baseline disease location (p-value of the interaction test: 0,413)					
Colonic	17/31 (54,8)	8/15 (53,3)	1,03 [0,58; 1,82]	1,06 [0,31; 3,66]	1,51 [-29,22; 32,23]
1,000					
Ileal	2/8 (25,0)	1/4 (25,0)	1,00 [0,13; 8,00]	1,00 [0,06; 15,99]	0,00 [-51,97; 51,97]
1,000					
Ileal-Colonic	24/34 (70,6)	8/18 (44,4)	1,59 [0,91; 2,78]	3,00 [0,92; 9,83]	26,14 [-1,45; 53,74]
0,080					
Baseline fecal calprotectin (p-value of the interaction test: 0,726)					
≤250	6/12 (50,0)	2/4 (50,0)	1,00 [0,32; 3,10]	1,00 [0,10; 9,61]	0,00 [-56,58; 56,58]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
>250	31/48 (64,6)	11/23 (47,8)	1,35 [0,84; 2,17]	1,99 [0,72; 5,46]	16,76 [-7,73; 41,25]
0,205					
Baseline CRP (p-value of the interaction test: 0,877)					
≤10	20/35 (57,1)	6/15 (40,0)	1,43 [0,72; 2,83]	2,00 [0,58; 6,85]	17,14 [-12,58; 46,87]
0,358					
>10	23/37 (62,2)	11/22 (50,0)	1,24 [0,76; 2,02]	1,64 [0,56; 4,78]	12,16 [-13,93; 38,25]
0,421					
Baseline SES-CD total score (p-value of the interaction test: 0,109)					
<12	15/35 (42,9)	10/21 (47,6)	0,90 [0,50; 1,62]	0,83 [0,28; 2,45]	-4,76 [-31,69; 22,17]
0,786					
≥12	28/38 (73,7)	7/16 (43,8)	1,68 [0,94; 3,03]	3,60 [1,06; 12,24]	29,93 [1,88; 57,99]
0,060					
Baseline AP average (p-value of the interaction test: 0,531)					
<2	13/20 (65,0)	6/10 (60,0)	1,08 [0,59; 1,97]	1,24 [0,26; 5,91]	5,00 [-31,86; 41,86]
1,000					
≥2	30/52 (57,7)	11/27 (40,7)	1,42 [0,85; 2,36]	1,98 [0,77; 5,10]	16,95 [-5,94; 39,84]
0,165					
Baseline SF average (p-value of the interaction test: 0,606)					
<7	28/48 (58,3)	11/23 (47,8)	1,22 [0,75; 1,99]	1,53 [0,56; 4,15]	10,51 [-14,22; 35,23]
0,452					
≥7	14/23 (60,9)	6/14 (42,9)	1,42 [0,71; 2,83]	2,07 [0,54; 8,00]	18,01 [-14,70; 50,72]
0,328					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Baseline CDAI 1 (p-value of the interaction test: 0,312)					
<300	15/22 (68,2)	8/13 (61,5)	1,11 [0,66; 1,86]	1,34 [0,32; 5,61]	6,64 [-26,19; 39,48]
				0,726	
≥300	27/49 (55,1)	9/24 (37,5)	1,47 [0,83; 2,61]	2,05 [0,75; 5,56]	17,60 [-6,25; 41,46]
				0,214	
OECD Country (p-value of the interaction test: 0,243)					
Yes	29/50 (58,0)	14/27 (51,9)	1,12 [0,73; 1,73]	1,28 [0,50; 3,29]	6,15 [-17,14; 29,44]
				0,637	
No	14/23 (60,9)	3/10 (30,0)	2,03 [0,75; 5,53]	3,63 [0,74; 17,81]	30,87 [-3,84; 65,58]
				0,141	
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; EIMs: Extra-Intestinal Manifestations; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_eimsresov_sub_eim_itb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Subgruppen für Resolution of extra-intestinal manifestations: Arthritis/Arthralgia in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population, Participants with EIMs at baseline)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 2 (p-value of the interaction test: 0,793)					
<40 years	26/40 (65,0)	10/16 (62,5)	1,04 [0,67; 1,62]	1,11 [0,33; 3,71]	2,50 [-25,45; 30,45]
			1,000		
≥40 years	7/22 (31,8)	6/18 (33,3)	0,95 [0,39; 2,34]	0,93 [0,25; 3,52]	-1,52 [-30,72; 27,69]
			1,000		
Geographic region 1 (p-value of the interaction test: 0,558)					
Europe	18/28 (64,3)	8/16 (50,0)	1,29 [0,73; 2,26]	1,80 [0,52; 6,27]	14,29 [-15,97; 44,54]
			0,525		
North America	6/20 (30,0)	5/12 (41,7)	0,72 [0,28; 1,86]	0,60 [0,13; 2,67]	-11,67 [-46,04; 22,71]
			0,703		
Other	9/14 (64,3)	3/6 (50,0)	1,29 [0,53; 3,13]	1,80 [0,26; 12,50]	14,29 [-32,94; 61,51]
			0,642		
Tobacco use (p-value of the interaction test: 0,426)					
Current	6/10 (60,0)	6/11 (54,5)	1,10 [0,52; 2,30]	1,25 [0,22; 7,08]	5,45 [-36,83; 47,74]
			1,000		
Former	6/14 (42,9)	4/6 (66,7)	0,64 [0,28; 1,47]	0,38 [0,05; 2,77]	-23,81 [-69,58; 21,96]
			0,628		
Never	21/38 (55,3)	6/17 (35,3)	1,57 [0,77; 3,17]	2,26 [0,69; 7,39]	19,97 [-7,71; 47,65]
			0,245		
Prior anti-integrin failure (p-value of the interaction test: 0,327)					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Ever	10/19 (52,6)	3/11 (27,3)	1,93 [0,67; 5,54]	2,96 [0,60; 14,73]	25,36 [-9,23; 59,95]
			0,259		
Never	23/43 (53,5)	13/23 (56,5)	0,95 [0,60; 1,49]	0,88 [0,32; 2,45]	-3,03 [-28,19; 22,12]
			1,000		
Baseline corticosteroid use (p-value of the interaction test: 0,566)					
Yes	9/21 (42,9)	5/11 (45,5)	0,94 [0,42; 2,13]	0,90 [0,21; 3,91]	-2,60 [-38,84; 33,65]
			1,000		
No	24/41 (58,5)	11/23 (47,8)	1,22 [0,74; 2,02]	1,54 [0,55; 4,30]	10,71 [-14,67; 36,09]
			0,443		
Baseline immunomodulator use (p-value of the interaction test: 0,518)					
Yes	8/15 (53,3)	6/11 (54,5)	0,98 [0,48; 2,00]	0,95 [0,20; 4,54]	-1,21 [-39,98; 37,56]
			1,000		
No	25/47 (53,2)	10/23 (43,5)	1,22 [0,71; 2,09]	1,48 [0,54; 4,03]	9,71 [-15,06; 34,49]
			0,611		
Baseline disease location (p-value of the interaction test: 0,306)					
Colonic	12/26 (46,2)	8/14 (57,1)	0,81 [0,44; 1,49]	0,64 [0,17; 2,38]	-10,99 [-43,23; 21,25]
			0,741		
Ileal	2/8 (25,0)	1/4 (25,0)	1,00 [0,13; 8,00]	1,00 [0,06; 15,99]	0,00 [-51,97; 51,97]
			1,000		
Ileal-Colonic	19/28 (67,9)	7/16 (43,8)	1,55 [0,84; 2,86]	2,71 [0,76; 9,63]	24,11 [-5,73; 53,94]
			0,202		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline fecal calprotectin (p-value of the interaction test: 0,792)					
≤250	5/11 (45,5)	2/4 (50,0)	0,91 [0,28; 2,94]	0,83 [0,08; 8,24]	-4,55 [-61,70; 52,61]
				1,000	
>250	24/40 (60,0)	11/21 (52,4)	1,15 [0,71; 1,85]	1,36 [0,47; 3,95]	7,62 [-18,59; 33,83]
				0,596	
Baseline CRP (p-value of the interaction test: 0,622)					
≤10	18/33 (54,5)	6/15 (40,0)	1,36 [0,68; 2,73]	1,80 [0,52; 6,22]	14,55 [-15,51; 44,60]
				0,534	
>10	15/28 (53,6)	10/19 (52,6)	1,02 [0,59; 1,76]	1,04 [0,32; 3,34]	0,94 [-28,13; 30,01]
				1,000	
Baseline SES-CD total score (p-value of the interaction test: 0,181)					
<12	14/34 (41,2)	10/20 (50,0)	0,82 [0,45; 1,49]	0,70 [0,23; 2,13]	-8,82 [-36,28; 18,63]
				0,580	
≥12	19/28 (67,9)	6/14 (42,9)	1,58 [0,82; 3,05]	2,81 [0,75; 10,57]	25,00 [-6,16; 56,16]
				0,184	
Baseline AP average (p-value of the interaction test: 0,624)					
<2	11/18 (61,1)	5/8 (62,5)	0,98 [0,51; 1,88]	0,94 [0,17; 5,25]	-1,39 [-41,79; 39,02]
				1,000	
≥2	22/43 (51,2)	11/26 (42,3)	1,21 [0,71; 2,07]	1,43 [0,54; 3,81]	8,86 [-15,31; 33,02]
				0,620	
Baseline SF average (p-value of the interaction test: 0,354)					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
<7	20/40 (50,0)	10/20 (50,0)	1,00 [0,58; 1,71]	1,00 [0,34; 2,93]	0,00 [-26,84; 26,84]
			1,000		
≥7	12/20 (60,0)	6/14 (42,9)	1,40 [0,69; 2,83]	2,00 [0,50; 8,00]	17,14 [-16,52; 50,80]
			0,487		
Baseline CDAI 1 (p-value of the interaction test: 0,540)					
<300	14/21 (66,7)	7/11 (63,6)	1,05 [0,61; 1,80]	1,14 [0,25; 5,26]	3,03 [-31,82; 37,88]
			1,000		
≥300	18/39 (46,2)	9/23 (39,1)	1,18 [0,64; 2,18]	1,33 [0,47; 3,80]	7,02 [-18,33; 32,37]
			0,609		
OECD Country (p-value of the interaction test: 0,413)					
Yes	24/45 (53,3)	13/25 (52,0)	1,03 [0,64; 1,63]	1,05 [0,40; 2,81]	1,33 [-23,08; 25,75]
			1,000		
No	9/17 (52,9)	3/9 (33,3)	1,59 [0,57; 4,43]	2,25 [0,42; 12,09]	19,61 [-19,27; 58,49]
			0,429		
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; EIMs: Extra-Intestinal Manifestations; ITT: Intention-to-treat Population; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_eimsresa_sub_eim_ittb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Anhang 4-G.4.6.1.3 Gesundheitszustand**Gesundheitszustand – EQ-5D VAS**

Subgruppen für Increase in EQ-5D VAS Score by at least 15 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,279)					
<65 years	150/287 (52,3)	64/141 (45,4)	1,15 [0,93; 1,42]	1,32 [0,88; 1,97]	6,87 [-3,17; 16,92]
			0,217		
≥65 years	7/13 (53,8)	0/4 (0,0)	5,36 [0,37; 77,70]	10,38 [0,47; >100]	53,85 [26,75; 80,95]
			0,103		
Age 2 (p-value of the interaction test: 0,843)					
<40 years	111/202 (55,0)	42/91 (46,2)	1,19 [0,92; 1,54]	1,42 [0,87; 2,34]	8,80 [-3,53; 21,12]
			0,167		
≥40 years	46/98 (46,9)	22/54 (40,7)	1,15 [0,78; 1,69]	1,29 [0,66; 2,52]	6,20 [-10,21; 22,61]
			0,499		
Sex (p-value of the interaction test: 0,147)					
Male	86/179 (48,0)	30/65 (46,2)	1,04 [0,77; 1,41]	1,08 [0,61; 1,91]	1,89 [-12,27; 16,05]
			0,885		
Female	71/121 (58,7)	34/80 (42,5)	1,38 [1,03; 1,86]	1,92 [1,08; 3,40]	16,18 [2,24; 30,12]
			0,031		
Race (p-value of the interaction test: 0,414)					
Asian	56/100 (56,0)	22/56 (39,3)	1,43 [0,99; 2,06]	1,97 [1,01; 3,83]	16,71 [0,64; 32,79]
			0,066		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
White	89/180 (49,4)	37/82 (45,1)	1,10 [0,83; 1,45]	1,19 [0,70; 2,01]	4,32 [-8,69; 17,34]
			0,594		
Other	8/13 (61,5)	5/7 (71,4)	0,86 [0,46; 1,63]	0,64 [0,09; 4,66]	-9,89 [-52,54; 32,76]
			1,000		
Geographic region 1 (p-value of the interaction test: 0,416)					
Europe	60/114 (52,6)	24/50 (48,0)	1,10 [0,78; 1,54]	1,20 [0,62; 2,34]	4,63 [-11,97; 21,24]
			0,614		
North America	28/54 (51,9)	14/26 (53,8)	0,96 [0,62; 1,49]	0,92 [0,36; 2,36]	-1,99 [-25,33; 21,35]
			1,000		
Other	69/132 (52,3)	26/69 (37,7)	1,39 [0,98; 1,96]	1,81 [1,00; 3,28]	14,59 [0,33; 28,85]
			0,054		
Geographic region 2 (p-value of the interaction test: 0,507)					
Asia	58/105 (55,2)	21/56 (37,5)	1,47 [1,01; 2,15]	2,06 [1,06; 3,99]	17,74 [1,89; 33,59]
			0,047		
Central America/South America	10/24 (41,7)	5/13 (38,5)	1,08 [0,47; 2,50]	1,14 [0,29; 4,55]	3,21 [-29,79; 36,20]
			1,000		
Europe and ROW	61/117 (52,1)	24/50 (48,0)	1,09 [0,78; 1,52]	1,18 [0,61; 2,29]	4,14 [-12,41; 20,68]
			0,736		
North America	28/54 (51,9)	14/26 (53,8)	0,96 [0,62; 1,49]	0,92 [0,36; 2,36]	-1,99 [-25,33; 21,35]
			1,000		
Weight (p-value of the interaction test: 0,852)					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
<100 kg	153/284 (53,9)	63/140 (45,0)	1,20 [0,97; 1,48]	1,43 [0,95; 2,14]	8,87 [-1,20; 18,95]
			0,098		
≥100 kg	4/15 (26,7)	1/5 (20,0)	1,33 [0,19; 9,31]	1,45 [0,12; 17,23]	6,67 [-34,93; 48,26]
			1,000		
BMI (p-value of the interaction test: 0,054)					
Underweight (<18.5 kg/m ²)	28/54 (51,9)	15/32 (46,9)	1,11 [0,71; 1,73]	1,22 [0,51; 2,93]	4,98 [-16,85; 26,81]
			0,824		
Normal (≥18.5 and <25 kg/m ²)	93/161 (57,8)	21/60 (35,0)	1,65 [1,14; 2,39]	2,54 [1,37; 4,70]	22,76 [8,49; 37,04]
			0,004		
Overweight (≥25 and <30 kg/m ²)	25/55 (45,5)	20/38 (52,6)	0,86 [0,57; 1,31]	0,75 [0,33; 1,72]	-7,18 [-27,80; 13,44]
			0,532		
Obese and Extreme obese (≥30 kg/m ²)	11/29 (37,9)	8/15 (53,3)	0,71 [0,37; 1,38]	0,53 [0,15; 1,89]	-15,40 [-46,21; 15,41]
			0,357		
Tobacco use (p-value of the interaction test: 0,976)					
Current	27/52 (51,9)	12/29 (41,4)	1,25 [0,76; 2,08]	1,53 [0,61; 3,83]	10,54 [-11,94; 33,03]
			0,487		
Former	23/49 (46,9)	8/21 (38,1)	1,23 [0,66; 2,29]	1,44 [0,51; 4,08]	8,84 [-16,19; 33,88]
			0,603		
Never	107/199 (53,8)	44/95 (46,3)	1,16 [0,90; 1,49]	1,35 [0,83; 2,20]	7,45 [-4,73; 19,64]
			0,262		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,767)					
Ever	150/280 (53,6)	63/140 (45,0)	1,19 [0,96; 1,47]	1,41 [0,94; 2,12]	8,57 [-1,53; 18,67]
			0,099		
Never	7/20 (35,0)	1/5 (20,0)	1,75 [0,27; 11,15]	2,15 [0,20; 23,18]	15,00 [-25,82; 55,82]
			1,000		
Prior anti-TNF failure (p-value of the interaction test: 0,568)					
Ever	149/282 (52,8)	61/139 (43,9)	1,20 [0,97; 1,50]	1,43 [0,95; 2,16]	8,95 [-1,15; 19,05]
			0,097		
Never	8/18 (44,4)	3/6 (50,0)	0,89 [0,34; 2,30]	0,80 [0,13; 5,09]	-5,56 [-51,68; 40,57]
			1,000		
Prior anti-integrin failure (p-value of the interaction test: 0,639)					
Ever	42/71 (59,2)	14/31 (45,2)	1,31 [0,85; 2,02]	1,76 [0,75; 4,12]	13,99 [-6,93; 34,91]
			0,203		
Never	115/229 (50,2)	50/114 (43,9)	1,14 [0,90; 1,46]	1,29 [0,82; 2,03]	6,36 [-4,82; 17,53]
			0,302		
Baseline corticosteroid use (p-value of the interaction test: 0,181)					
Yes	36/76 (47,4)	20/39 (51,3)	0,92 [0,63; 1,36]	0,86 [0,39; 1,85]	-3,91 [-23,20; 15,38]
			0,699		
No	121/224 (54,0)	44/106 (41,5)	1,30 [1,01; 1,68]	1,66 [1,04; 2,64]	12,51 [1,08; 23,94]
			0,045		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Baseline immunomodulator use (p-value of the interaction test: 0,683)					
Yes	31/66 (47,0)	14/39 (35,9)	1,31 [0,80; 2,14]	1,58 [0,70; 3,57]	11,07 [-8,21; 30,35]
			0,311		
No	126/234 (53,8)	50/106 (47,2)	1,14 [0,90; 1,44]	1,31 [0,82; 2,07]	6,68 [-4,77; 18,13]
			0,292		
Duration of CD (p-value of the interaction test: 0,217)					
<1 year	10/23 (43,5)	2/9 (22,2)	1,96 [0,53; 7,24]	2,69 [0,46; 15,88]	21,26 [-12,63; 55,14]
			0,422		
≥1 to <5 years	59/104 (56,7)	16/44 (36,4)	1,56 [1,02; 2,39]	2,29 [1,11; 4,74]	20,37 [3,26; 37,48]
			0,031		
≥5 years	88/173 (50,9)	46/92 (50,0)	1,02 [0,79; 1,31]	1,04 [0,62; 1,72]	0,87 [-11,78; 13,51]
			0,898		
Baseline disease location (p-value of the interaction test: 0,221)					
Colonic	68/120 (56,7)	22/59 (37,3)	1,52 [1,05; 2,19]	2,20 [1,16; 4,17]	19,38 [4,18; 34,57]
			0,017		
Ileal	9/32 (28,1)	2/6 (33,3)	0,84 [0,24; 2,97]	0,78 [0,12; 5,05]	-5,21 [-46,02; 35,60]
			1,000		
Ileal-Colonic	80/148 (54,1)	40/80 (50,0)	1,08 [0,83; 1,41]	1,18 [0,68; 2,03]	4,05 [-9,53; 17,64]
			0,581		
Baseline fecal calprotectin (p-value of the interaction test: 0,989)					
≤250	13/38 (34,2)	4/15 (26,7)	1,28 [0,50; 3,31]	1,43 [0,38; 5,39]	7,54 [-19,44; 34,53]
			0,748		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
>250	114/208 (54,8)	42/93 (45,2)	1,21 [0,94; 1,57]	1,47 [0,90; 2,41]	9,65 [-2,52; 21,81]
0,135					
Baseline CRP (p-value of the interaction test: 0,539)					
≤10	67/145 (46,2)	24/58 (41,4)	1,12 [0,78; 1,59]	1,22 [0,66; 2,25]	4,83 [-10,22; 19,88]
0,640					
>10	90/154 (58,4)	40/87 (46,0)	1,27 [0,98; 1,65]	1,65 [0,97; 2,81]	12,46 [-0,58; 25,51]
0,080					
Baseline SES-CD total score (p-value of the interaction test: 0,853)					
<12	70/143 (49,0)	26/66 (39,4)	1,24 [0,88; 1,75]	1,48 [0,82; 2,67]	9,56 [-4,80; 23,91]
0,233					
≥12	87/157 (55,4)	38/79 (48,1)	1,15 [0,88; 1,51]	1,34 [0,78; 2,31]	7,31 [-6,17; 20,80]
0,334					
Baseline AP average (p-value of the interaction test: 0,326)					
<2	30/72 (41,7)	13/48 (27,1)	1,54 [0,90; 2,64]	1,92 [0,87; 4,24]	14,58 [-2,38; 31,55]
0,122					
≥2	127/226 (56,2)	51/97 (52,6)	1,07 [0,86; 1,33]	1,16 [0,72; 1,86]	3,62 [-8,24; 15,47]
0,626					
Baseline SF average (p-value of the interaction test: 0,438)					
<7	115/220 (52,3)	41/100 (41,0)	1,27 [0,98; 1,66]	1,58 [0,98; 2,54]	11,27 [-0,41; 22,96]
0,071					
≥7	41/76 (53,9)	23/45 (51,1)	1,06 [0,74; 1,50]	1,12 [0,54; 2,34]	2,84 [-15,57; 21,25]
0,851					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Baseline CDAI 1 (p-value of the interaction test: 0,140)					
<300	48/109 (44,0)	16/59 (27,1)	1,62 [1,02; 2,60]	2,11 [1,06; 4,21]	16,92 [2,24; 31,60]
				0,045	
≥300	107/184 (58,2)	48/84 (57,1)	1,02 [0,81; 1,27]	1,04 [0,62; 1,76]	1,01 [-11,75; 13,77]
				0,895	
Baseline CDAI 2 (p-value of the interaction test: 0,312)					
<220	9/29 (31,0)	0/12 (0,0)	8,23 [0,52; >100]	11,59 [0,62; >100]	31,03 [14,20; 47,87]
				0,039	
≥220 and <450	134/244 (54,9)	59/119 (49,6)	1,11 [0,89; 1,37]	1,24 [0,80; 1,92]	5,34 [-5,60; 16,28]
				0,371	
≥450	12/20 (60,0)	5/12 (41,7)	1,44 [0,67; 3,08]	2,10 [0,49; 9,00]	18,33 [-16,87; 53,53]
				0,467	
OECD Country (p-value of the interaction test: 0,969)					
Yes	96/178 (53,9)	38/83 (45,8)	1,18 [0,90; 1,54]	1,39 [0,82; 2,34]	8,15 [-4,83; 21,13]
				0,234	
No	61/122 (50,0)	26/62 (41,9)	1,19 [0,85; 1,68]	1,38 [0,75; 2,57]	8,06 [-7,09; 23,22]
				0,350	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; EQ-5D: Fragebogen der EuroQol-Gruppe zur Lebensqualität auf 5 Dimensionen; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor; VAS: Visuelle Analogskala. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_vasi15_sub_ittb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Gesundheitszustand – PGRS

Subgruppen für Reduction in PGRS score by at least 1 point in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Age 1 (p-value of the interaction test: 0,411)					
<65 years	198/287 (69,0)	86/141 (61,0)	1,13 [0,97; 1,32]	1,42 [0,93; 2,17]	8,00 [-1,67; 17,66]
				0,104	
≥65 years	5/13 (38,5)	2/4 (50,0)	0,77 [0,23; 2,55]	0,63 [0,07; 5,97]	-11,54 [-67,22; 44,14]
				1,000	
Age 2 (p-value of the interaction test: 0,350)					
<40 years	139/202 (68,8)	53/91 (58,2)	1,18 [0,97; 1,44]	1,58 [0,95; 2,64]	10,57 [-1,41; 22,55]
				0,085	
≥40 years	64/98 (65,3)	35/54 (64,8)	1,01 [0,79; 1,29]	1,02 [0,51; 2,05]	0,49 [-15,35; 16,34]
				1,000	
Sex (p-value of the interaction test: 0,820)					
Male	124/179 (69,3)	40/65 (61,5)	1,13 [0,91; 1,40]	1,41 [0,78; 2,55]	7,74 [-5,89; 21,36]
				0,282	
Female	79/121 (65,3)	48/80 (60,0)	1,09 [0,87; 1,36]	1,25 [0,70; 2,25]	5,29 [-8,39; 18,97]
				0,459	
Race (p-value of the interaction test: 0,097)					
Asian	74/100 (74,0)	30/56 (53,6)	1,38 [1,05; 1,81]	2,47 [1,24; 4,92]	20,43 [4,79; 36,07]
				0,013	
White	116/180 (64,4)	54/82 (65,9)	0,98 [0,81; 1,18]	0,94 [0,54; 1,63]	-1,41 [-13,83; 11,01]
				0,889	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Other	8/13 (61,5)	4/7 (57,1)	1,08 [0,50; 2,33]	1,20 [0,19; 7,77]	4,40 [-40,81; 49,60]
1,000					
Geographic region 1 (p-value of the interaction test: 0,094)					
Europe	79/114 (69,3)	36/50 (72,0)	0,96 [0,78; 1,19]	0,88 [0,42; 1,83]	-2,70 [-17,75; 12,35]
0,853					
North America	31/54 (57,4)	16/26 (61,5)	0,93 [0,64; 1,37]	0,84 [0,32; 2,19]	-4,13 [-27,01; 18,75]
0,811					
Other	93/132 (70,5)	36/69 (52,2)	1,35 [1,05; 1,74]	2,19 [1,20; 3,99]	18,28 [4,16; 32,41]
0,013					
Geographic region 2 (p-value of the interaction test: 0,186)					
Asia	75/105 (71,4)	29/56 (51,8)	1,38 [1,04; 1,83]	2,33 [1,19; 4,57]	19,64 [3,96; 35,33]
0,016					
Central America/South America	16/24 (66,7)	7/13 (53,8)	1,24 [0,70; 2,21]	1,71 [0,43; 6,83]	12,82 [-20,20; 45,84]
0,495					
Europe and ROW	81/117 (69,2)	36/50 (72,0)	0,96 [0,78; 1,19]	0,88 [0,42; 1,82]	-2,77 [-17,76; 12,23]
0,854					
North America	31/54 (57,4)	16/26 (61,5)	0,93 [0,64; 1,37]	0,84 [0,32; 2,19]	-4,13 [-27,01; 18,75]
0,811					
Weight (p-value of the interaction test: 0,431)					
<100 kg	195/284 (68,7)	87/140 (62,1)	1,10 [0,95; 1,29]	1,33 [0,87; 2,04]	6,52 [-3,16; 16,20]
0,190					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
≥100 kg	8/15 (53,3)	1/5 (20,0)	2,67 [0,43; 16,39]	4,57 [0,41; 51,14]	33,33 [-9,87; 76,54]
0,319					
BMI (p-value of the interaction test: 0,979)					
Underweight ($<18.5 \text{ kg/m}^2$)	34/54 (63,0)	18/32 (56,3)	1,12 [0,77; 1,62]	1,32 [0,54; 3,22]	6,71 [-14,77; 28,19]
0,649					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	115/161 (71,4)	39/60 (65,0)	1,10 [0,89; 1,36]	1,35 [0,72; 2,53]	6,43 [-7,51; 20,37]
0,411					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	38/55 (69,1)	25/38 (65,8)	1,05 [0,79; 1,40]	1,16 [0,48; 2,81]	3,30 [-16,11; 22,71]
0,823					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	16/29 (55,2)	6/15 (40,0)	1,38 [0,68; 2,78]	1,85 [0,52; 6,55]	15,17 [-15,52; 45,87]
0,526					
Tobacco use (p-value of the interaction test: 0,758)					
Current	37/52 (71,2)	18/29 (62,1)	1,15 [0,82; 1,60]	1,51 [0,58; 3,94]	9,08 [-12,44; 30,61]
0,461					
Former	35/49 (71,4)	12/21 (57,1)	1,25 [0,83; 1,88]	1,88 [0,65; 5,43]	14,29 [-10,37; 38,94]
0,276					
Never	131/199 (65,8)	58/95 (61,1)	1,08 [0,89; 1,30]	1,23 [0,74; 2,04]	4,78 [-7,04; 16,59]
0,437					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,224)					
Ever	191/280 (68,2)	87/140 (62,1)	1,10 [0,94; 1,28]	1,31 [0,86; 2,00]	6,07 [-3,64; 15,78]
0,230					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Never	12/20 (60,0)	1/5 (20,0)	3,00 [0,50; 17,95]	6,00 [0,56; 63,98]	40,00 [-1,11; 81,11]
0,160					
Prior anti-TNF failure (p-value of the interaction test: 0,939)					
Ever	193/282 (68,4)	85/139 (61,2)	1,12 [0,96; 1,31]	1,38 [0,90; 2,10]	7,29 [-2,46; 17,04]
0,155					
Never	10/18 (55,6)	3/6 (50,0)	1,11 [0,45; 2,73]	1,25 [0,20; 7,96]	5,56 [-40,57; 51,68]
1,000					
Prior anti-integrin failure (p-value of the interaction test: 0,728)					
Ever	45/71 (63,4)	18/31 (58,1)	1,09 [0,77; 1,55]	1,25 [0,53; 2,96]	5,32 [-15,36; 25,99]
0,661					
Never	158/229 (69,0)	70/114 (61,4)	1,12 [0,95; 1,33]	1,40 [0,87; 2,24]	7,59 [-3,17; 18,35]
0,182					
Baseline corticosteroid use (p-value of the interaction test: 0,241)					
Yes	50/76 (65,8)	27/39 (69,2)	0,95 [0,73; 1,24]	0,85 [0,37; 1,96]	-3,44 [-21,43; 14,55]
0,835					
No	153/224 (68,3)	61/106 (57,5)	1,19 [0,99; 1,43]	1,59 [0,99; 2,56]	10,76 [-0,45; 21,97]
0,064					
Baseline immunomodulator use (p-value of the interaction test: 0,105)					
Yes	46/66 (69,7)	19/39 (48,7)	1,43 [1,00; 2,05]	2,42 [1,07; 5,49]	20,98 [1,77; 40,19]
0,039					
No	157/234 (67,1)	69/106 (65,1)	1,03 [0,87; 1,22]	1,09 [0,67; 1,77]	2,00 [-8,89; 12,89]
0,712					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Duration of CD (p-value of the interaction test: 0,180)					
<1 year	14/23 (60,9)	3/9 (33,3)	1,83 [0,69; 4,87]	3,11 [0,62; 15,71]	27,54 [-9,16; 64,23]
				0,243	
≥1 to <5 years	77/104 (74,0)	25/44 (56,8)	1,30 [0,98; 1,73]	2,17 [1,03; 4,54]	17,22 [0,33; 34,11]
				0,052	
≥5 years	112/173 (64,7)	60/92 (65,2)	0,99 [0,82; 1,19]	0,98 [0,58; 1,66]	-0,48 [-12,54; 11,58]
				1,000	
Baseline disease location (p-value of the interaction test: 0,271)					
Colonic	83/120 (69,2)	36/59 (61,0)	1,13 [0,89; 1,44]	1,43 [0,75; 2,75]	8,15 [-6,79; 23,09]
				0,314	
Ileal	17/32 (53,1)	5/6 (83,3)	0,64 [0,39; 1,03]	0,23 [0,02; 2,16]	-30,21 [-64,68; 4,26]
				0,370	
Ileal-Colonic	103/148 (69,6)	47/80 (58,8)	1,18 [0,96; 1,46]	1,61 [0,91; 2,83]	10,84 [-2,24; 23,93]
				0,109	
Baseline AP average (p-value of the interaction test: 0,764)					
<2	43/72 (59,7)	24/48 (50,0)	1,19 [0,85; 1,68]	1,48 [0,71; 3,10]	9,72 [-8,40; 27,84]
				0,350	
≥2	160/226 (70,8)	64/97 (66,0)	1,07 [0,91; 1,27]	1,25 [0,75; 2,08]	4,82 [-6,32; 15,95]
				0,430	
Baseline SF average (p-value of the interaction test: 0,137)					
<7	151/220 (68,6)	57/100 (57,0)	1,20 [0,99; 1,46]	1,65 [1,01; 2,69]	11,64 [0,16; 23,11]
				0,058	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
≥7	49/76 (64,5)	31/45 (68,9)	0,94 [0,72; 1,21]	0,82 [0,37; 1,80]	-4,42 [-21,70; 12,87]
0,693					
Baseline CDAI 1 (p-value of the interaction test: 0,856)					
<300	68/109 (62,4)	33/59 (55,9)	1,12 [0,85; 1,46]	1,31 [0,69; 2,49]	6,45 [-9,14; 22,05]
0,509					
≥300	131/184 (71,2)	55/84 (65,5)	1,09 [0,91; 1,30]	1,30 [0,75; 2,26]	5,72 [-6,37; 17,81]
0,392					
Baseline CDAI 2 (p-value of the interaction test: 0,493)					
<220	18/29 (62,1)	4/12 (33,3)	1,86 [0,80; 4,35]	3,27 [0,79; 13,48]	28,74 [-3,25; 60,72]
0,168					
≥220 and <450	170/244 (69,7)	78/119 (65,5)	1,06 [0,91; 1,24]	1,21 [0,76; 1,92]	4,13 [-6,18; 14,43]
0,471					
≥450	11/20 (55,0)	6/12 (50,0)	1,10 [0,55; 2,19]	1,22 [0,29; 5,13]	5,00 [-30,72; 40,72]
1,000					
OECD Country (p-value of the interaction test: 0,585)					
Yes	120/178 (67,4)	52/83 (62,7)	1,08 [0,89; 1,31]	1,23 [0,72; 2,13]	4,77 [-7,71; 17,24]
0,485					
No	83/122 (68,0)	36/62 (58,1)	1,17 [0,92; 1,50]	1,54 [0,82; 2,89]	9,97 [-4,84; 24,78]
0,195					

	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Subgruppe			p-Wert ^a		
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PGRS: Patient Global Rating of Severity; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SF: Stool Frequency; TNF: Tumor Necrosis Factor. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_pgarsi1_sub_ittb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Gesundheitszustand – PGIC

Subgruppen für Reaching a value of 1 or 2 or 3 of PGIC Score in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Age 1 (p-value of the interaction test: 0,547)					
<65 years	224/287 (78,0)	101/141 (71,6)	1,09 [0,97; 1,23]	1,41 [0,89; 2,23]	6,42 [-2,43; 15,27]
				0,150	
≥65 years	8/13 (61,5)	3/4 (75,0)	0,82 [0,40; 1,67]	0,53 [0,04; 6,65]	-13,46 [-63,46; 36,54]
				1,000	
Age 2 (p-value of the interaction test: 0,386)					
<40 years	159/202 (78,7)	64/91 (70,3)	1,12 [0,96; 1,30]	1,56 [0,89; 2,74]	8,38 [-2,57; 19,34]
				0,139	
≥40 years	73/98 (74,5)	40/54 (74,1)	1,01 [0,83; 1,22]	1,02 [0,48; 2,18]	0,42 [-14,11; 14,95]
				1,000	
Sex (p-value of the interaction test: 0,430)					
Male	142/179 (79,3)	46/65 (70,8)	1,12 [0,94; 1,33]	1,59 [0,83; 3,02]	8,56 [-3,99; 21,11]
				0,171	
Female	90/121 (74,4)	58/80 (72,5)	1,03 [0,86; 1,22]	1,10 [0,58; 2,08]	1,88 [-10,62; 14,38]
				0,870	
Weight (p-value of the interaction test: 0,987)					
<100 kg	222/284 (78,2)	101/140 (72,1)	1,08 [0,96; 1,22]	1,38 [0,87; 2,20]	6,03 [-2,82; 14,87]
				0,183	
≥100 kg	10/15 (66,7)	3/5 (60,0)	1,11 [0,50; 2,47]	1,33 [0,17; 10,74]	6,67 [-42,46; 55,79]
				1,000	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
BMI (p-value of the interaction test: 0,474)					
Underweight (<18.5 kg/m ²)	39/54 (72,2)	23/32 (71,9)	1,00 [0,77; 1,32]	1,02 [0,38; 2,69]	0,35 [-19,28; 19,98]
				1,000	
Normal (≥18.5 and <25 kg/m ²)	131/161 (81,4)	41/60 (68,3)	1,19 [0,99; 1,44]	2,02 [1,03; 3,97]	13,03 [-0,18; 26,25]
				0,046	
Overweight (≥25 and <30 kg/m ²)	41/55 (74,5)	29/38 (76,3)	0,98 [0,77; 1,24]	0,91 [0,35; 2,38]	-1,77 [-19,53; 15,98]
				1,000	
Obese and Extreme obese (≥30 kg/m ²)	21/29 (72,4)	11/15 (73,3)	0,99 [0,68; 1,44]	0,95 [0,23; 3,89]	-0,92 [-28,59; 26,75]
				1,000	
Tobacco use (p-value of the interaction test: 0,610)					
Current	39/52 (75,0)	22/29 (75,9)	0,99 [0,76; 1,28]	0,95 [0,33; 2,75]	-0,86 [-20,38; 18,66]
				1,000	
Former	36/49 (73,5)	12/21 (57,1)	1,29 [0,86; 1,93]	2,08 [0,71; 6,07]	16,33 [-8,18; 40,84]
				0,261	
Never	157/199 (78,9)	70/95 (73,7)	1,07 [0,93; 1,23]	1,34 [0,76; 2,36]	5,21 [-5,30; 15,72]
				0,373	
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,306)					
Ever	220/280 (78,6)	103/140 (73,6)	1,07 [0,95; 1,20]	1,32 [0,82; 2,11]	5,00 [-3,74; 13,74]
				0,270	
Never	12/20 (60,0)	1/5 (20,0)	3,00 [0,50; 17,95]	6,00 [0,56; 63,98]	40,00 [-1,11; 81,11]
				0,160	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Prior anti-TNF failure (p-value of the interaction test: 0,371)					
Ever	220/282 (78,0)	99/139 (71,2)	1,10 [0,97; 1,24]	1,43 [0,90; 2,28]	6,79 [-2,15; 15,74]
				0,147	
Never	12/18 (66,7)	5/6 (83,3)	0,80 [0,49; 1,30]	0,40 [0,04; 4,24]	-16,67 [-53,59; 20,26]
				0,629	
Prior anti-integrin failure (p-value of the interaction test: 0,262)					
Ever	52/71 (73,2)	24/31 (77,4)	0,95 [0,75; 1,20]	0,80 [0,30; 2,15]	-4,18 [-22,14; 13,78]
				0,806	
Never	180/229 (78,6)	80/114 (70,2)	1,12 [0,98; 1,29]	1,56 [0,94; 2,60]	8,43 [-1,51; 18,36]
				0,108	
Baseline corticosteroid use (p-value of the interaction test: 0,838)					
Yes	56/76 (73,7)	27/39 (69,2)	1,06 [0,83; 1,36]	1,24 [0,53; 2,91]	4,45 [-13,09; 22,00]
				0,663	
No	176/224 (78,6)	77/106 (72,6)	1,08 [0,94; 1,24]	1,38 [0,81; 2,35]	5,93 [-4,11; 15,97]
				0,265	
Baseline immunomodulator use (p-value of the interaction test: 0,258)					
Yes	52/66 (78,8)	25/39 (64,1)	1,23 [0,94; 1,60]	2,08 [0,86; 5,02]	14,69 [-3,31; 32,68]
				0,114	
No	180/234 (76,9)	79/106 (74,5)	1,03 [0,90; 1,18]	1,14 [0,67; 1,94]	2,39 [-7,50; 12,29]
				0,681	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Duration of CD (p-value of the interaction test: 0,127)					
<1 year	16/23 (69,6)	3/9 (33,3)	2,09 [0,80; 5,47]	4,57 [0,88; 23,71]	36,23 [0,15; 72,32]
				0,109	
≥1 to <5 years	88/104 (84,6)	32/44 (72,7)	1,16 [0,95; 1,42]	2,06 [0,88; 4,83]	11,89 [-2,99; 26,76]
				0,110	
≥5 years	128/173 (74,0)	69/92 (75,0)	0,99 [0,85; 1,14]	0,95 [0,53; 1,70]	-1,01 [-12,01; 9,99]
				0,884	
Baseline disease location (p-value of the interaction test: 0,213)					
Colonic	94/120 (78,3)	38/59 (64,4)	1,22 [0,98; 1,50]	2,00 [1,00; 3,97]	13,93 [-0,34; 28,20]
				0,070	
Ileal	20/32 (62,5)	6/6 (100)	0,67 [0,48; 0,94]	0,13 [0,01; 2,44]	-37,50 [-54,27; -20,73]
				0,149	
Ileal-Colonic	118/148 (79,7)	60/80 (75,0)	1,06 [0,91; 1,24]	1,31 [0,69; 2,50]	4,73 [-6,76; 16,22]
				0,408	
Baseline CRP (p-value of the interaction test: 0,061)					
≤10	109/145 (75,2)	46/58 (79,3)	0,95 [0,81; 1,11]	0,79 [0,38; 1,65]	-4,14 [-16,71; 8,44]
				0,587	
>10	123/154 (79,9)	58/87 (66,7)	1,20 [1,01; 1,42]	1,98 [1,09; 3,60]	13,20 [1,45; 24,96]
				0,030	
Baseline SES-CD total score (p-value of the interaction test: 0,053)					
<12	107/143 (74,8)	52/66 (78,8)	0,95 [0,81; 1,11]	0,80 [0,40; 1,61]	-3,96 [-16,12; 8,20]
				0,603	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
≥12	125/157 (79,6)	52/79 (65,8)	1,21 [1,01; 1,44]	2,03 [1,11; 3,72]	13,80 [1,58; 26,01]
0,026					
Baseline AP average (p-value of the interaction test: 0,529)					
<2	57/72 (79,2)	33/48 (68,8)	1,15 [0,92; 1,44]	1,73 [0,75; 3,98]	10,42 [-5,71; 26,54]
0,206					
≥2	175/226 (77,4)	71/97 (73,2)	1,06 [0,92; 1,22]	1,26 [0,73; 2,17]	4,24 [-6,13; 14,60]
0,476					
Baseline SF average (p-value of the interaction test: 0,268)					
<7	175/220 (79,5)	71/100 (71,0)	1,12 [0,97; 1,29]	1,59 [0,92; 2,73]	8,55 [-1,82; 18,91]
0,115					
≥7	54/76 (71,1)	33/45 (73,3)	0,97 [0,77; 1,22]	0,89 [0,39; 2,04]	-2,28 [-18,74; 14,18]
0,837					
Baseline CDAI 1 (p-value of the interaction test: 0,967)					
<300	85/109 (78,0)	43/59 (72,9)	1,07 [0,89; 1,29]	1,32 [0,63; 2,74]	5,10 [-8,65; 18,86]
0,456					
≥300	143/184 (77,7)	61/84 (72,6)	1,07 [0,92; 1,25]	1,32 [0,73; 2,38]	5,10 [-6,17; 16,37]
0,360					
Baseline CDAI 2 (p-value of the interaction test: 0,757)					
<220	22/29 (75,9)	8/12 (66,7)	1,14 [0,73; 1,78]	1,57 [0,36; 6,84]	9,20 [-21,69; 40,08]
0,701					
≥220 and <450	194/244 (79,5)	88/119 (73,9)	1,08 [0,95; 1,22]	1,37 [0,82; 2,29]	5,56 [-3,81; 14,93]
0,283					

Subgruppe	Mirikizumab Pat. mit Ereignis n/N (%)	Ustekinumab Pat. mit Ereignis n/N (%)	Mirikizumab vs. Ustekinumab		
			RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
≥450	12/20 (60,0)	8/12 (66,7)	0,90 [0,53; 1,54]	0,75 [0,17; 3,35]	-6,67 [-40,91; 27,57]
1,000					
OECD Country (p-value of the interaction test: 0,410)					
Yes	137/178 (77,0)	62/83 (74,7)	1,03 [0,89; 1,20]	1,13 [0,62; 2,07]	2,27 [-8,95; 13,48]
0,755					
No	95/122 (77,9)	42/62 (67,7)	1,15 [0,94; 1,40]	1,68 [0,85; 3,32]	10,13 [-3,64; 23,90]
0,154					
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PGIC: Patient Global Impression of Change; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_pgici_sub_ittb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Gesundheitszustand – WPAI-CD (Aktivitätsbeeinträchtigung)

Subgruppen für Reduction in percentage of impairment in activities by at least 15 percent-points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population, Participants with baseline employment status of Yes)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Age 2 (p-value of the interaction test: 0,953)					
<40 years	69/118 (58,5)	27/48 (56,3)	1,04 [0,78; 1,39]	1,10 [0,56; 2,16]	2,22 [-14,39; 18,84]
			0,863		
≥40 years	30/55 (54,5)	16/32 (50,0)	1,09 [0,72; 1,66]	1,20 [0,50; 2,87]	4,55 [-17,21; 26,30]
			0,824		
Sex (p-value of the interaction test: 0,870)					
Male	63/115 (54,8)	21/42 (50,0)	1,10 [0,78; 1,55]	1,21 [0,60; 2,46]	4,78 [-12,86; 22,43]
			0,718		
Female	36/58 (62,1)	22/38 (57,9)	1,07 [0,76; 1,50]	1,19 [0,52; 2,74]	4,17 [-15,88; 24,23]
			0,831		
Race (p-value of the interaction test: 0,424)					
Asian	34/62 (54,8)	13/27 (48,1)	1,14 [0,72; 1,79]	1,31 [0,53; 3,23]	6,69 [-15,86; 29,24]
			0,646		
White	59/101 (58,4)	26/49 (53,1)	1,10 [0,81; 1,50]	1,24 [0,63; 2,47]	5,35 [-11,61; 22,31]
			0,599		
Other	4/8 (50,0)	4/4 (100)	0,56 [0,27; 1,14]	0,11 [0,00; 2,73]	-50,00 [-84,65; -15,35]
			0,208		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Geographic region 1 (p-value of the interaction test: 0,953)					
Europe	41/65 (63,1)	16/27 (59,3)	1,06 [0,74; 1,53]	1,17 [0,47; 2,94]	3,82 [-18,12; 25,75]
				0,815	
North America	20/34 (58,8)	10/17 (58,8)	1,00 [0,61; 1,63]	1,00 [0,31; 3,26]	0,00 [-28,65; 28,65]
				1,000	
Other	38/74 (51,4)	17/36 (47,2)	1,09 [0,72; 1,64]	1,18 [0,53; 2,62]	4,13 [-15,76; 24,02]
				0,839	
Geographic region 2 (p-value of the interaction test: 0,695)					
Asia	35/63 (55,6)	12/27 (44,4)	1,25 [0,78; 2,01]	1,56 [0,63; 3,87]	11,11 [-11,29; 33,51]
				0,365	
Central America/South America	3/9 (33,3)	5/9 (55,6)	0,60 [0,20; 1,79]	0,40 [0,06; 2,70]	-22,22 [-66,97; 22,53]
				0,637	
Europe and ROW	41/67 (61,2)	16/27 (59,3)	1,03 [0,72; 1,49]	1,08 [0,44; 2,70]	1,93 [-19,97; 23,84]
				1,000	
North America	20/34 (58,8)	10/17 (58,8)	1,00 [0,61; 1,63]	1,00 [0,31; 3,26]	0,00 [-28,65; 28,65]
				1,000	
Weight (p-value of the interaction test: 0,414)					
<100 kg	92/162 (56,8)	42/76 (55,3)	1,03 [0,81; 1,31]	1,06 [0,61; 1,84]	1,53 [-12,01; 15,06]
				0,889	
≥100 kg	7/11 (63,6)	1/4 (25,0)	2,55 [0,44; 14,72]	5,25 [0,40; 68,95]	38,64 [-12,44; 89,71]
				0,282	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
BMI (p-value of the interaction test: 0,576)					
Underweight ($<18.5 \text{ kg/m}^2$)	16/29 (55,2)	8/14 (57,1)	0,97 [0,55; 1,69]	0,92 [0,25; 3,34]	-1,97 [-33,59; 29,65]
			1,000		
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	49/88 (55,7)	19/34 (55,9)	1,00 [0,70; 1,42]	0,99 [0,45; 2,20]	-0,20 [-19,85; 19,45]
			1,000		
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	22/36 (61,1)	13/21 (61,9)	0,99 [0,65; 1,51]	0,97 [0,32; 2,92]	-0,79 [-26,97; 25,38]
			1,000		
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	12/20 (60,0)	3/11 (27,3)	2,20 [0,79; 6,16]	4,00 [0,81; 19,82]	32,73 [-1,24; 66,69]
			0,135		
Tobacco use (p-value of the interaction test: 0,654)					
Current	17/25 (68,0)	10/20 (50,0)	1,36 [0,81; 2,27]	2,13 [0,63; 7,16]	18,00 [-10,54; 46,54]
			0,241		
Former	14/26 (53,8)	6/12 (50,0)	1,08 [0,55; 2,10]	1,17 [0,30; 4,59]	3,85 [-30,32; 38,01]
			1,000		
Never	68/122 (55,7)	27/48 (56,3)	0,99 [0,74; 1,33]	0,98 [0,50; 1,92]	-0,51 [-17,08; 16,06]
			1,000		
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,812)					
Ever	95/161 (59,0)	42/77 (54,5)	1,08 [0,85; 1,38]	1,20 [0,69; 2,07]	4,46 [-9,01; 17,93]
			0,576		
Never	4/12 (33,3)	1/3 (33,3)	1,00 [0,17; 5,98]	1,00 [0,07; 14,64]	0,00 [-59,64; 59,64]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Prior anti-TNF failure (p-value of the interaction test: 0,711)					
Ever	95/166 (57,2)	41/75 (54,7)	1,05 [0,82; 1,34]	1,11 [0,64; 1,92]	2,56 [-10,99; 16,11]
			0,779		
Never	4/7 (57,1)	2/5 (40,0)	1,43 [0,41; 4,99]	2,00 [0,19; 20,61]	17,14 [-39,32; 73,60]
			1,000		
Prior anti-integrin failure (p-value of the interaction test: 0,877)					
Ever	18/32 (56,3)	7/14 (50,0)	1,13 [0,61; 2,06]	1,29 [0,37; 4,53]	6,25 [-25,08; 37,58]
			0,755		
Never	81/141 (57,4)	36/66 (54,5)	1,05 [0,81; 1,37]	1,13 [0,62; 2,03]	2,90 [-11,62; 17,42]
			0,764		
Baseline immunomodulator use (p-value of the interaction test: 0,199)					
Yes	20/38 (52,6)	5/16 (31,3)	1,68 [0,77; 3,70]	2,44 [0,71; 8,40]	21,38 [-6,33; 49,09]
			0,232		
No	79/135 (58,5)	38/64 (59,4)	0,99 [0,77; 1,26]	0,97 [0,53; 1,77]	-0,86 [-15,48; 13,77]
			1,000		
Duration of CD (p-value of the interaction test: 0,913)					
<1 year	4/11 (36,4)	1/4 (25,0)	1,45 [0,22; 9,43]	1,71 [0,13; 22,51]	11,36 [-39,71; 62,44]
			1,000		
≥1 to <5 years	34/59 (57,6)	9/19 (47,4)	1,22 [0,72; 2,05]	1,51 [0,54; 4,27]	10,26 [-15,49; 36,01]
			0,597		
≥5 years	61/103 (59,2)	33/57 (57,9)	1,02 [0,78; 1,34]	1,06 [0,55; 2,04]	1,33 [-14,62; 17,28]
			0,869		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline disease location (p-value of the interaction test: 0,540)					
Colonic	41/68 (60,3)	15/32 (46,9)	1,29 [0,85; 1,95]	1,72 [0,74; 4,02]	13,42 [-7,42; 34,26]
				0,280	
Ileal	9/20 (45,0)	2/4 (50,0)	0,90 [0,30; 2,69]	0,82 [0,10; 7,02]	-5,00 [-58,63; 48,63]
				1,000	
Ileal-Colonic	49/85 (57,6)	26/44 (59,1)	0,98 [0,72; 1,32]	0,94 [0,45; 1,97]	-1,44 [-19,37; 16,48]
				1,000	
Baseline fecal calprotectin (p-value of the interaction test: 0,158)					
≤250	14/29 (48,3)	4/5 (80,0)	0,60 [0,34; 1,08]	0,23 [0,02; 2,35]	-31,72 [-71,22; 7,77]
				0,340	
>250	68/117 (58,1)	23/50 (46,0)	1,26 [0,90; 1,77]	1,63 [0,84; 3,17]	12,12 [-4,34; 28,57]
				0,176	
Baseline CRP (p-value of the interaction test: 0,377)					
≤10	49/90 (54,4)	21/36 (58,3)	0,93 [0,67; 1,30]	0,85 [0,39; 1,87]	-3,89 [-23,00; 15,22]
				0,843	
>10	50/83 (60,2)	22/44 (50,0)	1,20 [0,85; 1,70]	1,52 [0,73; 3,16]	10,24 [-7,90; 28,38]
				0,347	
Baseline SES-CD total score (p-value of the interaction test: 0,565)					
<12	51/86 (59,3)	19/38 (50,0)	1,19 [0,83; 1,71]	1,46 [0,68; 3,14]	9,30 [-9,69; 28,29]
				0,432	
≥12	48/87 (55,2)	24/42 (57,1)	0,97 [0,70; 1,33]	0,92 [0,44; 1,94]	-1,97 [-20,22; 16,28]
				0,852	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline AP average (p-value of the interaction test: 0,810)					
<2	21/48 (43,8)	9/24 (37,5)	1,17 [0,64; 2,14]	1,30 [0,47; 3,54]	6,25 [-17,67; 30,17]
				0,800	
≥2	78/125 (62,4)	34/56 (60,7)	1,03 [0,80; 1,32]	1,07 [0,56; 2,05]	1,69 [-13,67; 17,04]
				0,869	
Baseline SF average (p-value of the interaction test: 0,106)					
<7	75/134 (56,0)	27/59 (45,8)	1,22 [0,89; 1,68]	1,51 [0,81; 2,79]	10,21 [-5,03; 25,45]
				0,213	
≥7	22/37 (59,5)	16/21 (76,2)	0,78 [0,55; 1,12]	0,46 [0,14; 1,52]	-16,73 [-40,86; 7,40]
				0,256	
Baseline CDAI 1 (p-value of the interaction test: 0,097)					
<300	33/65 (50,8)	11/32 (34,4)	1,48 [0,86; 2,52]	1,97 [0,82; 4,73]	16,39 [-4,06; 36,85]
				0,137	
≥300	63/105 (60,0)	31/46 (67,4)	0,89 [0,69; 1,15]	0,73 [0,35; 1,51]	-7,39 [-23,86; 9,08]
				0,467	
Baseline CDAI 2 (p-value of the interaction test: 0,339)					
<220	9/20 (45,0)	0/6 (0,0)	6,33 [0,42; 95,39]	10,74 [0,53; >100]	45,00 [23,20; 66,80]
				0,063	
≥220 and <450	80/140 (57,1)	40/70 (57,1)	1,00 [0,78; 1,28]	1,00 [0,56; 1,79]	0,00 [-14,20; 14,20]
				1,000	
≥450	7/10 (70,0)	2/2 (100)	0,82 [0,43; 1,56]	0,43 [0,02; 11,51]	-30,00 [-58,40; -1,60]
				1,000	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
OECD Country (p-value of the interaction test: 0,347)					
Yes	66/104 (63,5)	29/52 (55,8)	1,14 [0,86; 1,51]	1,38 [0,70; 2,71]	7,69 [-8,67; 24,06]
			0,387		
No	33/69 (47,8)	14/28 (50,0)	0,96 [0,61; 1,49]	0,92 [0,38; 2,21]	-2,17 [-24,13; 19,78]
			1,000		
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_wpaii15p_sub_empl_itb_a.rtf

Dataset Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Allgemeinbefinden - CDAI-GWP

Subgruppen für Reduction in General well being score by at least 0.6 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Subgruppe			p-Wert ^a		
Age 1 (p-value of the interaction test: 0,426)					
<65 years	196/287 (68,3)	83/141 (58,9)	1,16 [0,99; 1,36]	1,51 [0,99; 2,29]	9,43 [-0,32; 19,17]
			0,066		
≥65 years	9/13 (69,2)	1/4 (25,0)	2,77 [0,49; 15,71]	6,75 [0,53; 86,56]	44,23 [-5,07; 93,53]
			0,250		
Age 2 (p-value of the interaction test: 0,921)					
<40 years	136/202 (67,3)	51/91 (56,0)	1,20 [0,98; 1,48]	1,62 [0,97; 2,69]	11,28 [-0,79; 23,36]
			0,067		
≥40 years	69/98 (70,4)	33/54 (61,1)	1,15 [0,90; 1,48]	1,51 [0,75; 3,04]	9,30 [-6,54; 25,13]
			0,281		
Sex (p-value of the interaction test: 0,354)					
Male	126/179 (70,4)	36/65 (55,4)	1,27 [1,00; 1,61]	1,92 [1,07; 3,44]	15,01 [1,19; 28,82]
			0,032		
Female	79/121 (65,3)	48/80 (60,0)	1,09 [0,87; 1,36]	1,25 [0,70; 2,25]	5,29 [-8,39; 18,97]
			0,459		
Race (p-value of the interaction test: 0,090)					
Asian	76/100 (76,0)	29/56 (51,8)	1,47 [1,11; 1,93]	2,95 [1,47; 5,92]	24,21 [8,68; 39,75]
			0,003		
White	116/180 (64,4)	51/82 (62,2)	1,04 [0,85; 1,27]	1,10 [0,64; 1,89]	2,25 [-10,36; 14,86]
			0,782		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Other	8/13 (61,5)	4/7 (57,1)	1,08 [0,50; 2,33]	1,20 [0,19; 7,77]	4,40 [-40,81; 49,60]
1,000					
Geographic region 1 (p-value of the interaction test: 0,059)					
Europe	78/114 (68,4)	34/50 (68,0)	1,01 [0,80; 1,26]	1,02 [0,50; 2,08]	0,42 [-15,07; 15,91]
1,000					
North America	30/54 (55,6)	15/26 (57,7)	0,96 [0,64; 1,45]	0,92 [0,36; 2,36]	-2,14 [-25,29; 21,02]
1,000					
Other	97/132 (73,5)	35/69 (50,7)	1,45 [1,12; 1,87]	2,69 [1,46; 4,95]	22,76 [8,77; 36,76]
0,002					
Geographic region 2 (p-value of the interaction test: 0,096)					
Asia	78/105 (74,3)	28/56 (50,0)	1,49 [1,12; 1,98]	2,89 [1,46; 5,72]	24,29 [8,75; 39,82]
0,003					
Central America/South America	18/24 (75,0)	7/13 (53,8)	1,39 [0,80; 2,42]	2,57 [0,62; 10,74]	21,15 [-11,01; 53,32]
0,274					
Europe and ROW	79/117 (67,5)	34/50 (68,0)	0,99 [0,79; 1,25]	0,98 [0,48; 1,99]	-0,48 [-15,94; 14,99]
1,000					
North America	30/54 (55,6)	15/26 (57,7)	0,96 [0,64; 1,45]	0,92 [0,36; 2,36]	-2,14 [-25,29; 21,02]
1,000					
Weight (p-value of the interaction test: 0,392)					
<100 kg	196/284 (69,0)	83/140 (59,3)	1,16 [0,99; 1,36]	1,53 [1,00; 2,33]	9,73 [-0,03; 19,48]
0,051					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
≥100 kg	9/15 (60,0)	1/5 (20,0)	3,00 [0,50; 18,17]	6,00 [0,53; 67,65]	40,00 [-2,94; 82,94]
0,303					
BMI (p-value of the interaction test: 0,884)					
Underweight ($<18.5 \text{ kg/m}^2$)	34/54 (63,0)	16/32 (50,0)	1,26 [0,84; 1,88]	1,70 [0,70; 4,12]	12,96 [-8,62; 34,55]
0,265					
Normal (≥18.5 and <25 kg/m ²)	115/161 (71,4)	39/60 (65,0)	1,10 [0,89; 1,36]	1,35 [0,72; 2,53]	6,43 [-7,51; 20,37]
0,411					
Overweight (≥25 and <30 kg/m ²)	40/55 (72,7)	22/38 (57,9)	1,26 [0,92; 1,72]	1,94 [0,81; 4,66]	14,83 [-4,79; 34,45]
0,180					
Obese and Extreme obese (≥30 kg/m ²)	16/29 (55,2)	7/15 (46,7)	1,18 [0,63; 2,23]	1,41 [0,40; 4,91]	8,51 [-22,56; 39,57]
0,752					
Tobacco use (p-value of the interaction test: 0,430)					
Current	33/52 (63,5)	17/29 (58,6)	1,08 [0,75; 1,57]	1,23 [0,48; 3,11]	4,84 [-17,35; 27,04]
0,812					
Former	34/49 (69,4)	9/21 (42,9)	1,62 [0,96; 2,74]	3,02 [1,05; 8,69]	26,53 [1,74; 51,32]
0,060					
Never	138/199 (69,3)	58/95 (61,1)	1,14 [0,94; 1,37]	1,44 [0,87; 2,41]	8,29 [-3,42; 20,01]
0,186					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,826)					
Ever	194/280 (69,3)	82/140 (58,6)	1,18 [1,01; 1,39]	1,60 [1,05; 2,43]	10,71 [0,93; 20,50]
0,038					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Never	11/20 (55,0)	2/5 (40,0)	1,38 [0,44; 4,32]	1,83 [0,25; 13,47]	15,00 [-33,16; 63,16]
0,645					
Prior anti-TNF failure (p-value of the interaction test: 0,825)					
Ever	193/282 (68,4)	81/139 (58,3)	1,17 [1,00; 1,38]	1,55 [1,02; 2,36]	10,17 [0,34; 20,00]
0,050					
Never	12/18 (66,7)	3/6 (50,0)	1,33 [0,56; 3,16]	2,00 [0,31; 13,06]	16,67 [-28,88; 62,22]
0,635					
Prior anti-integrin failure (p-value of the interaction test: 0,928)					
Ever	50/71 (70,4)	18/31 (58,1)	1,21 [0,87; 1,70]	1,72 [0,72; 4,13]	12,36 [-8,00; 32,72]
0,258					
Never	155/229 (67,7)	66/114 (57,9)	1,17 [0,98; 1,40]	1,52 [0,96; 2,42]	9,79 [-1,11; 20,69]
0,093					
Baseline corticosteroid use (p-value of the interaction test: 0,946)					
Yes	50/76 (65,8)	22/39 (56,4)	1,17 [0,85; 1,61]	1,49 [0,67; 3,28]	9,38 [-9,49; 28,25]
0,416					
No	155/224 (69,2)	62/106 (58,5)	1,18 [0,99; 1,42]	1,59 [0,99; 2,57]	10,71 [-0,45; 21,87]
0,063					
Baseline immunomodulator use (p-value of the interaction test: 0,147)					
Yes	47/66 (71,2)	19/39 (48,7)	1,46 [1,02; 2,09]	2,60 [1,14; 5,93]	22,49 [3,38; 41,61]
0,036					
No	158/234 (67,5)	65/106 (61,3)	1,10 [0,92; 1,31]	1,31 [0,81; 2,11]	6,20 [-4,84; 17,24]
0,270					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Duration of CD (p-value of the interaction test: 0,110)					
<1 year	15/23 (65,2)	1/9 (11,1)	5,87 [0,90; 38,15]	15,00 [1,58; >100]	54,11 [25,81; 82,40]
			0,015		
≥1 to <5 years	74/104 (71,2)	25/44 (56,8)	1,25 [0,94; 1,67]	1,87 [0,90; 3,90]	14,34 [-2,69; 31,37]
			0,126		
≥5 years	116/173 (67,1)	58/92 (63,0)	1,06 [0,88; 1,28]	1,19 [0,70; 2,02]	4,01 [-8,09; 16,11]
			0,587		
Baseline disease location (p-value of the interaction test: 0,101)					
Colonic	84/120 (70,0)	30/59 (50,8)	1,38 [1,04; 1,82]	2,26 [1,19; 4,29]	19,15 [3,99; 34,32]
			0,014		
Ileal	17/32 (53,1)	6/6 (100)	0,57 [0,39; 0,84]	0,09 [0,00; 1,67]	-46,88 [-64,16; -29,59]
			0,063		
Ileal-Colonic	104/148 (70,3)	48/80 (60,0)	1,17 [0,95; 1,44]	1,58 [0,89; 2,78]	10,27 [-2,75; 23,29]
			0,141		
Baseline fecal calprotectin (p-value of the interaction test: 0,053)					
≤250	19/38 (50,0)	10/15 (66,7)	0,75 [0,46; 1,21]	0,50 [0,14; 1,74]	-16,67 [-45,33; 12,00]
			0,363		
>250	149/208 (71,6)	51/93 (54,8)	1,31 [1,07; 1,60]	2,08 [1,25; 3,46]	16,80 [4,97; 28,62]
			0,005		
Baseline CRP (p-value of the interaction test: 0,103)					
≤10	88/145 (60,7)	34/58 (58,6)	1,04 [0,80; 1,33]	1,09 [0,59; 2,03]	2,07 [-12,89; 17,03]
			0,874		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
>10	117/154 (76,0)	50/87 (57,5)	1,32 [1,08; 1,62]	2,34 [1,33; 4,11]	18,50 [6,12; 30,89]
0,004					
Baseline AP average (p-value of the interaction test: 0,111)					
<2	42/72 (58,3)	17/48 (35,4)	1,65 [1,07; 2,53]	2,55 [1,20; 5,43]	22,92 [5,23; 40,60]
0,016					
≥2	163/226 (72,1)	67/97 (69,1)	1,04 [0,89; 1,22]	1,16 [0,69; 1,95]	3,05 [-7,85; 13,95]
0,594					
Baseline SF average (p-value of the interaction test: 0,490)					
<7	150/220 (68,2)	55/100 (55,0)	1,24 [1,02; 1,51]	1,75 [1,08; 2,85]	13,18 [1,65; 24,71]
0,024					
≥7	53/76 (69,7)	29/45 (64,4)	1,08 [0,83; 1,41]	1,27 [0,58; 2,78]	5,29 [-12,09; 22,68]
0,553					
Baseline CDAI 1 (p-value of the interaction test: 0,269)					
<300	66/109 (60,6)	25/59 (42,4)	1,43 [1,02; 2,00]	2,09 [1,10; 3,97]	18,18 [2,58; 33,77]
0,035					
≥300	137/184 (74,5)	59/84 (70,2)	1,06 [0,90; 1,25]	1,24 [0,70; 2,19]	4,22 [-7,41; 15,85]
0,463					
Baseline CDAI 2 (p-value of the interaction test: 0,160)					
<220	15/29 (51,7)	1/12 (8,3)	6,21 [0,92; 41,88]	11,79 [1,34; >100]	43,39 [19,41; 67,38]
0,013					
≥220 and <450	176/244 (72,1)	75/119 (63,0)	1,14 [0,98; 1,34]	1,52 [0,95; 2,42]	9,11 [-1,23; 19,44]
0,090					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
≥450	12/20 (60,0)	8/12 (66,7)	0,90 [0,53; 1,54]	0,75 [0,17; 3,35]	-6,67 [-40,91; 27,57]
1,000					
OECD Country (p-value of the interaction test: 0,281)					
Yes	120/178 (67,4)	51/83 (61,4)	1,10 [0,90; 1,34]	1,30 [0,76; 2,23]	5,97 [-6,56; 18,50]
0,402					
No	85/122 (69,7)	33/62 (53,2)	1,31 [1,01; 1,70]	2,02 [1,07; 3,79]	16,45 [1,59; 31,31]
0,035					
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SF: Stool Frequency; TNF: Tumor Necrosis Factor. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_gwbi0_6_sub_itb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

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Anhang 4-G.4.6.2 Gesundheitsbezogene Lebensqualität**Krankheitsspezifische Lebensqualität**

Subgruppen für Increase in IBDQ Total Score by at least 28.8 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,238)					
<65 years	160/287 (55,7)	75/141 (53,2)	1,05 [0,87; 1,26]	1,11 [0,74; 1,66]	2,56 [-7,48; 12,60]
			0,679		
≥65 years	7/13 (53,8)	0/4 (0,0)	5,36 [0,37; 77,70]	10,38 [0,47; >100]	53,85 [26,75; 80,95]
			0,103		
Age 2 (p-value of the interaction test: 0,634)					
<40 years	116/202 (57,4)	47/91 (51,6)	1,11 [0,88; 1,40]	1,26 [0,77; 2,08]	5,78 [-6,55; 18,10]
			0,376		
≥40 years	51/98 (52,0)	28/54 (51,9)	1,00 [0,73; 1,38]	1,01 [0,52; 1,96]	0,19 [-16,41; 16,79]
			1,000		
Sex (p-value of the interaction test: 0,354)					
Male	96/179 (53,6)	35/65 (53,8)	1,00 [0,77; 1,30]	0,99 [0,56; 1,75]	-0,21 [-14,37; 13,94]
			1,000		
Female	71/121 (58,7)	40/80 (50,0)	1,17 [0,90; 1,53]	1,42 [0,80; 2,51]	8,68 [-5,36; 22,71]
			0,248		
Weight (p-value of the interaction test: 0,482)					
<100 kg	160/284 (56,3)	74/140 (52,9)	1,07 [0,88; 1,28]	1,15 [0,77; 1,73]	3,48 [-6,60; 13,56]
			0,534		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
≥100 kg	7/15 (46,7)	1/5 (20,0)	2,33 [0,37; 14,61]	3,50 [0,31; 39,15]	26,67 [-16,54; 69,87]
0,603					
BMI (p-value of the interaction test: 0,497)					
Underweight ($<18.5 \text{ kg/m}^2$)	29/54 (53,7)	14/32 (43,8)	1,23 [0,77; 1,95]	1,49 [0,62; 3,59]	9,95 [-11,78; 31,69]
0,504					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	94/161 (58,4)	32/60 (53,3)	1,09 [0,84; 1,43]	1,23 [0,68; 2,23]	5,05 [-9,69; 19,79]
0,543					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	29/55 (52,7)	24/38 (63,2)	0,83 [0,59; 1,18]	0,65 [0,28; 1,52]	-10,43 [-30,66; 9,80]
0,395					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	15/29 (51,7)	5/15 (33,3)	1,55 [0,70; 3,44]	2,14 [0,59; 7,84]	18,39 [-11,61; 48,39]
0,342					
Tobacco use (p-value of the interaction test: 0,980)					
Current	28/52 (53,8)	14/29 (48,3)	1,12 [0,71; 1,75]	1,25 [0,50; 3,10]	5,57 [-17,11; 28,25]
0,651					
Former	25/49 (51,0)	10/21 (47,6)	1,07 [0,63; 1,81]	1,15 [0,41; 3,19]	3,40 [-22,14; 28,94]
1,000					
Never	114/199 (57,3)	51/95 (53,7)	1,07 [0,85; 1,33]	1,16 [0,71; 1,89]	3,60 [-8,55; 15,76]
0,616					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,300)					
Ever	157/280 (56,1)	74/140 (52,9)	1,06 [0,88; 1,28]	1,14 [0,76; 1,71]	3,21 [-6,89; 13,32]
0,535					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Never	10/20 (50,0)	1/5 (20,0)	2,50 [0,41; 15,23]	4,00 [0,38; 42,37]	30,00 [-11,35; 71,35]
0,341					
Prior anti-TNF failure (p-value of the interaction test: 0,068)					
Ever	159/282 (56,4)	69/139 (49,6)	1,14 [0,93; 1,38]	1,31 [0,87; 1,97]	6,74 [-3,39; 16,87]
0,212					
Never	8/18 (44,4)	6/6 (100)	0,48 [0,28; 0,83]	0,06 [0,00; 1,27]	-55,56 [-78,51; -32,60]
0,024					
Prior anti-integrin failure (p-value of the interaction test: 0,096)					
Ever	36/71 (50,7)	19/31 (61,3)	0,83 [0,58; 1,19]	0,65 [0,28; 1,53]	-10,59 [-31,30; 10,13]
0,390					
Never	131/229 (57,2)	56/114 (49,1)	1,16 [0,94; 1,45]	1,38 [0,88; 2,17]	8,08 [-3,11; 19,28]
0,168					
Baseline corticosteroid use (p-value of the interaction test: 0,270)					
Yes	42/76 (55,3)	24/39 (61,5)	0,90 [0,65; 1,24]	0,77 [0,35; 1,70]	-6,28 [-25,20; 12,65]
0,556					
No	125/224 (55,8)	51/106 (48,1)	1,16 [0,92; 1,46]	1,36 [0,86; 2,16]	7,69 [-3,83; 19,21]
0,196					
Baseline immunomodulator use (p-value of the interaction test: 0,266)					
Yes	36/66 (54,5)	16/39 (41,0)	1,33 [0,86; 2,06]	1,73 [0,77; 3,84]	13,52 [-6,04; 33,08]
0,227					
No	131/234 (56,0)	59/106 (55,7)	1,01 [0,82; 1,23]	1,01 [0,64; 1,61]	0,32 [-11,07; 11,72]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Duration of CD (p-value of the interaction test: 0,285)					
<1 year	10/23 (43,5)	2/9 (22,2)	1,96 [0,53; 7,24]	2,69 [0,46; 15,88]	21,26 [-12,63; 55,14]
				0,422	
≥1 to <5 years	64/104 (61,5)	21/44 (47,7)	1,29 [0,91; 1,82]	1,75 [0,86; 3,57]	13,81 [-3,66; 31,28]
				0,147	
≥5 years	93/173 (53,8)	52/92 (56,5)	0,95 [0,76; 1,19]	0,89 [0,54; 1,49]	-2,76 [-15,33; 9,80]
				0,699	
Baseline disease location (p-value of the interaction test: 0,089)					
Colonic	72/120 (60,0)	25/59 (42,4)	1,42 [1,02; 1,97]	2,04 [1,08; 3,84]	17,63 [2,27; 32,98]
				0,038	
Ileal	11/32 (34,4)	3/6 (50,0)	0,69 [0,27; 1,75]	0,52 [0,09; 3,04]	-15,63 [-58,88; 27,63]
				0,650	
Ileal-Colonic	84/148 (56,8)	47/80 (58,8)	0,97 [0,77; 1,22]	0,92 [0,53; 1,60]	-1,99 [-15,41; 11,43]
				0,781	
Baseline fecal calprotectin (p-value of the interaction test: 0,058)					
≤250	12/38 (31,6)	9/15 (60,0)	0,53 [0,28; 0,98]	0,31 [0,09; 1,06]	-28,42 [-57,28; 0,44]
				0,070	
>250	120/208 (57,7)	48/93 (51,6)	1,12 [0,89; 1,40]	1,28 [0,78; 2,09]	6,08 [-6,10; 18,25]
				0,379	
Baseline CRP (p-value of the interaction test: 0,060)					
≤10	70/145 (48,3)	32/58 (55,2)	0,88 [0,66; 1,17]	0,76 [0,41; 1,40]	-6,90 [-22,06; 8,27]
				0,438	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
>10	97/154 (63,0)	43/87 (49,4)	1,27 [1,00; 1,63]	1,74 [1,02; 2,97]	13,56 [0,58; 26,54]
0,043					
Baseline SES-CD total score (p-value of the interaction test: 0,842)					
<12	72/143 (50,3)	31/66 (47,0)	1,07 [0,79; 1,45]	1,14 [0,64; 2,05]	3,38 [-11,18; 17,94]
0,659					
≥12	95/157 (60,5)	44/79 (55,7)	1,09 [0,86; 1,37]	1,22 [0,71; 2,11]	4,81 [-8,55; 18,17]
0,487					
Baseline AP average (p-value of the interaction test: 0,336)					
<2	37/72 (51,4)	19/48 (39,6)	1,30 [0,86; 1,97]	1,61 [0,77; 3,38]	11,81 [-6,21; 29,82]
0,263					
≥2	130/226 (57,5)	56/97 (57,7)	1,00 [0,81; 1,22]	0,99 [0,61; 1,60]	-0,21 [-11,96; 11,54]
1,000					
Baseline SF average (p-value of the interaction test: 0,234)					
<7	124/220 (56,4)	48/100 (48,0)	1,17 [0,93; 1,49]	1,40 [0,87; 2,25]	8,36 [-3,42; 20,15]
0,184					
≥7	42/76 (55,3)	27/45 (60,0)	0,92 [0,67; 1,26]	0,82 [0,39; 1,74]	-4,74 [-22,90; 13,42]
0,705					
Baseline CDAI 1 (p-value of the interaction test: 0,328)					
<300	52/109 (47,7)	22/59 (37,3)	1,28 [0,87; 1,88]	1,53 [0,80; 2,93]	10,42 [-5,08; 25,92]
0,254					
≥300	113/184 (61,4)	53/84 (63,1)	0,97 [0,80; 1,19]	0,93 [0,55; 1,59]	-1,68 [-14,17; 10,81]
0,892					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline CDAI 2 (p-value of the interaction test: 0,675)					
<220	9/29 (31,0)	2/12 (16,7)	1,86 [0,47; 7,38]	2,25 [0,41; 12,44]	14,37 [-12,62; 41,35]
				0,457	
≥220 and <450	146/244 (59,8)	66/119 (55,5)	1,08 [0,89; 1,31]	1,20 [0,77; 1,86]	4,37 [-6,47; 15,22]
				0,430	
≥450	10/20 (50,0)	7/12 (58,3)	0,86 [0,45; 1,64]	0,71 [0,17; 3,03]	-8,33 [-43,81; 27,14]
				0,726	
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_ibdqtsi28_8_sub_itb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Subgruppen für Increase in IBDQ Emotional Function by at least 10.8 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,157)					
<65 years	134/287 (46,7)	66/141 (46,8)	1,00 [0,80; 1,24]	1,00 [0,66; 1,49]	-0,12 [-10,18; 9,94]
			1,000		
≥65 years	8/13 (61,5)	0/4 (0,0)	6,07 [0,42; 87,07]	13,91 [0,62; >100]	61,54 [35,09; 87,98]
			0,082		
Age 2 (p-value of the interaction test: 0,889)					
<40 years	96/202 (47,5)	42/91 (46,2)	1,03 [0,79; 1,34]	1,06 [0,64; 1,74]	1,37 [-10,97; 13,71]
			0,899		
≥40 years	46/98 (46,9)	24/54 (44,4)	1,06 [0,73; 1,52]	1,11 [0,57; 2,16]	2,49 [-14,04; 19,03]
			0,865		
Sex (p-value of the interaction test: 0,797)					
Male	78/179 (43,6)	27/65 (41,5)	1,05 [0,75; 1,46]	1,09 [0,61; 1,93]	2,04 [-11,97; 16,05]
			0,884		
Female	64/121 (52,9)	39/80 (48,8)	1,08 [0,82; 1,44]	1,18 [0,67; 2,08]	4,14 [-9,97; 18,25]
			0,666		
Weight (p-value of the interaction test: 0,870)					
<100 kg	136/284 (47,9)	64/140 (45,7)	1,05 [0,84; 1,30]	1,09 [0,73; 1,64]	2,17 [-7,92; 12,27]
			0,681		
≥100 kg	6/15 (40,0)	2/5 (40,0)	1,00 [0,29; 3,45]	1,00 [0,13; 7,89]	0,00 [-49,58; 49,58]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
BMI (p-value of the interaction test: 0,615)					
Underweight (<18.5 kg/m ²)	26/54 (48,1)	13/32 (40,6)	1,19 [0,72; 1,96]	1,36 [0,56; 3,29]	7,52 [-14,09; 29,14]
				0,512	
Normal (≥18.5 and <25 kg/m ²)	79/161 (49,1)	26/60 (43,3)	1,13 [0,81; 1,57]	1,26 [0,69; 2,29]	5,73 [-8,99; 20,46]
				0,545	
Overweight (≥25 and <30 kg/m ²)	24/55 (43,6)	21/38 (55,3)	0,79 [0,52; 1,20]	0,63 [0,27; 1,44]	-11,63 [-32,16; 8,91]
				0,298	
Obese and Extreme obese (≥30 kg/m ²)	13/29 (44,8)	6/15 (40,0)	1,12 [0,53; 2,35]	1,22 [0,34; 4,32]	4,83 [-25,87; 35,52]
				1,000	
Tobacco use (p-value of the interaction test: 0,550)					
Current	25/52 (48,1)	10/29 (34,5)	1,39 [0,78; 2,48]	1,76 [0,69; 4,50]	13,59 [-8,40; 35,59]
				0,254	
Former	20/49 (40,8)	8/21 (38,1)	1,07 [0,56; 2,03]	1,12 [0,39; 3,20]	2,72 [-22,19; 27,64]
				1,000	
Never	97/199 (48,7)	48/95 (50,5)	0,96 [0,76; 1,23]	0,93 [0,57; 1,52]	-1,78 [-14,00; 10,44]
				0,804	
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,168)					
Ever	133/280 (47,5)	66/140 (47,1)	1,01 [0,81; 1,25]	1,01 [0,68; 1,52]	0,36 [-9,77; 10,49]
				1,000	
Never	9/20 (45,0)	0/5 (0,0)	5,43 [0,37; 80,39]	9,09 [0,44; >100]	45,00 [23,20; 66,80]
				0,123	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Prior anti-TNF failure (p-value of the interaction test: 0,058)					
Ever	136/282 (48,2)	61/139 (43,9)	1,10 [0,88; 1,37]	1,19 [0,79; 1,79]	4,34 [-5,76; 14,45]
			0,408		
Never	6/18 (33,3)	5/6 (83,3)	0,40 [0,19; 0,84]	0,10 [0,01; 1,06]	-50,00 [-86,93; -13,07]
			0,061		
Prior anti-integrin failure (p-value of the interaction test: 0,053)					
Ever	30/71 (42,3)	18/31 (58,1)	0,73 [0,49; 1,09]	0,53 [0,22; 1,24]	-15,81 [-36,64; 5,02]
			0,196		
Never	112/229 (48,9)	48/114 (42,1)	1,16 [0,90; 1,50]	1,32 [0,84; 2,07]	6,80 [-4,34; 17,94]
			0,252		
Baseline corticosteroid use (p-value of the interaction test: 0,997)					
Yes	40/76 (52,6)	20/39 (51,3)	1,03 [0,71; 1,49]	1,06 [0,49; 2,29]	1,35 [-17,94; 20,64]
			1,000		
No	102/224 (45,5)	46/106 (43,4)	1,05 [0,81; 1,36]	1,09 [0,68; 1,74]	2,14 [-9,33; 13,61]
			0,724		
Baseline immunomodulator use (p-value of the interaction test: 0,334)					
Yes	30/66 (45,5)	14/39 (35,9)	1,27 [0,77; 2,08]	1,49 [0,66; 3,36]	9,56 [-9,70; 28,82]
			0,414		
No	112/234 (47,9)	52/106 (49,1)	0,98 [0,77; 1,23]	0,95 [0,60; 1,51]	-1,19 [-12,66; 10,28]
			0,907		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Duration of CD (p-value of the interaction test: 0,559)					
<1 year	8/23 (34,8)	2/9 (22,2)	1,57 [0,41; 6,00]	1,87 [0,31; 11,19]	12,56 [-20,86; 45,98]
			0,681		
≥1 to <5 years	54/104 (51,9)	19/44 (43,2)	1,20 [0,82; 1,77]	1,42 [0,70; 2,89]	8,74 [-8,76; 26,25]
			0,371		
≥5 years	80/173 (46,2)	45/92 (48,9)	0,95 [0,73; 1,23]	0,90 [0,54; 1,49]	-2,67 [-15,30; 9,96]
			0,700		
Baseline disease location (p-value of the interaction test: 0,074)					
Colonic	61/120 (50,8)	22/59 (37,3)	1,36 [0,94; 1,98]	1,74 [0,92; 3,29]	13,55 [-1,69; 28,79]
			0,111		
Ileal	10/32 (31,3)	4/6 (66,7)	0,47 [0,22; 1,01]	0,23 [0,04; 1,45]	-35,42 [-76,41; 5,58]
			0,167		
Ileal-Colonic	71/148 (48,0)	40/80 (50,0)	0,96 [0,73; 1,26]	0,92 [0,54; 1,59]	-2,03 [-15,62; 11,57]
			0,783		
Baseline fecal calprotectin (p-value of the interaction test: 0,150)					
≤250	12/38 (31,6)	8/15 (53,3)	0,59 [0,30; 1,15]	0,40 [0,12; 1,37]	-21,75 [-51,01; 7,50]
			0,209		
>250	98/208 (47,1)	40/93 (43,0)	1,10 [0,83; 1,44]	1,18 [0,72; 1,93]	4,10 [-8,03; 16,24]
			0,533		
Baseline CRP (p-value of the interaction test: 0,661)					
≤10	68/145 (46,9)	28/58 (48,3)	0,97 [0,71; 1,33]	0,95 [0,51; 1,74]	-1,38 [-16,59; 13,83]
			0,877		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
>10	74/154 (48,1)	38/87 (43,7)	1,10 [0,82; 1,47]	1,19 [0,70; 2,02]	4,37 [-8,70; 17,45]
0,591					
Baseline SES-CD total score (p-value of the interaction test: 0,330)					
<12	67/143 (46,9)	26/66 (39,4)	1,19 [0,84; 1,68]	1,36 [0,75; 2,45]	7,46 [-6,89; 21,81]
0,370					
≥12	75/157 (47,8)	40/79 (50,6)	0,94 [0,72; 1,24]	0,89 [0,52; 1,53]	-2,86 [-16,37; 10,65]
0,682					
Baseline AP average (p-value of the interaction test: 0,241)					
<2	32/72 (44,4)	16/48 (33,3)	1,33 [0,83; 2,15]	1,60 [0,75; 3,42]	11,11 [-6,48; 28,71]
0,257					
≥2	110/226 (48,7)	50/97 (51,5)	0,94 [0,75; 1,19]	0,89 [0,55; 1,43]	-2,87 [-14,76; 9,02]
0,716					
Baseline SF average (p-value of the interaction test: 0,244)					
<7	104/220 (47,3)	41/100 (41,0)	1,15 [0,88; 1,52]	1,29 [0,80; 2,08]	6,27 [-5,41; 17,95]
0,333					
≥7	37/76 (48,7)	25/45 (55,6)	0,88 [0,62; 1,24]	0,76 [0,36; 1,59]	-6,87 [-25,23; 11,49]
0,573					
Baseline CDAI 1 (p-value of the interaction test: 0,130)					
<300	46/109 (42,2)	18/59 (30,5)	1,38 [0,89; 2,16]	1,66 [0,85; 3,26]	11,69 [-3,27; 26,66]
0,183					
≥300	94/184 (51,1)	47/84 (56,0)	0,91 [0,72; 1,16]	0,82 [0,49; 1,38]	-4,87 [-17,71; 7,98]
0,510					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline CDAI 2 (p-value of the interaction test: 0,636)					
<220	8/29 (27,6)	2/12 (16,7)	1,66 [0,41; 6,68]	1,90 [0,34; 10,67]	10,92 [-15,71; 37,55]
				0,694	
≥220 and <450	123/244 (50,4)	56/119 (47,1)	1,07 [0,85; 1,34]	1,14 [0,74; 1,77]	3,35 [-7,59; 14,30]
				0,577	
≥450	9/20 (45,0)	7/12 (58,3)	0,77 [0,39; 1,52]	0,58 [0,14; 2,48]	-13,33 [-48,74; 22,07]
				0,716	
OECD Country (p-value of the interaction test: 0,104)					
Yes	81/178 (45,5)	42/83 (50,6)	0,90 [0,69; 1,17]	0,82 [0,48; 1,37]	-5,10 [-18,10; 7,91]
				0,506	
No	61/122 (50,0)	24/62 (38,7)	1,29 [0,90; 1,85]	1,58 [0,85; 2,95]	11,29 [-3,73; 26,31]
				0,162	
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_ibdqe110_8_sub_itb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Subgruppen für Increase in IBDQ Social Function by at least 4.5 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,209)					
<65 years	154/287 (53,7)	76/141 (53,9)	1,00 [0,83; 1,20]	0,99 [0,66; 1,48]	-0,24 [-10,29; 9,81]
			1,000		
≥65 years	7/13 (53,8)	0/4 (0,0)	5,36 [0,37; 77,70]	10,38 [0,47; >100]	53,85 [26,75; 80,95]
			0,103		
Age 2 (p-value of the interaction test: 0,701)					
<40 years	112/202 (55,4)	48/91 (52,7)	1,05 [0,83; 1,32]	1,11 [0,68; 1,83]	2,70 [-9,64; 15,04]
			0,705		
≥40 years	49/98 (50,0)	28/54 (51,9)	0,96 [0,70; 1,33]	0,93 [0,48; 1,80]	-1,85 [-18,45; 14,75]
			0,866		
Sex (p-value of the interaction test: 0,563)					
Male	90/179 (50,3)	33/65 (50,8)	0,99 [0,75; 1,31]	0,98 [0,56; 1,73]	-0,49 [-14,68; 13,70]
			1,000		
Female	71/121 (58,7)	43/80 (53,8)	1,09 [0,85; 1,41]	1,22 [0,69; 2,16]	4,93 [-9,08; 18,94]
			0,561		
Race (p-value of the interaction test: 0,067)					
Asian	59/100 (59,0)	24/56 (42,9)	1,38 [0,98; 1,94]	1,92 [0,99; 3,72]	16,14 [-0,01; 32,30]
			0,066		
White	90/180 (50,0)	48/82 (58,5)	0,85 [0,68; 1,08]	0,71 [0,42; 1,20]	-8,54 [-21,46; 4,39]
			0,230		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Other	7/13 (53,8)	4/7 (57,1)	0,94 [0,42; 2,13]	0,88 [0,14; 5,58]	-3,30 [-48,89; 42,29]
1,000					
Weight (p-value of the interaction test: 0,433)					
<100 kg	155/284 (54,6)	73/140 (52,1)	1,05 [0,86; 1,27]	1,10 [0,74; 1,65]	2,43 [-7,67; 12,53]
0,679					
≥100 kg	6/15 (40,0)	3/5 (60,0)	0,67 [0,26; 1,72]	0,44 [0,06; 3,51]	-20,00 [-69,58; 29,58]
0,617					
BMI (p-value of the interaction test: 0,916)					
Underweight (<18.5 kg/m ²)	27/54 (50,0)	15/32 (46,9)	1,07 [0,68; 1,68]	1,13 [0,47; 2,72]	3,13 [-18,71; 24,96]
0,826					
Normal (≥18.5 and <25 kg/m ²)	92/161 (57,1)	32/60 (53,3)	1,07 [0,82; 1,41]	1,17 [0,64; 2,12]	3,81 [-10,95; 18,57]
0,649					
Overweight (≥25 and <30 kg/m ²)	28/55 (50,9)	21/38 (55,3)	0,92 [0,63; 1,36]	0,84 [0,37; 1,92]	-4,35 [-24,96; 16,25]
0,833					
Obese and Extreme obese (≥30 kg/m ²)	14/29 (48,3)	8/15 (53,3)	0,91 [0,49; 1,66]	0,82 [0,23; 2,85]	-5,06 [-36,17; 26,06]
1,000					
Tobacco use (p-value of the interaction test: 0,401)					
Current	27/52 (51,9)	14/29 (48,3)	1,08 [0,68; 1,70]	1,16 [0,47; 2,87]	3,65 [-19,05; 26,34]
0,819					
Former	27/49 (55,1)	8/21 (38,1)	1,45 [0,79; 2,64]	1,99 [0,70; 5,67]	17,01 [-8,00; 42,01]
0,297					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Never	107/199 (53,8)	54/95 (56,8)	0,95 [0,76; 1,18]	0,88 [0,54; 1,44]	-3,07 [-15,21; 9,06]
0,707					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,359)					
Ever	152/280 (54,3)	75/140 (53,6)	1,01 [0,84; 1,22]	1,03 [0,69; 1,55]	0,71 [-9,40; 10,83]
0,917					
Never	9/20 (45,0)	1/5 (20,0)	2,25 [0,37; 13,87]	3,27 [0,31; 34,72]	25,00 [-16,29; 66,29]
0,615					
Prior anti-TNF failure (p-value of the interaction test: 0,058)					
Ever	154/282 (54,6)	70/139 (50,4)	1,08 [0,89; 1,32]	1,19 [0,79; 1,78]	4,25 [-5,89; 14,39]
0,467					
Never	7/18 (38,9)	6/6 (100)	0,43 [0,23; 0,77]	0,05 [0,00; 1,03]	-61,11 [-83,63; -38,59]
0,016					
Baseline corticosteroid use (p-value of the interaction test: 0,720)					
Yes	39/76 (51,3)	21/39 (53,8)	0,95 [0,66; 1,37]	0,90 [0,42; 1,96]	-2,53 [-21,79; 16,73]
0,845					
No	122/224 (54,5)	55/106 (51,9)	1,05 [0,84; 1,31]	1,11 [0,70; 1,76]	2,58 [-8,96; 14,11]
0,723					
Baseline immunomodulator use (p-value of the interaction test: 0,339)					
Yes	35/66 (53,0)	17/39 (43,6)	1,22 [0,80; 1,86]	1,46 [0,66; 3,24]	9,44 [-10,24; 29,12]
0,421					
No	126/234 (53,8)	59/106 (55,7)	0,97 [0,79; 1,19]	0,93 [0,59; 1,47]	-1,81 [-13,23; 9,60]
0,814					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Duration of CD (p-value of the interaction test: 0,753)					
<1 year	10/23 (43,5)	4/9 (44,4)	0,98 [0,41; 2,33]	0,96 [0,20; 4,54]	-0,97 [-39,23; 37,30]
				1,000	
≥1 to <5 years	60/104 (57,7)	22/44 (50,0)	1,15 [0,82; 1,62]	1,36 [0,67; 2,77]	7,69 [-9,87; 25,25]
				0,470	
≥5 years	91/173 (52,6)	50/92 (54,3)	0,97 [0,77; 1,22]	0,93 [0,56; 1,55]	-1,75 [-14,35; 10,86]
				0,797	
Baseline disease location (p-value of the interaction test: 0,588)					
Colonic	67/120 (55,8)	28/59 (47,5)	1,18 [0,86; 1,61]	1,40 [0,75; 2,62]	8,38 [-7,16; 23,91]
				0,340	
Ileal	12/32 (37,5)	2/6 (33,3)	1,13 [0,33; 3,80]	1,20 [0,19; 7,57]	4,17 [-37,11; 45,45]
				1,000	
Ileal-Colonic	82/148 (55,4)	46/80 (57,5)	0,96 [0,76; 1,22]	0,92 [0,53; 1,59]	-2,09 [-15,57; 11,38]
				0,781	
Baseline fecal calprotectin (p-value of the interaction test: 0,507)					
≤250	16/38 (42,1)	8/15 (53,3)	0,79 [0,43; 1,44]	0,64 [0,19; 2,12]	-11,23 [-40,96; 18,50]
				0,547	
>250	110/208 (52,9)	47/93 (50,5)	1,05 [0,82; 1,33]	1,10 [0,67; 1,79]	2,35 [-9,87; 14,56]
				0,710	
Baseline CRP (p-value of the interaction test: 0,072)					
≤10	69/145 (47,6)	33/58 (56,9)	0,84 [0,63; 1,11]	0,69 [0,37; 1,27]	-9,31 [-24,43; 5,81]
				0,277	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
>10	92/154 (59,7)	43/87 (49,4)	1,21 [0,94; 1,55]	1,52 [0,89; 2,58]	10,31 [-2,74; 23,37]
0,138					
Baseline SES-CD total score (p-value of the interaction test: 0,624)					
<12	70/143 (49,0)	33/66 (50,0)	0,98 [0,73; 1,31]	0,96 [0,54; 1,72]	-1,05 [-15,63; 13,53]
1,000					
≥12	91/157 (58,0)	43/79 (54,4)	1,06 [0,84; 1,36]	1,15 [0,67; 1,99]	3,53 [-9,89; 16,96]
0,677					
Baseline AP average (p-value of the interaction test: 0,640)					
<2	37/72 (51,4)	22/48 (45,8)	1,12 [0,77; 1,64]	1,25 [0,60; 2,60]	5,56 [-12,66; 23,78]
0,581					
≥2	124/226 (54,9)	54/97 (55,7)	0,99 [0,80; 1,22]	0,97 [0,60; 1,56]	-0,80 [-12,63; 11,02]
0,904					
Baseline SF average (p-value of the interaction test: 0,803)					
<7	116/220 (52,7)	50/100 (50,0)	1,05 [0,84; 1,33]	1,12 [0,70; 1,79]	2,73 [-9,09; 14,54]
0,718					
≥7	44/76 (57,9)	26/45 (57,8)	1,00 [0,73; 1,37]	1,00 [0,48; 2,12]	0,12 [-18,09; 18,32]
1,000					
Baseline CDAI 1 (p-value of the interaction test: 0,847)					
<300	47/109 (43,1)	25/59 (42,4)	1,02 [0,70; 1,47]	1,03 [0,54; 1,96]	0,75 [-14,92; 16,41]
1,000					
≥300	112/184 (60,9)	50/84 (59,5)	1,02 [0,83; 1,26]	1,06 [0,62; 1,79]	1,35 [-11,30; 13,99]
0,893					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline CDAI 2 (p-value of the interaction test: 0,586)					
<220	10/29 (34,5)	4/12 (33,3)	1,03 [0,40; 2,66]	1,05 [0,25; 4,37]	1,15 [-30,64; 32,94]
				1,000	
≥220 and <450	139/244 (57,0)	63/119 (52,9)	1,08 [0,88; 1,32]	1,18 [0,76; 1,83]	4,03 [-6,88; 14,94]
				0,500	
≥450	10/20 (50,0)	8/12 (66,7)	0,75 [0,41; 1,36]	0,50 [0,11; 2,21]	-16,67 [-51,19; 17,85]
				0,471	
OECD Country (p-value of the interaction test: 0,142)					
Yes	96/178 (53,9)	49/83 (59,0)	0,91 [0,73; 1,14]	0,81 [0,48; 1,38]	-5,10 [-17,97; 7,76]
				0,504	
No	65/122 (53,3)	27/62 (43,5)	1,22 [0,88; 1,70]	1,48 [0,80; 2,73]	9,73 [-5,46; 24,92]
				0,275	
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; IBDQ: Inflammatory Bowel Disease Questionnaire; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_ibdqsf4_5_sub_itb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Gesundheitsbezogene Lebensqualität

Subgruppen für Increase in SF-36 PCS Score by at least 9.4 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,835)					
<65 years	127/287 (44,3)	60/141 (42,6)	1,04 [0,82; 1,31]	1,07 [0,71; 1,61]	1,70 [-8,28; 11,68]
			0,757		
≥65 years	2/13 (15,4)	0/4 (0,0)	1,79 [0,10; 31,17]	1,96 [0,08; 49,26]	15,38 [-4,23; 35,00]
			1,000		
Age 2 (p-value of the interaction test: 0,629)					
<40 years	97/202 (48,0)	41/91 (45,1)	1,07 [0,81; 1,39]	1,13 [0,69; 1,85]	2,96 [-9,36; 15,29]
			0,705		
≥40 years	32/98 (32,7)	19/54 (35,2)	0,93 [0,59; 1,47]	0,89 [0,44; 1,80]	-2,53 [-18,29; 13,23]
			0,858		
Sex (p-value of the interaction test: 0,760)					
Male	76/179 (42,5)	25/65 (38,5)	1,10 [0,78; 1,57]	1,18 [0,66; 2,11]	4,00 [-9,87; 17,86]
			0,660		
Female	53/121 (43,8)	35/80 (43,8)	1,00 [0,73; 1,38]	1,00 [0,57; 1,77]	0,05 [-13,96; 14,06]
			1,000		
Geographic region 1 (p-value of the interaction test: 0,081)					
Europe	45/114 (39,5)	22/50 (44,0)	0,90 [0,61; 1,32]	0,83 [0,42; 1,63]	-4,53 [-20,95; 11,90]
			0,608		
North America	21/54 (38,9)	14/26 (53,8)	0,72 [0,44; 1,18]	0,55 [0,21; 1,40]	-14,96 [-38,11; 8,20]
			0,236		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Other	63/132 (47,7)	24/69 (34,8)	1,37 [0,95; 1,98]	1,71 [0,94; 3,12]	12,94 [-1,16; 27,05]
0,099					
Geographic region 2 (p-value of the interaction test: 0,079)					
Asia	53/105 (50,5)	18/56 (32,1)	1,57 [1,03; 2,40]	2,15 [1,09; 4,24]	18,33 [2,81; 33,86]
0,031					
Central America/South America	9/24 (37,5)	6/13 (46,2)	0,81 [0,37; 1,78]	0,70 [0,18; 2,75]	-8,65 [-41,96; 24,66]
0,730					
Europe and ROW	46/117 (39,3)	22/50 (44,0)	0,89 [0,61; 1,31]	0,82 [0,42; 1,61]	-4,68 [-21,04; 11,68]
0,608					
North America	21/54 (38,9)	14/26 (53,8)	0,72 [0,44; 1,18]	0,55 [0,21; 1,40]	-14,96 [-38,11; 8,20]
0,236					
Weight (p-value of the interaction test: 0,975)					
<100 kg	125/284 (44,0)	59/140 (42,1)	1,04 [0,83; 1,32]	1,08 [0,72; 1,62]	1,87 [-8,14; 11,88]
0,755					
≥100 kg	4/15 (26,7)	1/5 (20,0)	1,33 [0,19; 9,31]	1,45 [0,12; 17,23]	6,67 [-34,93; 48,26]
1,000					
BMI (p-value of the interaction test: 0,918)					
Underweight (<18.5 kg/m ²)	26/54 (48,1)	13/32 (40,6)	1,19 [0,72; 1,96]	1,36 [0,56; 3,29]	7,52 [-14,09; 29,14]
0,512					
Normal (≥18.5 and <25 kg/m ²)	71/161 (44,1)	27/60 (45,0)	0,98 [0,70; 1,36]	0,96 [0,53; 1,75]	-0,90 [-15,64; 13,84]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Overweight (≥25 and <30 kg/m²)	22/55 (40,0)	16/38 (42,1)	0,95 [0,58; 1,56]	0,92 [0,40; 2,12]	-2,11 [-22,45; 18,24]
			1,000		
Obese and Extreme obese (≥30 kg/m²)	10/29 (34,5)	4/15 (26,7)	1,29 [0,49; 3,44]	1,45 [0,37; 5,74]	7,82 [-20,47; 36,10]
			0,738		
Tobacco use (p-value of the interaction test: 0,492)					
Current	23/52 (44,2)	11/29 (37,9)	1,17 [0,67; 2,03]	1,30 [0,51; 3,28]	6,30 [-15,93; 28,53]
			0,643		
Former	21/49 (42,9)	6/21 (28,6)	1,50 [0,71; 3,17]	1,88 [0,62; 5,65]	14,29 [-9,49; 38,06]
			0,296		
Never	85/199 (42,7)	43/95 (45,3)	0,94 [0,72; 1,24]	0,90 [0,55; 1,47]	-2,55 [-14,69; 9,59]
			0,707		
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,562)					
Ever	122/280 (43,6)	59/140 (42,1)	1,03 [0,82; 1,31]	1,06 [0,70; 1,60]	1,43 [-8,60; 11,46]
			0,835		
Never	7/20 (35,0)	1/5 (20,0)	1,75 [0,27; 11,15]	2,15 [0,20; 23,18]	15,00 [-25,82; 55,82]
			1,000		
Prior anti-TNF failure (p-value of the interaction test: 0,437)					
Ever	123/282 (43,6)	57/139 (41,0)	1,06 [0,84; 1,35]	1,11 [0,74; 1,68]	2,61 [-7,41; 12,63]
			0,675		
Never	6/18 (33,3)	3/6 (50,0)	0,67 [0,24; 1,87]	0,50 [0,08; 3,27]	-16,67 [-62,22; 28,88]
			0,635		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Prior anti-integrin failure (p-value of the interaction test: 0,331)					
Ever	28/71 (39,4)	14/31 (45,2)	0,87 [0,54; 1,42]	0,79 [0,34; 1,85]	-5,72 [-26,61; 15,16]
				0,664	
Never	101/229 (44,1)	46/114 (40,4)	1,09 [0,84; 1,43]	1,17 [0,74; 1,84]	3,75 [-7,31; 14,82]
				0,563	
Baseline corticosteroid use (p-value of the interaction test: 0,380)					
Yes	32/76 (42,1)	19/39 (48,7)	0,86 [0,57; 1,31]	0,77 [0,35; 1,66]	-6,61 [-25,83; 12,60]
				0,555	
No	97/224 (43,3)	41/106 (38,7)	1,12 [0,84; 1,49]	1,21 [0,76; 1,94]	4,62 [-6,69; 15,94]
				0,474	
Baseline immunomodulator use (p-value of the interaction test: 0,063)					
Yes	28/66 (42,4)	10/39 (25,6)	1,65 [0,90; 3,03]	2,14 [0,90; 5,09]	16,78 [-1,38; 34,95]
				0,096	
No	101/234 (43,2)	50/106 (47,2)	0,92 [0,71; 1,17]	0,85 [0,54; 1,35]	-4,01 [-15,43; 7,42]
				0,556	
Duration of CD (p-value of the interaction test: 0,214)					
<1 year	7/23 (30,4)	1/9 (11,1)	2,74 [0,39; 19,22]	3,50 [0,36; 33,56]	19,32 [-8,52; 47,17]
				0,386	
≥1 to <5 years	53/104 (51,0)	17/44 (38,6)	1,32 [0,87; 2,00]	1,65 [0,80; 3,39]	12,33 [-4,98; 29,63]
				0,208	
≥5 years	69/173 (39,9)	42/92 (45,7)	0,87 [0,65; 1,17]	0,79 [0,47; 1,32]	-5,77 [-18,29; 6,76]
				0,433	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Baseline disease location (p-value of the interaction test: 0,475)					
Colonic	55/120 (45,8)	22/59 (37,3)	1,23 [0,84; 1,80]	1,42 [0,75; 2,69]	8,55 [-6,68; 23,77]
				0,336	
Ileal	8/32 (25,0)	2/6 (33,3)	0,75 [0,21; 2,70]	0,67 [0,10; 4,35]	-8,33 [-48,93; 32,26]
				0,644	
Ileal-Colonic	66/148 (44,6)	36/80 (45,0)	0,99 [0,73; 1,34]	0,98 [0,57; 1,70]	-0,41 [-13,93; 13,12]
				1,000	
Baseline fecal calprotectin (p-value of the interaction test: 0,845)					
≤250	10/38 (26,3)	4/15 (26,7)	0,99 [0,37; 2,67]	0,98 [0,25; 3,80]	-0,35 [-26,75; 26,05]
				1,000	
>250	96/208 (46,2)	38/93 (40,9)	1,13 [0,85; 1,50]	1,24 [0,76; 2,04]	5,29 [-6,78; 17,36]
				0,452	
Baseline CRP (p-value of the interaction test: 0,433)					
≤10	51/145 (35,2)	22/58 (37,9)	0,93 [0,62; 1,38]	0,89 [0,47; 1,67]	-2,76 [-17,47; 11,95]
				0,747	
>10	78/154 (50,6)	38/87 (43,7)	1,16 [0,87; 1,54]	1,32 [0,78; 2,24]	6,97 [-6,10; 20,05]
				0,348	
Baseline SES-CD total score (p-value of the interaction test: 0,584)					
<12	57/143 (39,9)	23/66 (34,8)	1,14 [0,78; 1,68]	1,24 [0,68; 2,27]	5,01 [-9,01; 19,03]
				0,542	
≥12	72/157 (45,9)	37/79 (46,8)	0,98 [0,73; 1,31]	0,96 [0,56; 1,65]	-0,98 [-14,46; 12,51]
				0,891	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline AP average (p-value of the interaction test: 0,087)					
<2	23/72 (31,9)	9/48 (18,8)	1,70 [0,86; 3,36]	2,03 [0,85; 4,89]	13,19 [-2,23; 28,62]
				0,141	
≥2	106/226 (46,9)	51/97 (52,6)	0,89 [0,71; 1,13]	0,80 [0,49; 1,28]	-5,67 [-17,55; 6,20]
				0,396	
Baseline SF average (p-value of the interaction test: 0,276)					
<7	95/220 (43,2)	38/100 (38,0)	1,14 [0,85; 1,52]	1,24 [0,76; 2,01]	5,18 [-6,37; 16,73]
				0,395	
≥7	32/76 (42,1)	22/45 (48,9)	0,86 [0,58; 1,28]	0,76 [0,36; 1,60]	-6,78 [-25,13; 11,56]
				0,571	
Baseline CDAI 1 (p-value of the interaction test: 0,100)					
<300	36/109 (33,0)	13/59 (22,0)	1,50 [0,87; 2,60]	1,74 [0,84; 3,63]	10,99 [-2,78; 24,77]
				0,157	
≥300	90/184 (48,9)	47/84 (56,0)	0,87 [0,69; 1,11]	0,75 [0,45; 1,27]	-7,04 [-19,88; 5,80]
				0,295	
Baseline CDAI 2 (p-value of the interaction test: 0,301)					
<220	8/29 (27,6)	0/12 (0,0)	7,37 [0,46; >100]	9,88 [0,52; >100]	27,59 [11,32; 43,85]
				0,079	
≥220 and <450	110/244 (45,1)	54/119 (45,4)	0,99 [0,78; 1,26]	0,99 [0,64; 1,53]	-0,30 [-11,20; 10,61]
				1,000	
≥450	8/20 (40,0)	6/12 (50,0)	0,80 [0,37; 1,74]	0,67 [0,16; 2,82]	-10,00 [-45,51; 25,51]
				0,718	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
OECD Country (p-value of the interaction test: 0,643)					
Yes	77/178 (43,3)	36/83 (43,4)	1,00 [0,74; 1,34]	1,00 [0,59; 1,68]	-0,12 [-13,02; 12,79]
			1,000		
No	52/122 (42,6)	24/62 (38,7)	1,10 [0,76; 1,60]	1,18 [0,63; 2,20]	3,91 [-11,05; 18,88]
			0,638		
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PCS: Physical Health Component Summary Score; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF-36: 36-Item Short Form Health Survey; SF: Stool Frequency; TNF: Tumor Necrosis Factor. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_sf36psi9_4_sub_ittb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Subgruppen für Increase in SF-36 MCS Score by at least 9.6 points in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (ITT-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,247)					
<65 years	70/287 (24,4)	36/141 (25,5)	0,96 [0,67; 1,35]	0,94 [0,59; 1,50]	-1,14 [-9,89; 7,60]
			0,812		
≥65 years	6/13 (46,2)	0/4 (0,0)	4,64 [0,32; 68,34]	7,80 [0,35; >100]	46,15 [19,05; 73,25]
			0,237		
Age 2 (p-value of the interaction test: 0,426)					
<40 years	51/202 (25,2)	25/91 (27,5)	0,92 [0,61; 1,38]	0,89 [0,51; 1,56]	-2,23 [-13,18; 8,73]
			0,773		
≥40 years	25/98 (25,5)	11/54 (20,4)	1,25 [0,67; 2,34]	1,34 [0,60; 2,99]	5,14 [-8,64; 18,92]
			0,553		
Sex (p-value of the interaction test: 0,254)					
Male	42/179 (23,5)	18/65 (27,7)	0,85 [0,53; 1,36]	0,80 [0,42; 1,52]	-4,23 [-16,75; 8,30]
			0,505		
Female	34/121 (28,1)	18/80 (22,5)	1,25 [0,76; 2,05]	1,35 [0,70; 2,60]	5,60 [-6,56; 17,76]
			0,414		
Race (p-value of the interaction test: 0,127)					
Asian	30/100 (30,0)	10/56 (17,9)	1,68 [0,89; 3,18]	1,97 [0,88; 4,42]	12,14 [-1,32; 25,61]
			0,126		
White	40/180 (22,2)	24/82 (29,3)	0,76 [0,49; 1,17]	0,69 [0,38; 1,25]	-7,05 [-18,62; 4,52]
			0,220		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Other	3/13 (23,1)	2/7 (28,6)	0,81 [0,17; 3,75]	0,75 [0,09; 6,04]	-5,49 [-46,05; 35,06]
1,000					
Geographic region 1 (p-value of the interaction test: 0,245)					
Europe	29/114 (25,4)	16/50 (32,0)	0,79 [0,48; 1,33]	0,73 [0,35; 1,50]	-6,56 [-21,76; 8,64]
0,448					
North America	11/54 (20,4)	7/26 (26,9)	0,76 [0,33; 1,72]	0,69 [0,23; 2,07]	-6,55 [-26,70; 13,60]
0,572					
Other	36/132 (27,3)	13/69 (18,8)	1,45 [0,82; 2,54]	1,62 [0,79; 3,30]	8,43 [-3,52; 20,38]
0,227					
Geographic region 2 (p-value of the interaction test: 0,121)					
Asia	32/105 (30,5)	9/56 (16,1)	1,90 [0,98; 3,69]	2,29 [1,00; 5,23]	14,40 [1,36; 27,44]
0,057					
Central America/South America	4/24 (16,7)	4/13 (30,8)	0,54 [0,16; 1,82]	0,45 [0,09; 2,21]	-14,10 [-43,29; 15,08]
0,413					
Europe and ROW	29/117 (24,8)	16/50 (32,0)	0,77 [0,46; 1,29]	0,70 [0,34; 1,45]	-7,21 [-22,33; 7,90]
0,347					
North America	11/54 (20,4)	7/26 (26,9)	0,76 [0,33; 1,72]	0,69 [0,23; 2,07]	-6,55 [-26,70; 13,60]
0,572					
Weight (p-value of the interaction test: 0,980)					
<100 kg	75/284 (26,4)	36/140 (25,7)	1,03 [0,73; 1,45]	1,04 [0,65; 1,65]	0,69 [-8,18; 9,57]
0,907					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
≥100 kg	1/15 (6,7)	0/5 (0,0)	1,13 [0,05; 23,99]	1,14 [0,04; 32,36]	6,67 [-5,96; 19,29]
1,000					
BMI (p-value of the interaction test: 0,817)					
Underweight ($<18.5 \text{ kg/m}^2$)	16/54 (29,6)	7/32 (21,9)	1,35 [0,63; 2,93]	1,50 [0,54; 4,18]	7,75 [-11,05; 26,56]
0,464					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	42/161 (26,1)	15/60 (25,0)	1,04 [0,63; 1,74]	1,06 [0,54; 2,09]	1,09 [-11,80; 13,97]
1,000					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	14/55 (25,5)	11/38 (28,9)	0,88 [0,45; 1,72]	0,84 [0,33; 2,12]	-3,49 [-21,94; 14,96]
0,813					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	4/29 (13,8)	3/15 (20,0)	0,69 [0,18; 2,69]	0,64 [0,12; 3,32]	-6,21 [-30,02; 17,61]
0,675					
Tobacco use (p-value of the interaction test: 0,770)					
Current	11/52 (21,2)	7/29 (24,1)	0,88 [0,38; 2,01]	0,84 [0,29; 2,48]	-2,98 [-22,11; 16,14]
0,785					
Former	8/49 (16,3)	4/21 (19,0)	0,86 [0,29; 2,54]	0,83 [0,22; 3,13]	-2,72 [-22,45; 17,01]
0,743					
Never	57/199 (28,6)	25/95 (26,3)	1,09 [0,73; 1,63]	1,12 [0,65; 1,95]	2,33 [-8,53; 13,18]
0,781					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,411)					
Ever	71/280 (25,4)	36/140 (25,7)	0,99 [0,70; 1,39]	0,98 [0,62; 1,56]	-0,36 [-9,21; 8,50]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Never	5/20 (25,0)	0/5 (0,0)	3,14 [0,20; 49,12]	3,90 [0,18; 82,76]	25,00 [6,02; 43,98]
0,544					
Prior anti-TNF failure (p-value of the interaction test: 0,827)					
Ever	73/282 (25,9)	35/139 (25,2)	1,03 [0,73; 1,46]	1,04 [0,65; 1,65]	0,71 [-8,14; 9,55]
0,906					
Never	3/18 (16,7)	1/6 (16,7)	1,00 [0,13; 7,89]	1,00 [0,08; 11,93]	0,00 [-34,43; 34,43]
1,000					
Prior anti-integrin failure (p-value of the interaction test: 0,365)					
Ever	20/71 (28,2)	6/31 (19,4)	1,46 [0,65; 3,27]	1,63 [0,58; 4,58]	8,81 [-8,59; 26,22]
0,461					
Never	56/229 (24,5)	30/114 (26,3)	0,93 [0,63; 1,36]	0,91 [0,54; 1,52]	-1,86 [-11,68; 7,95]
0,792					
Baseline corticosteroid use (p-value of the interaction test: 0,221)					
Yes	21/76 (27,6)	7/39 (17,9)	1,54 [0,72; 3,30]	1,75 [0,67; 4,56]	9,68 [-6,01; 25,37]
0,359					
No	55/224 (24,6)	29/106 (27,4)	0,90 [0,61; 1,32]	0,86 [0,51; 1,46]	-2,80 [-12,99; 7,38]
0,591					
Baseline immunomodulator use (p-value of the interaction test: 0,227)					
Yes	16/66 (24,2)	6/39 (15,4)	1,58 [0,67; 3,69]	1,76 [0,62; 4,96]	8,86 [-6,48; 24,19]
0,329					
No	60/234 (25,6)	30/106 (28,3)	0,91 [0,62; 1,32]	0,87 [0,52; 1,46]	-2,66 [-12,90; 7,58]
0,599					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Duration of CD (p-value of the interaction test: 0,585)					
<1 year	6/23 (26,1)	1/9 (11,1)	2,35 [0,33; 16,87]	2,82 [0,29; 27,54]	14,98 [-12,29; 42,24]
			0,640		
≥1 to <5 years	26/104 (25,0)	9/44 (20,5)	1,22 [0,62; 2,39]	1,30 [0,55; 3,05]	4,55 [-9,99; 19,08]
			0,673		
≥5 years	44/173 (25,4)	26/92 (28,3)	0,90 [0,60; 1,36]	0,87 [0,49; 1,53]	-2,83 [-14,09; 8,43]
			0,662		
Baseline disease location (p-value of the interaction test: 0,259)					
Colonic	32/120 (26,7)	10/59 (16,9)	1,57 [0,83; 2,98]	1,78 [0,81; 3,93]	9,72 [-2,70; 22,14]
			0,190		
Ileal	6/32 (18,8)	1/6 (16,7)	1,13 [0,16; 7,74]	1,15 [0,11; 11,78]	2,08 [-30,66; 34,83]
			1,000		
Ileal-Colonic	38/148 (25,7)	25/80 (31,3)	0,82 [0,54; 1,26]	0,76 [0,42; 1,38]	-5,57 [-17,93; 6,78]
			0,438		
Baseline fecal calprotectin (p-value of the interaction test: 0,628)					
≤250	10/38 (26,3)	5/15 (33,3)	0,79 [0,32; 1,93]	0,71 [0,20; 2,60]	-7,02 [-34,68; 20,64]
			0,737		
>250	50/208 (24,0)	22/93 (23,7)	1,02 [0,66; 1,57]	1,02 [0,58; 1,81]	0,38 [-10,03; 10,79]
			1,000		
Baseline CRP (p-value of the interaction test: 0,911)					
≤10	37/145 (25,5)	15/58 (25,9)	0,99 [0,59; 1,65]	0,98 [0,49; 1,97]	-0,34 [-13,66; 12,97]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
>10	39/154 (25,3)	21/87 (24,1)	1,05 [0,66; 1,66]	1,07 [0,58; 1,96]	1,19 [-10,13; 12,50]
0,878					
Baseline SES-CD total score (p-value of the interaction test: 0,082)					
<12	41/143 (28,7)	13/66 (19,7)	1,46 [0,84; 2,53]	1,64 [0,81; 3,32]	8,97 [-3,15; 21,10]
0,179					
≥12	35/157 (22,3)	23/79 (29,1)	0,77 [0,49; 1,20]	0,70 [0,38; 1,29]	-6,82 [-18,77; 5,13]
0,265					
Baseline AP average (p-value of the interaction test: 0,459)					
<2	10/72 (13,9)	9/48 (18,8)	0,74 [0,33; 1,69]	0,70 [0,26; 1,87]	-4,86 [-18,49; 8,77]
0,611					
≥2	66/226 (29,2)	27/97 (27,8)	1,05 [0,72; 1,53]	1,07 [0,63; 1,81]	1,37 [-9,34; 12,08]
0,894					
Baseline SF average (p-value of the interaction test: 0,601)					
<7	58/220 (26,4)	24/100 (24,0)	1,10 [0,73; 1,66]	1,13 [0,66; 1,96]	2,36 [-7,83; 12,56]
0,681					
≥7	18/76 (23,7)	12/45 (26,7)	0,89 [0,47; 1,67]	0,85 [0,37; 1,99]	-2,98 [-19,05; 13,09]
0,828					
Baseline CDAI 1 (p-value of the interaction test: 0,987)					
<300	18/109 (16,5)	10/59 (16,9)	0,97 [0,48; 1,97]	0,97 [0,42; 2,26]	-0,44 [-12,28; 11,41]
1,000					
≥300	58/184 (31,5)	26/84 (31,0)	1,02 [0,69; 1,49]	1,03 [0,59; 1,79]	0,57 [-11,38; 12,52]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline CDAI 2 (p-value of the interaction test: 0,930)					
<220	2/29 (6,9)	1/12 (8,3)	0,83 [0,08; 8,29]	0,81 [0,07; 9,93]	-1,44 [-19,59; 16,72]
				1,000	
≥220 and <450	70/244 (28,7)	33/119 (27,7)	1,03 [0,73; 1,47]	1,05 [0,64; 1,71]	0,96 [-8,89; 10,80]
				0,902	
≥450	4/20 (20,0)	2/12 (16,7)	1,20 [0,26; 5,59]	1,25 [0,19; 8,13]	3,33 [-24,09; 30,75]
				1,000	
OECD Country (p-value of the interaction test: 0,528)					
Yes	46/178 (25,8)	23/83 (27,7)	0,93 [0,61; 1,43]	0,91 [0,51; 1,63]	-1,87 [-13,45; 9,71]
				0,765	
No	30/122 (24,6)	13/62 (21,0)	1,17 [0,66; 2,08]	1,23 [0,59; 2,57]	3,62 [-9,07; 16,31]
				0,713	
Datenschnitt: 23. August 2023; Biologic-failed ITT Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; ITT: Intention-to-treat Population; kg: Kilogramm; KI: Konfidenzintervall; MCS: Mental Health Component Summary Score; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF-36: 36-Item Short Form Health Survey; SF: Stool Frequency; TNF: Tumor Necrosis Factor. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lilyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lilyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_sf36mcsi9_6_sub_itb_a.rtf

Dataset Location: /lilyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adresp_gba

20DEC2024 / 04:00

Anhang 4-G.4.6.3 Sicherheit**Anhang 4-G.4.6.3.1 Unerwünschte Ereignisse (UE) Gesamtraten**

Subgruppen für Jegliche unerwünschte Ereignisse: Gesamtrate in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (Safety-Population)

	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Subgruppe			p-Wert ^a		
Age 1 (p-value of the interaction test: 0,155)					
<65 years	237/286 (82,9)	118/141 (83,7)	0,99 [0,91; 1,08]	0,94 [0,55; 1,62]	-0,82 [-8,32; 6,68]
			0,891		
≥65 years	13/13 (100)	3/4 (75,0)	1,38 [0,77; 2,47]	11,57 [0,38; >100]	25,00 [-17,43; 67,43]
			0,235		
Age 2 (p-value of the interaction test: 0,573)					
<40 years	170/202 (84,2)	75/91 (82,4)	1,02 [0,91; 1,14]	1,13 [0,59; 2,19]	1,74 [-7,56; 11,04]
			0,734		
≥40 years	80/97 (82,5)	46/54 (85,2)	0,97 [0,84; 1,12]	0,82 [0,33; 2,04]	-2,71 [-14,84; 9,41]
			0,820		
Sex (p-value of the interaction test: 0,319)					
Male	141/178 (79,2)	53/65 (81,5)	0,97 [0,85; 1,12]	0,86 [0,42; 1,78]	-2,32 [-13,48; 8,83]
			0,857		
Female	109/121 (90,1)	68/80 (85,0)	1,06 [0,95; 1,18]	1,60 [0,68; 3,77]	5,08 [-4,38; 14,55]
			0,374		
Race (p-value of the interaction test: 0,976)					
Asian	87/100 (87,0)	49/56 (87,5)	0,99 [0,88; 1,13]	0,96 [0,36; 2,56]	-0,50 [-11,38; 10,38]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
White	146/179 (81,6)	67/82 (81,7)	1,00 [0,88; 1,13]	0,99 [0,50; 1,95]	-0,14 [-10,26; 9,97]
			1,000		
Other	10/13 (76,9)	5/7 (71,4)	1,08 [0,62; 1,88]	1,33 [0,17; 10,74]	5,49 [-35,06; 46,05]
			1,000		
Geographic region 1 (p-value of the interaction test: 0,476)					
Europe	87/114 (76,3)	41/50 (82,0)	0,93 [0,79; 1,10]	0,71 [0,31; 1,64]	-5,68 [-18,89; 7,52]
			0,539		
North America	45/53 (84,9)	21/26 (80,8)	1,05 [0,84; 1,31]	1,34 [0,39; 4,59]	4,14 [-13,82; 22,09]
			0,749		
Other	118/132 (89,4)	59/69 (85,5)	1,05 [0,93; 1,17]	1,43 [0,60; 3,41]	3,89 [-5,94; 13,71]
			0,493		
Geographic region 2 (p-value of the interaction test: 0,391)					
Asia	92/105 (87,6)	49/56 (87,5)	1,00 [0,89; 1,13]	1,01 [0,38; 2,70]	0,12 [-10,59; 10,83]
			1,000		
Central America/South America	23/24 (95,8)	10/13 (76,9)	1,25 [0,91; 1,70]	6,90 [0,64; 74,69]	18,91 [-5,35; 43,17]
			0,115		
Europe and ROW	90/117 (76,9)	41/50 (82,0)	0,94 [0,80; 1,10]	0,73 [0,32; 1,69]	-5,08 [-18,18; 8,03]
			0,541		
North America	45/53 (84,9)	21/26 (80,8)	1,05 [0,84; 1,31]	1,34 [0,39; 4,59]	4,14 [-13,82; 22,09]
			0,749		

	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Subgruppe			p-Wert ^a		
Weight (p-value of the interaction test: 0,621)					
<100 kg	235/284 (82,7)	116/140 (82,9)	1,00 [0,91; 1,10]	0,99 [0,58; 1,70]	-0,11 [-7,75; 7,52]
			1,000		
≥100 kg	15/15 (100)	5/5 (100)	NB	NB	NB
			NB		
BMI (p-value of the interaction test: 0,892)					
Underweight (<18.5 kg/m ²)	46/54 (85,2)	28/32 (87,5)	0,97 [0,82; 1,16]	0,82 [0,23; 2,98]	-2,31 [-17,18; 12,55]
			1,000		
Normal (≥18.5 and <25 kg/m ²)	134/161 (83,2)	50/60 (83,3)	1,00 [0,87; 1,14]	0,99 [0,45; 2,20]	-0,10 [-11,16; 10,95]
			1,000		
Overweight (≥25 and <30 kg/m ²)	43/55 (78,2)	28/38 (73,7)	1,06 [0,84; 1,34]	1,28 [0,49; 3,36]	4,50 [-13,26; 22,25]
			0,629		
Obese and Extreme obese (≥30 kg/m ²)	27/29 (93,1)	15/15 (100)	0,95 [0,82; 1,09]	0,35 [0,02; 7,87]	-6,90 [-16,12; 2,33]
			0,540		
Tobacco use (p-value of the interaction test: 0,532)					
Current	42/52 (80,8)	26/29 (89,7)	0,90 [0,75; 1,08]	0,48 [0,12; 1,93]	-8,89 [-24,30; 6,53]
			0,360		
Former	41/49 (83,7)	18/21 (85,7)	0,98 [0,79; 1,21]	0,85 [0,20; 3,60]	-2,04 [-20,24; 16,16]
			1,000		
Never	167/198 (84,3)	77/95 (81,1)	1,04 [0,93; 1,17]	1,26 [0,66; 2,39]	3,29 [-6,08; 12,66]
			0,506		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,949)					
Ever	234/279 (83,9)	117/140 (83,6)	1,00 [0,92; 1,10]	1,02 [0,59; 1,77]	0,30 [-7,20; 7,80]
			1,000		
Never	16/20 (80,0)	4/5 (80,0)	1,00 [0,61; 1,63]	1,00 [0,09; 11,59]	0,00 [-39,20; 39,20]
			1,000		
Prior anti-TNF failure (p-value of the interaction test: 0,950)					
Ever	233/281 (82,9)	115/139 (82,7)	1,00 [0,91; 1,10]	1,01 [0,59; 1,74]	0,18 [-7,49; 7,86]
			1,000		
Never	17/18 (94,4)	6/6 (100)	0,99 [0,78; 1,27]	0,90 [0,03; 24,94]	-5,56 [-16,14; 5,03]
			1,000		
Prior anti-integrin failure (p-value of the interaction test: 0,280)					
Ever	64/71 (90,1)	26/31 (83,9)	1,07 [0,90; 1,28]	1,76 [0,51; 6,04]	6,27 [-8,42; 20,96]
			0,504		
Never	186/228 (81,6)	95/114 (83,3)	0,98 [0,88; 1,08]	0,89 [0,49; 1,61]	-1,75 [-10,25; 6,74]
			0,765		
Baseline corticosteroid use (p-value of the interaction test: 0,763)					
Yes	65/76 (85,5)	34/39 (87,2)	0,98 [0,84; 1,14]	0,87 [0,28; 2,71]	-1,65 [-14,79; 11,49]
			1,000		
No	185/223 (83,0)	87/106 (82,1)	1,01 [0,91; 1,12]	1,06 [0,58; 1,95]	0,88 [-7,93; 9,70]
			0,877		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Baseline immunomodulator use (p-value of the interaction test: 0,661)					
Yes	56/66 (84,8)	34/39 (87,2)	0,97 [0,83; 1,14]	0,82 [0,26; 2,61]	-2,33 [-15,93; 11,27]
				1,000	
No	194/233 (83,3)	87/106 (82,1)	1,01 [0,91; 1,13]	1,09 [0,59; 1,99]	1,19 [-7,55; 9,92]
				0,876	
Duration of CD (p-value of the interaction test: 0,622)					
<1 year	21/23 (91,3)	8/9 (88,9)	1,03 [0,79; 1,34]	1,31 [0,10; 16,56]	2,42 [-21,13; 25,96]
				1,000	
≥1 to <5 years	82/104 (78,8)	37/44 (84,1)	0,94 [0,80; 1,10]	0,71 [0,28; 1,80]	-5,24 [-18,60; 8,11]
				0,507	
≥5 years	147/172 (85,5)	76/92 (82,6)	1,03 [0,92; 1,16]	1,24 [0,62; 2,46]	2,86 [-6,51; 12,22]
				0,594	
Baseline disease location (p-value of the interaction test: 0,858)					
Colonic	95/120 (79,2)	47/59 (79,7)	0,99 [0,85; 1,16]	0,97 [0,45; 2,10]	-0,49 [-13,08; 12,09]
				1,000	
Ileal	27/31 (87,1)	5/6 (83,3)	1,05 [0,71; 1,53]	1,35 [0,12; 14,73]	3,76 [-28,31; 35,83]
				1,000	
Ileal-Colonic	128/148 (86,5)	69/80 (86,3)	1,00 [0,90; 1,12]	1,02 [0,46; 2,25]	0,24 [-9,11; 9,58]
				1,000	
Baseline fecal calprotectin (p-value of the interaction test: 0,103)					
≤250	32/38 (84,2)	10/15 (66,7)	1,26 [0,86; 1,85]	2,67 [0,67; 10,63]	17,54 [-8,98; 44,07]
				0,258	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
>250	174/208 (83,7)	82/93 (88,2)	0,95 [0,86; 1,04]	0,69 [0,33; 1,42]	-4,52 [-12,78; 3,75]
0,383					
Baseline CRP (p-value of the interaction test: 0,448)					
≤10	119/145 (82,1)	45/58 (77,6)	1,06 [0,90; 1,24]	1,32 [0,63; 2,80]	4,48 [-7,93; 16,90]
0,554					
>10	131/154 (85,1)	76/87 (87,4)	0,97 [0,88; 1,08]	0,82 [0,38; 1,78]	-2,29 [-11,26; 6,68]
0,703					
Baseline SES-CD total score (p-value of the interaction test: 0,774)					
<12	120/142 (84,5)	55/66 (83,3)	1,01 [0,89; 1,15]	1,09 [0,49; 2,41]	1,17 [-9,61; 11,96]
0,840					
≥12	130/157 (82,8)	66/79 (83,5)	0,99 [0,88; 1,12]	0,95 [0,46; 1,96]	-0,74 [-10,83; 9,34]
1,000					
Baseline AP average (p-value of the interaction test: 0,944)					
<2	65/72 (90,3)	43/48 (89,6)	1,01 [0,89; 1,14]	1,08 [0,32; 3,62]	0,69 [-10,33; 11,72]
1,000					
≥2	184/226 (81,4)	78/97 (80,4)	1,01 [0,90; 1,14]	1,07 [0,58; 1,95]	1,00 [-8,38; 10,39]
0,877					
Baseline SF average (p-value of the interaction test: 0,735)					
<7	187/220 (85,0)	84/100 (84,0)	1,01 [0,91; 1,12]	1,08 [0,56; 2,07]	1,00 [-7,60; 9,60]
0,867					
≥7	61/76 (80,3)	37/45 (82,2)	0,98 [0,82; 1,16]	0,88 [0,34; 2,27]	-1,96 [-16,27; 12,35]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline CDAI 1 (p-value of the interaction test: 0,384)					
<300	92/109 (84,4)	52/59 (88,1)	0,96 [0,85; 1,08]	0,73 [0,28; 1,87]	-3,73 [-14,43; 6,97]
				0,646	
≥300	154/184 (83,7)	67/84 (79,8)	1,05 [0,93; 1,19]	1,30 [0,67; 2,52]	3,93 [-6,18; 14,05]
				0,489	
Baseline CDAI 2 (p-value of the interaction test: 0,377)					
<220	27/29 (93,1)	10/12 (83,3)	1,12 [0,85; 1,47]	2,70 [0,33; 21,83]	9,77 [-13,24; 32,78]
				0,567	
≥220 and <450	202/244 (82,8)	97/119 (81,5)	1,02 [0,92; 1,13]	1,09 [0,62; 1,93]	1,27 [-7,16; 9,71]
				0,771	
≥450	17/20 (85,0)	12/12 (100)	0,87 [0,70; 1,08]	0,20 [0,01; 4,23]	-15,00 [-30,65; 0,65]
				0,274	
OECD Country (p-value of the interaction test: 0,140)					
Yes	147/177 (83,1)	73/83 (88,0)	0,94 [0,85; 1,05]	0,67 [0,31; 1,45]	-4,90 [-13,82; 4,02]
				0,360	
No	103/122 (84,4)	48/62 (77,4)	1,09 [0,93; 1,27]	1,58 [0,73; 3,42]	7,01 [-5,23; 19,24]
				0,309	
Datenschnitt: 23. August 2023; Biologic-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_teae_sub_safb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba

20DEC2024 / 04:00

Subgruppen für Jegliche unerwünschte Ereignisse: Nicht schwer in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,279)					
<65 years	204/286 (71,3)	105/141 (74,5)	0,96 [0,85; 1,08]	0,85 [0,54; 1,35]	-3,14 [-12,04; 5,76]
			0,565		
≥65 years	12/13 (92,3)	3/4 (75,0)	1,23 [0,68; 2,21]	4,00 [0,19; 84,20]	17,31 [-27,53; 62,15]
			0,426		
Age 2 (p-value of the interaction test: 0,323)					
<40 years	146/202 (72,3)	71/91 (78,0)	0,93 [0,81; 1,06]	0,73 [0,41; 1,32]	-5,74 [-16,26; 4,77]
			0,317		
≥40 years	70/97 (72,2)	37/54 (68,5)	1,05 [0,85; 1,31]	1,19 [0,58; 2,46]	3,65 [-11,62; 18,91]
			0,710		
Sex (p-value of the interaction test: 0,339)					
Male	119/178 (66,9)	47/65 (72,3)	0,92 [0,77; 1,11]	0,77 [0,41; 1,45]	-5,45 [-18,34; 7,44]
			0,441		
Female	97/121 (80,2)	61/80 (76,3)	1,05 [0,90; 1,22]	1,26 [0,64; 2,49]	3,92 [-7,81; 15,64]
			0,599		
Race (p-value of the interaction test: 0,811)					
Asian	73/100 (73,0)	43/56 (76,8)	0,95 [0,79; 1,15]	0,82 [0,38; 1,75]	-3,79 [-17,86; 10,29]
			0,703		
White	130/179 (72,6)	60/82 (73,2)	0,99 [0,85; 1,16]	0,97 [0,54; 1,75]	-0,55 [-12,15; 11,06]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Other	7/13 (53,8)	5/7 (71,4)	0,75 [0,38; 1,50]	0,47 [0,07; 3,34]	-17,58 [-60,64; 25,48]
0,642					
Geographic region 1 (p-value of the interaction test: 0,525)					
Europe	79/114 (69,3)	37/50 (74,0)	0,94 [0,76; 1,15]	0,79 [0,38; 1,67]	-4,70 [-19,52; 10,11]
0,581					
North America	35/53 (66,0)	20/26 (76,9)	0,86 [0,65; 1,14]	0,58 [0,20; 1,71]	-10,89 [-31,50; 9,73]
0,437					
Other	102/132 (77,3)	51/69 (73,9)	1,05 [0,88; 1,24]	1,20 [0,61; 2,35]	3,36 [-9,23; 15,95]
0,605					
Geographic region 2 (p-value of the interaction test: 0,196)					
Asia	78/105 (74,3)	42/56 (75,0)	0,99 [0,82; 1,20]	0,96 [0,46; 2,03]	-0,71 [-14,80; 13,37]
1,000					
Central America/South America	23/24 (95,8)	9/13 (69,2)	1,38 [0,95; 2,01]	10,22 [1,00; >100]	26,60 [0,27; 52,93]
0,042					
Europe and ROW	80/117 (68,4)	37/50 (74,0)	0,92 [0,75; 1,13]	0,76 [0,36; 1,60]	-5,62 [-20,42; 9,17]
0,581					
North America	35/53 (66,0)	20/26 (76,9)	0,86 [0,65; 1,14]	0,58 [0,20; 1,71]	-10,89 [-31,50; 9,73]
0,437					
Weight (p-value of the interaction test: 0,574)					
<100 kg	204/284 (71,8)	103/140 (73,6)	0,98 [0,86; 1,10]	0,92 [0,58; 1,45]	-1,74 [-10,72; 7,24]
0,730					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
≥100 kg	12/15 (80,0)	5/5 (100)	0,85 [0,60; 1,21]	0,32 [0,01; 7,41]	-20,00 [-40,24; 0,24]
0,539					
BMI (p-value of the interaction test: 0,578)					
Underweight ($<18.5 \text{ kg/m}^2$)	37/54 (68,5)	24/32 (75,0)	0,91 [0,70; 1,20]	0,73 [0,27; 1,94]	-6,48 [-25,94; 12,97]
0,626					
Normal (≥18.5 and <25 kg/m ²)	121/161 (75,2)	45/60 (75,0)	1,00 [0,84; 1,19]	1,01 [0,51; 2,00]	0,16 [-12,67; 12,98]
1,000					
Overweight (≥25 and <30 kg/m ²)	37/55 (67,3)	25/38 (65,8)	1,02 [0,76; 1,37]	1,07 [0,45; 2,57]	1,48 [-18,04; 21,01]
1,000					
Obese and Extreme obese (≥30 kg/m ²)	21/29 (72,4)	14/15 (93,3)	0,78 [0,60; 1,01]	0,19 [0,02; 1,67]	-20,92 [-41,51; -0,33]
0,135					
Tobacco use (p-value of the interaction test: 0,355)					
Current	34/52 (65,4)	23/29 (79,3)	0,82 [0,63; 1,08]	0,49 [0,17; 1,43]	-13,93 [-33,54; 5,68]
0,215					
Former	37/49 (75,5)	18/21 (85,7)	0,88 [0,70; 1,12]	0,51 [0,13; 2,05]	-10,20 [-29,41; 9,00]
0,527					
Never	145/198 (73,2)	67/95 (70,5)	1,04 [0,89; 1,21]	1,14 [0,67; 1,97]	2,71 [-8,34; 13,76]
0,676					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,322)					
Ever	203/279 (72,8)	106/140 (75,7)	0,96 [0,85; 1,08]	0,86 [0,54; 1,37]	-2,95 [-11,77; 5,86]
0,557					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Never	13/20 (65,0)	2/5 (40,0)	1,63 [0,53; 4,98]	2,79 [0,37; 20,82]	25,00 [-22,76; 72,76]
0,358					
Prior anti-TNF failure (p-value of the interaction test: 0,535)					
Ever	200/281 (71,2)	103/139 (74,1)	0,96 [0,85; 1,09]	0,86 [0,55; 1,37]	-2,93 [-11,93; 6,08]
0,564					
Never	16/18 (88,9)	5/6 (83,3)	1,07 [0,72; 1,58]	1,60 [0,12; 21,59]	5,56 [-27,61; 38,72]
1,000					
Prior anti-integrin failure (p-value of the interaction test: 0,353)					
Ever	56/71 (78,9)	23/31 (74,2)	1,06 [0,84; 1,35]	1,30 [0,48; 3,48]	4,68 [-13,42; 22,77]
0,614					
Never	160/228 (70,2)	85/114 (74,6)	0,94 [0,82; 1,08]	0,80 [0,48; 1,33]	-4,39 [-14,34; 5,57]
0,446					
Baseline corticosteroid use (p-value of the interaction test: 0,718)					
Yes	61/76 (80,3)	31/39 (79,5)	1,01 [0,83; 1,23]	1,05 [0,40; 2,74]	0,78 [-14,74; 16,29]
1,000					
No	155/223 (69,5)	77/106 (72,6)	0,96 [0,83; 1,11]	0,86 [0,51; 1,43]	-3,13 [-13,55; 7,28]
0,606					
Baseline immunomodulator use (p-value of the interaction test: 0,880)					
Yes	49/66 (74,2)	30/39 (76,9)	0,97 [0,77; 1,21]	0,86 [0,34; 2,18]	-2,68 [-19,60; 14,24]
0,819					
No	167/233 (71,7)	78/106 (73,6)	0,97 [0,85; 1,12]	0,91 [0,54; 1,52]	-1,91 [-12,10; 8,28]
0,794					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Duration of CD (p-value of the interaction test: 0,535)					
<1 year	20/23 (87,0)	7/9 (77,8)	1,12 [0,76; 1,64]	1,90 [0,26; 13,87]	9,18 [-21,27; 39,63]
				0,604	
≥1 to <5 years	72/104 (69,2)	34/44 (77,3)	0,90 [0,73; 1,10]	0,66 [0,29; 1,50]	-8,04 [-23,27; 7,19]
				0,425	
≥5 years	124/172 (72,1)	67/92 (72,8)	0,99 [0,85; 1,16]	0,96 [0,55; 1,70]	-0,73 [-12,03; 10,56]
				1,000	
Baseline disease location (p-value of the interaction test: 0,762)					
Colonic	82/120 (68,3)	43/59 (72,9)	0,94 [0,77; 1,14]	0,80 [0,40; 1,60]	-4,55 [-18,62; 9,52]
				0,605	
Ileal	23/31 (74,2)	4/6 (66,7)	1,11 [0,61; 2,03]	1,44 [0,22; 9,41]	7,53 [-33,22; 48,27]
				0,653	
Ileal-Colonic	111/148 (75,0)	61/80 (76,3)	0,98 [0,84; 1,15]	0,93 [0,50; 1,76]	-1,25 [-12,90; 10,40]
				0,873	
Baseline fecal calprotectin (p-value of the interaction test: 0,052)					
≤250	30/38 (78,9)	8/15 (53,3)	1,48 [0,90; 2,44]	3,28 [0,91; 11,80]	25,61 [-2,77; 53,99]
				0,091	
>250	151/208 (72,6)	72/93 (77,4)	0,94 [0,82; 1,08]	0,77 [0,44; 1,37]	-4,82 [-15,26; 5,61]
				0,397	
Baseline CRP (p-value of the interaction test: 0,514)					
≤10	105/145 (72,4)	41/58 (70,7)	1,02 [0,84; 1,24]	1,09 [0,56; 2,13]	1,72 [-12,07; 15,51]
				0,863	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
>10	111/154 (72,1)	67/87 (77,0)	0,94 [0,80; 1,09]	0,77 [0,42; 1,42]	-4,93 [-16,26; 6,40]
0,448					
Baseline SES-CD total score (p-value of the interaction test: 0,654)					
<12	103/142 (72,5)	48/66 (72,7)	1,00 [0,83; 1,19]	0,99 [0,51; 1,91]	-0,19 [-13,21; 12,82]
1,000					
≥12	113/157 (72,0)	60/79 (75,9)	0,95 [0,81; 1,11]	0,81 [0,44; 1,52]	-3,97 [-15,73; 7,78]
0,538					
Baseline AP average (p-value of the interaction test: 0,765)					
<2	56/72 (77,8)	39/48 (81,3)	0,96 [0,80; 1,15]	0,81 [0,32; 2,01]	-3,47 [-18,11; 11,16]
0,819					
≥2	160/226 (70,8)	69/97 (71,1)	1,00 [0,85; 1,16]	0,98 [0,58; 1,66]	-0,34 [-11,13; 10,45]
1,000					
Baseline SF average (p-value of the interaction test: 0,323)					
<7	162/220 (73,6)	73/100 (73,0)	1,01 [0,87; 1,16]	1,03 [0,61; 1,76]	0,64 [-9,83; 11,11]
0,892					
≥7	52/76 (68,4)	35/45 (77,8)	0,88 [0,71; 1,09]	0,62 [0,26; 1,45]	-9,36 [-25,38; 6,67]
0,302					
Baseline CDAI 1 (p-value of the interaction test: 0,636)					
<300	83/109 (76,1)	47/59 (79,7)	0,96 [0,81; 1,13]	0,82 [0,38; 1,76]	-3,51 [-16,53; 9,51]
0,701					
≥300	131/184 (71,2)	59/84 (70,2)	1,01 [0,86; 1,20]	1,05 [0,59; 1,84]	0,96 [-10,81; 12,72]
0,885					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Baseline CDAI 2 (p-value of the interaction test: 0,068)					
<220	25/29 (86,2)	8/12 (66,7)	1,29 [0,84; 1,98]	3,13 [0,63; 15,45]	19,54 [-9,94; 49,02]
				0,202	
≥220 and <450	178/244 (73,0)	87/119 (73,1)	1,00 [0,87; 1,14]	0,99 [0,61; 1,63]	-0,16 [-9,88; 9,56]
				1,000	
≥450	11/20 (55,0)	11/12 (91,7)	0,60 [0,39; 0,92]	0,11 [0,01; 1,03]	-36,67 [-63,50; -9,84]
				0,050	
OECD Country (p-value of the interaction test: 0,127)					
Yes	124/177 (70,1)	65/83 (78,3)	0,89 [0,77; 1,04]	0,65 [0,35; 1,20]	-8,26 [-19,40; 2,88]
				0,181	
No	92/122 (75,4)	43/62 (69,4)	1,09 [0,90; 1,32]	1,36 [0,69; 2,67]	6,05 [-7,73; 19,84]
				0,384	
Datenschnitt: 23. August 2023; Biologic-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_aemaxns_sub_safb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba

20DEC2024 / 04:00

Subgruppen für Jegliche unerwünschte Ereignisse: Schwer in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,930)					
<65 years	33/286 (11,5)	13/141 (9,2)	1,25 [0,68; 2,30]	1,28 [0,65; 2,53]	2,32 [-3,72; 8,36]
			0,511		
≥65 years	1/13 (7,7)	0/4 (0,0)	1,07 [0,05; 22,25]	1,08 [0,04; 31,63]	7,69 [-6,79; 22,18]
			1,000		
Sex (p-value of the interaction test: 0,821)					
Male	22/178 (12,4)	6/65 (9,2)	1,34 [0,57; 3,15]	1,39 [0,54; 3,59]	3,13 [-5,41; 11,67]
			0,651		
Female	12/121 (9,9)	7/80 (8,8)	1,13 [0,47; 2,76]	1,15 [0,43; 3,05]	1,17 [-7,00; 9,33]
			1,000		
Race (p-value of the interaction test: 0,693)					
Asian	14/100 (14,0)	6/56 (10,7)	1,31 [0,53; 3,21]	1,36 [0,49; 3,75]	3,29 [-7,29; 13,86]
			0,626		
White	16/179 (8,9)	7/82 (8,5)	1,05 [0,45; 2,45]	1,05 [0,42; 2,66]	0,40 [-6,95; 7,75]
			1,000		
Other	3/13 (23,1)	0/7 (0,0)	4,00 [0,24; 67,99]	5,00 [0,22; >100]	23,08 [0,17; 45,98]
			0,521		
Geographic region 1 (p-value of the interaction test: 0,329)					
Europe	8/114 (7,0)	4/50 (8,0)	0,88 [0,28; 2,78]	0,87 [0,25; 3,03]	-0,98 [-9,84; 7,88]
			0,757		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
North America	10/53 (18,9)	1/26 (3,8)	4,91 [0,66; 36,30]	5,81 [0,70; 48,14]	15,02 [2,15; 27,89]
			0,090		
Other	16/132 (12,1)	8/69 (11,6)	1,05 [0,47; 2,32]	1,05 [0,43; 2,60]	0,53 [-8,86; 9,91]
			1,000		
Geographic region 2 (p-value of the interaction test: 0,363)					
Asia	14/105 (13,3)	7/56 (12,5)	1,07 [0,46; 2,49]	1,08 [0,41; 2,85]	0,83 [-10,00; 11,66]
			1,000		
Central America/South America	0/24 (0,0)	1/13 (7,7)	0,19 [0,01; 4,28]	0,17 [0,01; 4,49]	-7,69 [-22,18; 6,79]
			0,351		
Europe and ROW	10/117 (8,5)	4/50 (8,0)	1,07 [0,35; 3,25]	1,07 [0,32; 3,60]	0,55 [-8,52; 9,61]
			1,000		
North America	10/53 (18,9)	1/26 (3,8)	4,91 [0,66; 36,30]	5,81 [0,70; 48,14]	15,02 [2,15; 27,89]
			0,090		
Weight (p-value of the interaction test: 0,599)					
<100 kg	31/284 (10,9)	13/140 (9,3)	1,18 [0,64; 2,17]	1,20 [0,61; 2,37]	1,63 [-4,39; 7,65]
			0,735		
≥100 kg	3/15 (20,0)	0/5 (0,0)	2,63 [0,16; 43,63]	3,08 [0,13; 70,33]	20,00 [-0,24; 40,24]
			0,539		
BMI (p-value of the interaction test: 0,807)					
Underweight (<18.5 kg/m²)	9/54 (16,7)	4/32 (12,5)	1,33 [0,45; 3,98]	1,40 [0,39; 4,98]	4,17 [-11,00; 19,34]
			0,759		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Normal (≥18.5 and <25 kg/m ²)	13/161 (8,1)	5/60 (8,3)	0,97 [0,36; 2,60]	0,97 [0,33; 2,84]	-0,26 [-8,42; 7,90]
			1,000		
Overweight (≥25 and <30 kg/m ²)	6/55 (10,9)	3/38 (7,9)	1,38 [0,37; 5,19]	1,43 [0,33; 6,10]	3,01 [-8,88; 14,91]
			0,733		
Obese and Extreme obese (≥30 kg/m ²)	6/29 (20,7)	1/15 (6,7)	3,10 [0,41; 23,47]	3,65 [0,40; 33,59]	14,02 [-5,39; 33,43]
			0,393		
Tobacco use (p-value of the interaction test: 0,659)					
Current	8/52 (15,4)	3/29 (10,3)	1,49 [0,43; 5,17]	1,58 [0,38; 6,47]	5,04 [-9,76; 19,84]
			0,738		
Former	4/49 (8,2)	0/21 (0,0)	3,96 [0,22; 70,43]	4,25 [0,22; 82,60]	8,16 [0,50; 15,83]
			0,309		
Never	22/198 (11,1)	10/95 (10,5)	1,06 [0,52; 2,14]	1,06 [0,48; 2,34]	0,58 [-6,98; 8,15]
			1,000		
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,143)					
Ever	31/279 (11,1)	11/140 (7,9)	1,41 [0,73; 2,73]	1,47 [0,71; 3,01]	3,25 [-2,53; 9,04]
			0,389		
Never	3/20 (15,0)	2/5 (40,0)	0,38 [0,08; 1,68]	0,26 [0,03; 2,32]	-25,00 [-70,70; 20,70]
			0,252		
Prior anti-TNF failure (p-value of the interaction test: 0,265)					
Ever	33/281 (11,7)	12/139 (8,6)	1,36 [0,73; 2,55]	1,41 [0,70; 2,82]	3,11 [-2,89; 9,11]
			0,403		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Never	1/18 (5,6)	1/6 (16,7)	0,33 [0,02; 4,55]	0,29 [0,02; 5,60]	-11,11 [-42,75; 20,53]
0,446					
Prior anti-integrin failure (p-value of the interaction test: 0,824)					
Ever	8/71 (11,3)	3/31 (9,7)	1,16 [0,33; 4,10]	1,19 [0,29; 4,80]	1,59 [-11,15; 14,33]
1,000					
Never	26/228 (11,4)	10/114 (8,8)	1,30 [0,65; 2,60]	1,34 [0,62; 2,88]	2,63 [-4,00; 9,26]
0,576					
Baseline corticosteroid use (p-value of the interaction test: 0,331)					
Yes	4/76 (5,3)	3/39 (7,7)	0,68 [0,16; 2,91]	0,67 [0,14; 3,14]	-2,43 [-12,18; 7,32]
0,688					
No	30/223 (13,5)	10/106 (9,4)	1,43 [0,72; 2,81]	1,49 [0,70; 3,18]	4,02 [-3,12; 11,16]
0,368					
Baseline immunomodulator use (p-value of the interaction test: 0,705)					
Yes	7/66 (10,6)	4/39 (10,3)	1,03 [0,32; 3,31]	1,04 [0,28; 3,80]	0,35 [-11,73; 12,43]
1,000					
No	27/233 (11,6)	9/106 (8,5)	1,36 [0,67; 2,80]	1,41 [0,64; 3,12]	3,10 [-3,61; 9,81]
0,451					
Duration of CD (p-value of the interaction test: 0,612)					
<1 year	1/23 (4,3)	1/9 (11,1)	0,39 [0,03; 5,61]	0,36 [0,02; 6,53]	-6,76 [-28,92; 15,40]
0,490					
≥1 to <5 years	10/104 (9,6)	3/44 (6,8)	1,41 [0,41; 4,88]	1,45 [0,38; 5,56]	2,80 [-6,56; 12,16]
0,756					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
≥5 years	23/172 (13,4)	9/92 (9,8)	1,37 [0,66; 2,83]	1,42 [0,63; 3,22]	3,59 [-4,33; 11,51]
0,436					
Baseline disease location (p-value of the interaction test: 0,744)					
Colonic	13/120 (10,8)	4/59 (6,8)	1,60 [0,54; 4,69]	1,67 [0,52; 5,37]	4,05 [-4,44; 12,54]
0,588					
Ileal	4/31 (12,9)	1/6 (16,7)	0,77 [0,10; 5,77]	0,74 [0,07; 8,08]	-3,76 [-35,83; 28,31]
1,000					
Ileal-Colonic	17/148 (11,5)	8/80 (10,0)	1,15 [0,52; 2,54]	1,17 [0,48; 2,84]	1,49 [-6,86; 9,83]
0,827					
Baseline fecal calprotectin (p-value of the interaction test: 0,329)					
≤250	2/38 (5,3)	2/15 (13,3)	0,39 [0,06; 2,55]	0,36 [0,05; 2,83]	-8,07 [-26,68; 10,54]
0,568					
>250	23/208 (11,1)	10/93 (10,8)	1,03 [0,51; 2,07]	1,03 [0,47; 2,27]	0,31 [-7,30; 7,91]
1,000					
Baseline CRP (p-value of the interaction test: 0,917)					
≤10	14/145 (9,7)	4/58 (6,9)	1,40 [0,48; 4,08]	1,44 [0,45; 4,58]	2,76 [-5,34; 10,86]
0,785					
>10	20/154 (13,0)	9/87 (10,3)	1,26 [0,60; 2,64]	1,29 [0,56; 2,98]	2,64 [-5,67; 10,96]
0,681					
Baseline SES-CD total score (p-value of the interaction test: 0,718)					
<12	17/142 (12,0)	7/66 (10,6)	1,13 [0,49; 2,59]	1,15 [0,45; 2,91]	1,37 [-7,78; 10,51]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
≥12	17/157 (10,8)	6/79 (7,6)	1,43 [0,59; 3,47]	1,48 [0,56; 3,91]	3,23 [-4,37; 10,83]
0,494					
Baseline AP average (p-value of the interaction test: 0,725)					
<2	9/72 (12,5)	4/48 (8,3)	1,50 [0,49; 4,60]	1,57 [0,46; 5,43]	4,17 [-6,76; 15,10]
0,560					
≥2	24/226 (10,6)	9/97 (9,3)	1,14 [0,55; 2,37]	1,16 [0,52; 2,60]	1,34 [-5,69; 8,37]
0,842					
Baseline SF average (p-value of the interaction test: 0,279)					
<7	25/220 (11,4)	11/100 (11,0)	1,03 [0,53; 2,02]	1,04 [0,49; 2,20]	0,36 [-7,07; 7,79]
1,000					
≥7	9/76 (11,8)	2/45 (4,4)	2,66 [0,60; 11,79]	2,89 [0,60; 14,01]	7,40 [-2,04; 16,83]
0,208					
Baseline CDAI 1 (p-value of the interaction test: 0,690)					
<300	9/109 (8,3)	5/59 (8,5)	0,97 [0,34; 2,77]	0,97 [0,31; 3,05]	-0,22 [-9,00; 8,57]
1,000					
≥300	23/184 (12,5)	8/84 (9,5)	1,31 [0,61; 2,81]	1,36 [0,58; 3,17]	2,98 [-4,91; 10,87]
0,543					
Baseline CDAI 2 (p-value of the interaction test: 0,301)					
<220	2/29 (6,9)	2/12 (16,7)	0,41 [0,07; 2,61]	0,37 [0,05; 2,99]	-9,77 [-32,78; 13,24]
0,567					
≥220 and <450	24/244 (9,8)	10/119 (8,4)	1,17 [0,58; 2,37]	1,19 [0,55; 2,57]	1,43 [-4,80; 7,66]
0,706					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
≥450	6/20 (30,0)	1/12 (8,3)	3,60 [0,49; 26,40]	4,71 [0,49; 45,15]	21,67 [-3,79; 47,12]
0,212					
OECD Country (p-value of the interaction test: 0,747)					
Yes	23/177 (13,0)	8/83 (9,6)	1,35 [0,63; 2,89]	1,40 [0,60; 3,28]	3,36 [-4,70; 11,41]
0,540					
No	11/122 (9,0)	5/62 (8,1)	1,12 [0,41; 3,08]	1,13 [0,37; 3,41]	0,95 [-7,52; 9,42]
1,000					
Datenschnitt: 23. August 2023; Biologic-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_aemaxse_sub_safb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
20DEC2024 / 04:00

Subgruppen für Abbruch der Behandlung aufgrund unerwünschter Ereignisse: Gesamtrate in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,500)					
<65 years	12/286 (4,2)	4/141 (2,8)	1,48 [0,49; 4,50]	1,50 [0,47; 4,74]	1,36 [-2,23; 4,95]
			0,595		
≥65 years	0/13 (0,0)	0/4 (0,0)	NB	NB	NB
			NB		
Age 2 (p-value of the interaction test: 0,132)					
<40 years	11/202 (5,4)	2/91 (2,2)	2,48 [0,56; 10,95]	2,56 [0,56; 11,81]	3,25 [-1,10; 7,59]
			0,357		
≥40 years	1/97 (1,0)	2/54 (3,7)	0,28 [0,03; 3,00]	0,27 [0,02; 3,06]	-2,67 [-8,10; 2,75]
			0,291		
Weight (p-value of the interaction test: 0,536)					
<100 kg	12/284 (4,2)	4/140 (2,9)	1,48 [0,49; 4,50]	1,50 [0,47; 4,74]	1,37 [-2,25; 4,99]
			0,595		
≥100 kg	0/15 (0,0)	0/5 (0,0)	NB	NB	NB
			NB		
Tobacco use (p-value of the interaction test: 0,622)					
Current	1/52 (1,9)	0/29 (0,0)	1,70 [0,07; 40,39]	1,72 [0,07; 43,55]	1,92 [-1,81; 5,66]
			1,000		
Former	1/49 (2,0)	1/21 (4,8)	0,43 [0,03; 6,53]	0,42 [0,02; 6,99]	-2,72 [-12,65; 7,21]
			0,513		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Never	10/198 (5,1)	3/95 (3,2)	1,60 [0,45; 5,68]	1,63 [0,44; 6,07]	1,89 [-2,76; 6,55]
0,558					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,868)					
Ever	11/279 (3,9)	4/140 (2,9)	1,38 [0,45; 4,26]	1,40 [0,44; 4,46]	1,09 [-2,50; 4,67]
0,782					
Never	1/20 (5,0)	0/5 (0,0)	0,86 [0,04; 18,45]	0,85 [0,03; 23,82]	5,00 [-4,55; 14,55]
1,000					
Prior anti-TNF failure (p-value of the interaction test: 0,536)					
Ever	12/281 (4,3)	4/139 (2,9)	1,48 [0,49; 4,52]	1,51 [0,48; 4,76]	1,39 [-2,26; 5,04]
0,595					
Never	0/18 (0,0)	0/6 (0,0)	NB	NB	NB
NB					
Prior anti-integrin failure (p-value of the interaction test: 0,522)					
Ever	2/71 (2,8)	1/31 (3,2)	0,87 [0,08; 9,28]	0,87 [0,08; 9,96]	-0,41 [-7,72; 6,91]
1,000					
Never	10/228 (4,4)	3/114 (2,6)	1,67 [0,47; 5,94]	1,70 [0,46; 6,29]	1,75 [-2,21; 5,72]
0,556					
Baseline corticosteroid use (p-value of the interaction test: 0,611)					
Yes	4/76 (5,3)	2/39 (5,1)	1,03 [0,20; 5,36]	1,03 [0,18; 5,87]	0,13 [-8,42; 8,69]
1,000					
No	8/223 (3,6)	2/106 (1,9)	1,90 [0,41; 8,80]	1,93 [0,40; 9,27]	1,70 [-1,86; 5,26]
0,510					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline immunomodulator use (p-value of the interaction test: 0,294)					
Yes	2/66 (3,0)	2/39 (5,1)	0,59 [0,09; 4,03]	0,58 [0,08; 4,28]	-2,10 [-10,16; 5,97]
			0,627		
No	10/233 (4,3)	2/106 (1,9)	2,27 [0,51; 10,20]	2,33 [0,50; 10,83]	2,41 [-1,27; 6,08]
			0,354		
Baseline fecal calprotectin (p-value of the interaction test: 0,333)					
≤250	1/38 (2,6)	1/15 (6,7)	0,39 [0,03; 5,91]	0,38 [0,02; 6,47]	-4,04 [-17,65; 9,58]
			0,490		
>250	11/208 (5,3)	3/93 (3,2)	1,64 [0,47; 5,74]	1,68 [0,46; 6,15]	2,06 [-2,64; 6,77]
			0,561		
Baseline CRP (p-value of the interaction test: 0,832)					
≤10	5/145 (3,4)	1/58 (1,7)	2,00 [0,24; 16,75]	2,04 [0,23; 17,81]	1,72 [-2,75; 6,20]
			0,676		
>10	7/154 (4,5)	3/87 (3,4)	1,32 [0,35; 4,97]	1,33 [0,34; 5,29]	1,10 [-3,95; 6,15]
			1,000		
Baseline AP average (p-value of the interaction test: 0,820)					
<2	3/72 (4,2)	1/48 (2,1)	2,00 [0,21; 18,67]	2,04 [0,21; 20,25]	2,08 [-4,05; 8,22]
			0,649		
≥2	9/226 (4,0)	3/97 (3,1)	1,29 [0,36; 4,65]	1,30 [0,34; 4,91]	0,89 [-3,40; 5,18]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline SF average (p-value of the interaction test: 0,917)					
<7	9/220 (4,1)	3/100 (3,0)	1,36 [0,38; 4,93]	1,38 [0,37; 5,21]	1,09 [-3,16; 5,34]
				0,760	
≥7	3/76 (3,9)	1/45 (2,2)	1,78 [0,19; 16,57]	1,81 [0,18; 17,93]	1,73 [-4,42; 7,87]
				1,000	
Baseline CDAI 1 (p-value of the interaction test: 0,418)					
<300	3/109 (2,8)	2/59 (3,4)	0,81 [0,14; 4,72]	0,81 [0,13; 4,97]	-0,64 [-6,18; 4,91]
				1,000	
≥300	9/184 (4,9)	2/84 (2,4)	2,05 [0,45; 9,30]	2,11 [0,45; 9,98]	2,51 [-2,00; 7,02]
				0,511	
Baseline CDAI 2 (p-value of the interaction test: 0,541)					
<220	1/29 (3,4)	1/12 (8,3)	0,41 [0,03; 6,09]	0,39 [0,02; 6,85]	-4,89 [-21,87; 12,10]
				0,505	
≥220 and <450	9/244 (3,7)	3/119 (2,5)	1,46 [0,40; 5,31]	1,48 [0,39; 5,57]	1,17 [-2,51; 4,85]
				0,758	
≥450	2/20 (10,0)	0/12 (0,0)	3,10 [0,16; 59,52]	3,38 [0,15; 76,51]	10,00 [-3,15; 23,15]
				0,516	
Datenschnitt: 23. August 2023; Biologic-failed Safety Population. Abkürzungen: AP: Abdominal Pain; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; RR: relatives Risiko; SF: Stool Frequency; TNF: Tumor Necrosis Factor. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_aedst_sub_safb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba

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Subgruppen für Schwerwiegende unerwünschte Ereignisse: Gesamtrate in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,960)					
<65 years	39/286 (13,6)	18/141 (12,8)	1,07 [0,63; 1,80]	1,08 [0,59; 1,96]	0,87 [-5,92; 7,66]
			0,880		
≥65 years	4/13 (30,8)	1/4 (25,0)	1,23 [0,19; 8,09]	1,33 [0,10; 17,10]	5,77 [-43,53; 55,07]
			1,000		
Age 2 (p-value of the interaction test: 0,852)					
<40 years	28/202 (13,9)	11/91 (12,1)	1,15 [0,60; 2,20]	1,17 [0,56; 2,47]	1,77 [-6,45; 9,99]
			0,853		
≥40 years	15/97 (15,5)	8/54 (14,8)	1,04 [0,47; 2,30]	1,05 [0,41; 2,67]	0,65 [-11,25; 12,55]
			1,000		
Sex (p-value of the interaction test: 0,973)					
Male	29/178 (16,3)	10/65 (15,4)	1,06 [0,55; 2,05]	1,07 [0,49; 2,34]	0,91 [-9,41; 11,22]
			1,000		
Female	14/121 (11,6)	9/80 (11,3)	1,03 [0,47; 2,26]	1,03 [0,42; 2,51]	0,32 [-8,65; 9,29]
			1,000		
Race (p-value of the interaction test: 0,662)					
Asian	17/100 (17,0)	10/56 (17,9)	0,95 [0,47; 1,93]	0,94 [0,40; 2,23]	-0,86 [-13,30; 11,59]
			1,000		
White	22/179 (12,3)	9/82 (11,0)	1,12 [0,54; 2,32]	1,14 [0,50; 2,59]	1,31 [-6,99; 9,62]
			0,839		

Subgruppe	Mirikizumab Pat. mit Ereignis n/N (%)	Ustekinumab Pat. mit Ereignis n/N (%)	Mirikizumab vs. Ustekinumab		
			RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Other	3/13 (23,1)	0/7 (0,0)	4,00 [0,24; 67,99]	5,00 [0,22; >100]	23,08 [0,17; 45,98]
0,521					
Geographic region 1 (p-value of the interaction test: 0,497)					
Europe	13/114 (11,4)	7/50 (14,0)	0,81 [0,35; 1,92]	0,79 [0,30; 2,12]	-2,60 [-13,85; 8,65]
0,615					
North America	7/53 (13,2)	1/26 (3,8)	3,43 [0,45; 26,46]	3,80 [0,44; 32,70]	9,36 [-2,37; 21,10]
0,260					
Other	23/132 (17,4)	11/69 (15,9)	1,09 [0,57; 2,11]	1,11 [0,51; 2,44]	1,48 [-9,31; 12,27]
0,845					
Geographic region 2 (p-value of the interaction test: 0,622)					
Asia	18/105 (17,1)	11/56 (19,6)	0,87 [0,44; 1,72]	0,85 [0,37; 1,94]	-2,50 [-15,16; 10,16]
0,674					
Central America/South America	2/24 (8,3)	0/13 (0,0)	2,80 [0,14; 54,31]	3,00 [0,13; 67,29]	8,33 [-2,72; 19,39]
0,532					
Europe and ROW	16/117 (13,7)	7/50 (14,0)	0,98 [0,43; 2,23]	0,97 [0,37; 2,53]	-0,32 [-11,78; 11,13]
1,000					
North America	7/53 (13,2)	1/26 (3,8)	3,43 [0,45; 26,46]	3,80 [0,44; 32,70]	9,36 [-2,37; 21,10]
0,260					
Weight (p-value of the interaction test: 0,565)					
<100 kg	41/284 (14,4)	18/140 (12,9)	1,12 [0,67; 1,88]	1,14 [0,63; 2,07]	1,58 [-5,31; 8,47]
0,766					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
≥100 kg	2/15 (13,3)	1/5 (20,0)	0,67 [0,08; 5,88]	0,62 [0,04; 8,70]	-6,67 [-45,72; 32,39]
1,000					
BMI (p-value of the interaction test: 0,986)					
Underweight ($<18.5 \text{ kg/m}^2$)	10/54 (18,5)	6/32 (18,8)	0,99 [0,40; 2,46]	0,98 [0,32; 3,03]	-0,23 [-17,27; 16,80]
1,000					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	21/161 (13,0)	7/60 (11,7)	1,12 [0,50; 2,49]	1,14 [0,46; 2,83]	1,38 [-8,27; 11,02]
1,000					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	6/55 (10,9)	3/38 (7,9)	1,38 [0,37; 5,19]	1,43 [0,33; 6,10]	3,01 [-8,88; 14,91]
0,733					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	6/29 (20,7)	3/15 (20,0)	1,03 [0,30; 3,57]	1,04 [0,22; 4,92]	0,69 [-24,35; 25,73]
1,000					
Tobacco use (p-value of the interaction test: 0,969)					
Current	12/52 (23,1)	6/29 (20,7)	1,12 [0,47; 2,66]	1,15 [0,38; 3,48]	2,39 [-16,28; 21,06]
1,000					
Former	7/49 (14,3)	3/21 (14,3)	1,00 [0,29; 3,50]	1,00 [0,23; 4,31]	0,00 [-17,89; 17,89]
1,000					
Never	24/198 (12,1)	10/95 (10,5)	1,15 [0,57; 2,31]	1,17 [0,54; 2,56]	1,59 [-6,07; 9,26]
0,846					
Prior anti-TNF failure (p-value of the interaction test: 0,316)					
Ever	42/281 (14,9)	18/139 (12,9)	1,15 [0,69; 1,93]	1,18 [0,65; 2,14]	2,00 [-4,97; 8,96]
0,658					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert ^a					
Never	1/18 (5,6)	1/6 (16,7)	0,33 [0,02; 4,55]	0,29 [0,02; 5,60]	-11,11 [-42,75; 20,53]
0,446					
Prior anti-integrin failure (p-value of the interaction test: 0,881)					
Ever	11/71 (15,5)	4/31 (12,9)	1,20 [0,41; 3,48]	1,24 [0,36; 4,24]	2,59 [-11,91; 17,08]
1,000					
Never	32/228 (14,0)	15/114 (13,2)	1,07 [0,60; 1,89]	1,08 [0,56; 2,08]	0,88 [-6,79; 8,55]
0,869					
Baseline corticosteroid use (p-value of the interaction test: 0,843)					
Yes	8/76 (10,5)	4/39 (10,3)	1,03 [0,33; 3,20]	1,03 [0,29; 3,66]	0,27 [-11,49; 12,03]
1,000					
No	35/223 (15,7)	15/106 (14,2)	1,11 [0,63; 1,94]	1,13 [0,59; 2,17]	1,54 [-6,63; 9,72]
0,870					
Baseline immunomodulator use (p-value of the interaction test: 0,636)					
Yes	9/66 (13,6)	6/39 (15,4)	0,89 [0,34; 2,30]	0,87 [0,28; 2,66]	-1,75 [-15,78; 12,28]
0,782					
No	34/233 (14,6)	13/106 (12,3)	1,19 [0,66; 2,16]	1,22 [0,62; 2,42]	2,33 [-5,39; 10,04]
0,615					
Duration of CD (p-value of the interaction test: 0,115)					
<1 year	1/23 (4,3)	3/9 (33,3)	0,13 [0,02; 1,10]	0,09 [0,01; 1,04]	-28,99 [-60,89; 2,92]
0,057					
≥1 to <5 years	13/104 (12,5)	4/44 (9,1)	1,38 [0,47; 3,98]	1,43 [0,44; 4,65]	3,41 [-7,20; 14,02]
0,779					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
≥5 years	29/172 (16,9)	12/92 (13,0)	1,29 [0,69; 2,41]	1,35 [0,65; 2,80]	3,82 [-5,05; 12,69]
0,478					
Baseline disease location (p-value of the interaction test: 0,816)					
Colonic	14/120 (11,7)	5/59 (8,5)	1,38 [0,52; 3,64]	1,43 [0,49; 4,17]	3,19 [-5,95; 12,33]
0,612					
Ileal	7/31 (22,6)	1/6 (16,7)	1,35 [0,20; 9,10]	1,46 [0,15; 14,64]	5,91 [-27,34; 39,17]
1,000					
Ileal-Colonic	22/148 (14,9)	13/80 (16,3)	0,91 [0,49; 1,72]	0,90 [0,43; 1,90]	-1,39 [-11,29; 8,52]
0,848					
Baseline fecal calprotectin (p-value of the interaction test: 0,104)					
≤250	4/38 (10,5)	4/15 (26,7)	0,39 [0,11; 1,38]	0,32 [0,07; 1,51]	-16,14 [-40,55; 8,27]
0,202					
>250	32/208 (15,4)	11/93 (11,8)	1,30 [0,69; 2,47]	1,36 [0,65; 2,82]	3,56 [-4,64; 11,75]
0,479					
Baseline CRP (p-value of the interaction test: 0,893)					
≤10	18/145 (12,4)	6/58 (10,3)	1,20 [0,50; 2,87]	1,23 [0,46; 3,27]	2,07 [-7,43; 11,57]
0,812					
>10	25/154 (16,2)	13/87 (14,9)	1,09 [0,59; 2,01]	1,10 [0,53; 2,29]	1,29 [-8,20; 10,78]
0,856					
Baseline SES-CD total score (p-value of the interaction test: 0,797)					
<12	22/142 (15,5)	10/66 (15,2)	1,02 [0,51; 2,03]	1,03 [0,46; 2,31]	0,34 [-10,16; 10,84]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
≥12	21/157 (13,4)	9/79 (11,4)	1,17 [0,56; 2,44]	1,20 [0,52; 2,76]	1,98 [-6,82; 10,78]
0,836					
Baseline AP average (p-value of the interaction test: 0,192)					
<2	11/72 (15,3)	10/48 (20,8)	0,73 [0,34; 1,59]	0,69 [0,27; 1,77]	-5,56 [-19,73; 8,62]
0,469					
≥2	31/226 (13,7)	9/97 (9,3)	1,48 [0,73; 2,99]	1,55 [0,71; 3,40]	4,44 [-2,87; 11,75]
0,357					
Baseline SF average (p-value of the interaction test: 0,540)					
<7	35/220 (15,9)	16/100 (16,0)	0,99 [0,58; 1,71]	0,99 [0,52; 1,89]	-0,09 [-8,75; 8,57]
1,000					
≥7	8/76 (10,5)	3/45 (6,7)	1,58 [0,44; 5,65]	1,65 [0,41; 6,56]	3,86 [-6,18; 13,90]
0,745					
Baseline CDAI 1 (p-value of the interaction test: 0,810)					
<300	15/109 (13,8)	8/59 (13,6)	1,01 [0,46; 2,25]	1,02 [0,40; 2,56]	0,20 [-10,67; 11,07]
1,000					
≥300	26/184 (14,1)	10/84 (11,9)	1,19 [0,60; 2,35]	1,22 [0,56; 2,66]	2,23 [-6,34; 10,79]
0,702					
Baseline CDAI 2 (p-value of the interaction test: 0,910)					
<220	7/29 (24,1)	3/12 (25,0)	0,97 [0,30; 3,12]	0,95 [0,20; 4,54]	-0,86 [-29,89; 28,17]
1,000					
≥220 and <450	31/244 (12,7)	14/119 (11,8)	1,08 [0,60; 1,95]	1,09 [0,56; 2,14]	0,94 [-6,20; 8,08]
0,866					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
≥450	3/20 (15,0)	1/12 (8,3)	1,80 [0,21; 15,41]	1,94 [0,18; 21,12]	6,67 [-15,46; 28,79]
1,000					
OECD Country (p-value of the interaction test: 0,599)					
Yes	25/177 (14,1)	12/83 (14,5)	0,98 [0,52; 1,85]	0,97 [0,46; 2,05]	-0,33 [-9,47; 8,81]
1,000					
No	18/122 (14,8)	7/62 (11,3)	1,31 [0,58; 2,96]	1,36 [0,54; 3,45]	3,46 [-6,62; 13,55]
0,651					
Datenschnitt: 23. August 2023; Biologic-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_sae_sub_safb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
20DEC2024 / 04:00

Anhang 4-G.4.6.3.2 Unerwünschte Ereignisse von speziellem Interesse (UESI)**Hepatische Ereignisse**

Subgruppen für Hepatic Safety: Gesamtrate in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,621)					
<65 years	20/286 (7,0)	7/141 (5,0)	1,41 [0,61; 3,25]	1,44 [0,59; 3,49]	2,03 [-2,62; 6,67]
			0,528		
≥65 years	0/13 (0,0)	0/4 (0,0)	NB	NB	NB
			NB		
Age 2 (p-value of the interaction test: 0,301)					
<40 years	14/202 (6,9)	3/91 (3,3)	2,10 [0,62; 7,14]	2,18 [0,61; 7,80]	3,63 [-1,44; 8,71]
			0,286		
≥40 years	6/97 (6,2)	4/54 (7,4)	0,84 [0,25; 2,83]	0,82 [0,22; 3,06]	-1,22 [-9,69; 7,25]
			0,746		
Sex (p-value of the interaction test: 0,246)					
Male	11/178 (6,2)	1/65 (1,5)	4,02 [0,53; 30,50]	4,22 [0,53; 33,32]	4,64 [0,01; 9,27]
			0,190		
Female	9/121 (7,4)	6/80 (7,5)	0,99 [0,37; 2,68]	0,99 [0,34; 2,90]	-0,06 [-7,49; 7,37]
			1,000		
Race (p-value of the interaction test: 0,130)					
Asian	15/100 (15,0)	3/56 (5,4)	2,80 [0,85; 9,26]	3,12 [0,86; 11,28]	9,64 [0,49; 18,79]
			0,115		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
White	4/179 (2,2)	4/82 (4,9)	0,46 [0,12; 1,79]	0,45 [0,11; 1,83]	-2,64 [-7,78; 2,50]
			0,264		
Other	0/13 (0,0)	0/7 (0,0)	NB	NB	NB
			NB		
Geographic region 1 (p-value of the interaction test: 0,636)					
Europe	3/114 (2,6)	1/50 (2,0)	1,32 [0,14; 12,34]	1,32 [0,13; 13,05]	0,63 [-4,24; 5,50]
			1,000		
North America	1/53 (1,9)	1/26 (3,8)	0,49 [0,03; 7,54]	0,48 [0,03; 8,01]	-1,96 [-10,21; 6,29]
			1,000		
Other	16/132 (12,1)	5/69 (7,2)	1,67 [0,64; 4,37]	1,77 [0,62; 5,04]	4,87 [-3,40; 13,15]
			0,339		
Geographic region 2 (p-value of the interaction test: 0,160)					
Asia	16/105 (15,2)	3/56 (5,4)	2,84 [0,87; 9,35]	3,18 [0,88; 11,41]	9,88 [0,82; 18,94]
			0,076		
Central America/South America	0/24 (0,0)	2/13 (15,4)	0,11 [0,01; 2,17]	0,09 [0,00; 2,12]	-15,38 [-35,00; 4,23]
			0,117		
Europe and ROW	3/117 (2,6)	1/50 (2,0)	1,28 [0,14; 12,03]	1,29 [0,13; 12,71]	0,56 [-4,26; 5,39]
			1,000		
North America	1/53 (1,9)	1/26 (3,8)	0,49 [0,03; 7,54]	0,48 [0,03; 8,01]	-1,96 [-10,21; 6,29]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Weight (p-value of the interaction test: 0,592)					
<100 kg	20/284 (7,0)	7/140 (5,0)	1,41 [0,61; 3,25]	1,44 [0,59; 3,49]	2,04 [-2,64; 6,72]
			0,528		
≥100 kg	0/15 (0,0)	0/5 (0,0)	NB	NB	NB
			NB		
BMI (p-value of the interaction test: 0,565)					
Underweight (<18.5 kg/m²)	5/54 (9,3)	2/32 (6,3)	1,48 [0,31; 7,20]	1,53 [0,28; 8,39]	3,01 [-8,40; 14,42]
			1,000		
Normal (≥18.5 and <25 kg/m²)	12/161 (7,5)	2/60 (3,3)	2,24 [0,52; 9,70]	2,34 [0,51; 10,76]	4,12 [-1,97; 10,21]
			0,361		
Overweight (≥25 and <30 kg/m²)	3/55 (5,5)	2/38 (5,3)	1,04 [0,18; 5,91]	1,04 [0,17; 6,53]	0,19 [-9,11; 9,49]
			1,000		
Obese and Extreme obese (≥30 kg/m²)	0/29 (0,0)	1/15 (6,7)	0,18 [0,01; 4,12]	0,16 [0,01; 4,28]	-6,67 [-19,29; 5,96]
			0,341		
Tobacco use (p-value of the interaction test: 0,590)					
Current	1/52 (1,9)	1/29 (3,4)	0,56 [0,04; 8,59]	0,55 [0,03; 9,12]	-1,53 [-9,14; 6,09]
			1,000		
Former	4/49 (8,2)	0/21 (0,0)	3,96 [0,22; 70,43]	4,25 [0,22; 82,60]	8,16 [0,50; 15,83]
			0,309		
Never	15/198 (7,6)	6/95 (6,3)	1,20 [0,48; 2,99]	1,22 [0,46; 3,24]	1,26 [-4,86; 7,38]
			0,812		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,300)					
Ever	18/279 (6,5)	6/140 (4,3)	1,51 [0,61; 3,71]	1,54 [0,60; 3,97]	2,17 [-2,26; 6,59]
			0,504		
Never	2/20 (10,0)	1/5 (20,0)	0,50 [0,06; 4,47]	0,44 [0,03; 6,19]	-10,00 [-47,45; 27,45]
			0,504		
Prior anti-TNF failure (p-value of the interaction test: 0,993)					
Ever	19/281 (6,8)	7/139 (5,0)	1,34 [0,58; 3,12]	1,37 [0,56; 3,33]	1,73 [-2,95; 6,40]
			0,667		
Never	1/18 (5,6)	0/6 (0,0)	1,11 [0,05; 24,07]	1,11 [0,04; 30,97]	5,56 [-5,03; 16,14]
			1,000		
Prior anti-integrin failure (p-value of the interaction test: 0,520)					
Ever	6/71 (8,5)	1/31 (3,2)	2,62 [0,33; 20,86]	2,77 [0,32; 24,03]	5,22 [-3,75; 14,20]
			0,672		
Never	14/228 (6,1)	6/114 (5,3)	1,17 [0,46; 2,96]	1,18 [0,44; 3,15]	0,88 [-4,27; 6,03]
			0,812		
Baseline corticosteroid use (p-value of the interaction test: 0,238)					
Yes	2/76 (2,6)	2/39 (5,1)	0,51 [0,08; 3,51]	0,50 [0,07; 3,69]	-2,50 [-10,30; 5,31]
			0,603		
No	18/223 (8,1)	5/106 (4,7)	1,71 [0,65; 4,48]	1,77 [0,64; 4,91]	3,35 [-2,04; 8,75]
			0,356		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline immunomodulator use (p-value of the interaction test: 0,640)					
Yes	6/66 (9,1)	3/39 (7,7)	1,18 [0,31; 4,46]	1,20 [0,28; 5,10]	1,40 [-9,47; 12,26]
				1,000	
No	14/233 (6,0)	4/106 (3,8)	1,59 [0,54; 4,72]	1,63 [0,52; 5,08]	2,23 [-2,51; 6,98]
				0,602	
Duration of CD (p-value of the interaction test: 0,253)					
<1 year	1/23 (4,3)	1/9 (11,1)	0,39 [0,03; 5,61]	0,36 [0,02; 6,53]	-6,76 [-28,92; 15,40]
				0,490	
≥1 to <5 years	9/104 (8,7)	0/44 (0,0)	8,14 [0,48; >100]	8,85 [0,50; >100]	8,65 [3,25; 14,06]
				0,058	
≥5 years	10/172 (5,8)	6/92 (6,5)	0,89 [0,33; 2,38]	0,88 [0,31; 2,52]	-0,71 [-6,85; 5,43]
				0,793	
Baseline disease location (p-value of the interaction test: 0,574)					
Colonic	6/120 (5,0)	2/59 (3,4)	1,48 [0,31; 7,09]	1,50 [0,29; 7,67]	1,61 [-4,43; 7,65]
				1,000	
Ileal	2/31 (6,5)	1/6 (16,7)	0,39 [0,04; 3,62]	0,34 [0,03; 4,56]	-10,22 [-41,26; 20,83]
				0,421	
Ileal-Colonic	12/148 (8,1)	4/80 (5,0)	1,62 [0,54; 4,86]	1,68 [0,52; 5,38]	3,11 [-3,38; 9,60]
				0,431	
Baseline fecal calprotectin (p-value of the interaction test: 0,582)					
≤250	4/38 (10,5)	2/15 (13,3)	0,79 [0,16; 3,87]	0,76 [0,12; 4,69]	-2,81 [-22,58; 16,97]
				1,000	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert ^a					
>250	14/208 (6,7)	5/93 (5,4)	1,25 [0,46; 3,37]	1,27 [0,44; 3,64]	1,35 [-4,36; 7,06]
0,800					
Baseline CRP (p-value of the interaction test: 0,947)					
≤10	8/145 (5,5)	2/58 (3,4)	1,60 [0,35; 7,31]	1,64 [0,34; 7,94]	2,07 [-3,92; 8,06]
0,728					
>10	12/154 (7,8)	5/87 (5,7)	1,36 [0,49; 3,72]	1,39 [0,47; 4,07]	2,05 [-4,42; 8,51]
0,612					
Baseline SES-CD total score (p-value of the interaction test: 0,096)					
<12	7/142 (4,9)	5/66 (7,6)	0,65 [0,21; 1,97]	0,63 [0,19; 2,07]	-2,65 [-9,96; 4,66]
0,525					
≥12	13/157 (8,3)	2/79 (2,5)	3,27 [0,76; 14,14]	3,48 [0,76; 15,80]	5,75 [0,22; 11,28]
0,098					
Baseline AP average (p-value of the interaction test: 0,239)					
<2	4/72 (5,6)	4/48 (8,3)	0,67 [0,18; 2,54]	0,65 [0,15; 2,72]	-2,78 [-12,22; 6,66]
0,712					
≥2	16/226 (7,1)	3/97 (3,1)	2,29 [0,68; 7,68]	2,39 [0,68; 8,39]	3,99 [-0,81; 8,79]
0,203					
Baseline SF average (p-value of the interaction test: 0,127)					
<7	17/220 (7,7)	4/100 (4,0)	1,93 [0,67; 5,59]	2,01 [0,66; 6,13]	3,73 [-1,49; 8,94]
0,329					
≥7	2/76 (2,6)	3/45 (6,7)	0,39 [0,07; 2,27]	0,38 [0,06; 2,36]	-4,04 [-12,16; 4,09]
0,359					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline CDAI 1 (p-value of the interaction test: 0,757)					
<300	6/109 (5,5)	3/59 (5,1)	1,08 [0,28; 4,17]	1,09 [0,26; 4,51]	0,42 [-6,63; 7,47]
			1,000		
≥300	13/184 (7,1)	4/84 (4,8)	1,48 [0,50; 4,42]	1,52 [0,48; 4,81]	2,30 [-3,57; 8,17]
			0,595		
Baseline CDAI 2 (p-value of the interaction test: 0,688)					
<220	3/29 (10,3)	2/12 (16,7)	0,62 [0,12; 3,26]	0,58 [0,08; 3,98]	-6,32 [-30,14; 17,50]
			0,620		
≥220 and <450	15/244 (6,1)	5/119 (4,2)	1,46 [0,54; 3,93]	1,49 [0,53; 4,21]	1,95 [-2,75; 6,64]
			0,625		
≥450	1/20 (5,0)	0/12 (0,0)	1,86 [0,08; 42,27]	1,92 [0,07; 51,03]	5,00 [-4,55; 14,55]
			1,000		
OECD Country (p-value of the interaction test: 0,294)					
Yes	8/177 (4,5)	1/83 (1,2)	3,75 [0,48; 29,51]	3,88 [0,48; 31,56]	3,31 [-0,54; 7,17]
			0,279		
No	12/122 (9,8)	6/62 (9,7)	1,02 [0,40; 2,58]	1,02 [0,36; 2,86]	0,16 [-8,90; 9,22]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Datenschnitt: 23. August 2023; Biologic-failed Safety Population.					
Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; SMQ: Standardised MedDRA Queries; TNF: Tumor Necrosis Factor.					
Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt.					
RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald.					
Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm.					
a: Exakter Test nach Fisher.					
The number and percentage of participants reporting hepatic events were assessed using the MedDRA PTs contained in 5 SMQs: broad and narrow terms in the Liver-related investigations, signs and symptoms SMQ (SMQ 20000008), broad and narrow terms in the Cholestasis and jaundice of hepatic origin SMQ (SMQ 20000009); broad and narrow terms in the Hepatitis non-infectious SMQ (SMQ 20000010); broad and narrow terms in the Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions SMQ (SMQ 20000013), and narrow terms in the Liver-related coagulation and bleeding disturbances SMQ (SMQ 20000015).					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_heaeasi_sub_safb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
20DEC2024 / 04:00

Subgruppen für Hepatic Safety: Nicht schwer in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,628)					
<65 years	19/286 (6,6)	6/141 (4,3)	1,56 [0,64; 3,82]	1,60 [0,62; 4,10]	2,39 [-2,02; 6,80]
			0,386		
≥65 years	0/13 (0,0)	0/4 (0,0)	NB	NB	NB
			NB		
Age 2 (p-value of the interaction test: 0,536)					
<40 years	13/202 (6,4)	3/91 (3,3)	1,95 [0,57; 6,68]	2,02 [0,56; 7,26]	3,14 [-1,85; 8,13]
			0,406		
≥40 years	6/97 (6,2)	3/54 (5,6)	1,11 [0,29; 4,27]	1,12 [0,27; 4,67]	0,63 [-7,14; 8,40]
			1,000		
Sex (p-value of the interaction test: 0,371)					
Male	10/178 (5,6)	1/65 (1,5)	3,65 [0,48; 27,97]	3,81 [0,48; 30,36]	4,08 [-0,44; 8,60]
			0,297		
Female	9/121 (7,4)	5/80 (6,3)	1,19 [0,41; 3,42]	1,21 [0,39; 3,74]	1,19 [-5,88; 8,26]
			1,000		
Race (p-value of the interaction test: 0,272)					
Asian	14/100 (14,0)	3/56 (5,4)	2,61 [0,78; 8,71]	2,88 [0,79; 10,48]	8,64 [-0,36; 17,64]
			0,114		
White	4/179 (2,2)	3/82 (3,7)	0,61 [0,14; 2,67]	0,60 [0,13; 2,75]	-1,42 [-6,03; 3,18]
			0,682		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Other	0/13 (0,0)	0/7 (0,0)	NB	NB NB	NB
Geographic region 1 (p-value of the interaction test: 0,568)					
Europe	3/114 (2,6)	1/50 (2,0)	1,32 [0,14; 12,34]	1,32 [0,13; 13,05]	0,63 [-4,24; 5,50]
			1,000		
North America	1/53 (1,9)	1/26 (3,8)	0,49 [0,03; 7,54]	0,48 [0,03; 8,01]	-1,96 [-10,21; 6,29]
			1,000		
Other	15/132 (11,4)	4/69 (5,8)	1,96 [0,68; 5,68]	2,08 [0,66; 6,54]	5,57 [-2,16; 13,29]
			0,309		
Geographic region 2 (p-value of the interaction test: 0,301)					
Asia	15/105 (14,3)	3/56 (5,4)	2,67 [0,81; 8,82]	2,94 [0,81; 10,65]	8,93 [0,01; 17,85]
			0,116		
Central America/South America	0/24 (0,0)	1/13 (7,7)	0,19 [0,01; 4,28]	0,17 [0,01; 4,49]	-7,69 [-22,18; 6,79]
			0,351		
Europe and ROW	3/117 (2,6)	1/50 (2,0)	1,28 [0,14; 12,03]	1,29 [0,13; 12,71]	0,56 [-4,26; 5,39]
			1,000		
North America	1/53 (1,9)	1/26 (3,8)	0,49 [0,03; 7,54]	0,48 [0,03; 8,01]	-1,96 [-10,21; 6,29]
			1,000		
Weight (p-value of the interaction test: 0,578)					
<100 kg	19/284 (6,7)	6/140 (4,3)	1,56 [0,64; 3,82]	1,60 [0,62; 4,10]	2,40 [-2,03; 6,84]
			0,386		

	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Subgruppe			p-Wert ^a		
≥100 kg	0/15 (0,0)	0/5 (0,0)	NB	NB NB	NB
BMI (p-value of the interaction test: 0,598)					
Underweight ($<18.5 \text{ kg/m}^2$)	4/54 (7,4)	2/32 (6,3)	1,19 [0,23; 6,11]	1,20 [0,21; 6,95]	1,16 [-9,76; 12,07]
			1,000		
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	12/161 (7,5)	2/60 (3,3)	2,24 [0,52; 9,70]	2,34 [0,51; 10,76]	4,12 [-1,97; 10,21]
			0,361		
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	3/55 (5,5)	1/38 (2,6)	2,07 [0,22; 19,18]	2,13 [0,21; 21,34]	2,82 [-5,05; 10,69]
			0,642		
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	0/29 (0,0)	1/15 (6,7)	0,18 [0,01; 4,12]	0,16 [0,01; 4,28]	-6,67 [-19,29; 5,96]
			0,341		
Tobacco use (p-value of the interaction test: 0,604)					
Current	1/52 (1,9)	1/29 (3,4)	0,56 [0,04; 8,59]	0,55 [0,03; 9,12]	-1,53 [-9,14; 6,09]
			1,000		
Former	4/49 (8,2)	0/21 (0,0)	3,96 [0,22; 70,43]	4,25 [0,22; 82,60]	8,16 [0,50; 15,83]
			0,309		
Never	14/198 (7,1)	5/95 (5,3)	1,34 [0,50; 3,62]	1,37 [0,48; 3,92]	1,81 [-3,93; 7,54]
			0,623		
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,252)					
Ever	17/279 (6,1)	5/140 (3,6)	1,71 [0,64; 4,53]	1,75 [0,63; 4,85]	2,52 [-1,64; 6,68]
			0,356		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Never	2/20 (10,0)	1/5 (20,0)	0,50 [0,06; 4,47]	0,44 [0,03; 6,19]	-10,00 [-47,45; 27,45]
0,504					
Prior anti-TNF failure (p-value of the interaction test: 0,973)					
Ever	18/281 (6,4)	6/139 (4,3)	1,48 [0,60; 3,65]	1,52 [0,59; 3,91]	2,09 [-2,34; 6,52]
0,504					
Never	1/18 (5,6)	0/6 (0,0)	1,11 [0,05; 24,07]	1,11 [0,04; 30,97]	5,56 [-5,03; 16,14]
1,000					
Prior anti-integrin failure (p-value of the interaction test: 0,565)					
Ever	6/71 (8,5)	1/31 (3,2)	2,62 [0,33; 20,86]	2,77 [0,32; 24,03]	5,22 [-3,75; 14,20]
0,672					
Never	13/228 (5,7)	5/114 (4,4)	1,30 [0,48; 3,56]	1,32 [0,46; 3,79]	1,32 [-3,50; 6,13]
0,798					
Baseline corticosteroid use (p-value of the interaction test: 0,578)					
Yes	2/76 (2,6)	1/39 (2,6)	1,03 [0,10; 10,97]	1,03 [0,09; 11,69]	0,07 [-6,06; 6,20]
1,000					
No	17/223 (7,6)	5/106 (4,7)	1,62 [0,61; 4,26]	1,67 [0,60; 4,65]	2,91 [-2,42; 8,24]
0,479					
Baseline immunomodulator use (p-value of the interaction test: 0,990)					
Yes	6/66 (9,1)	2/39 (5,1)	1,77 [0,38; 8,36]	1,85 [0,35; 9,65]	3,96 [-5,84; 13,76]
0,707					
No	13/233 (5,6)	4/106 (3,8)	1,48 [0,49; 4,43]	1,51 [0,48; 4,74]	1,81 [-2,87; 6,48]
0,598					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Duration of CD (p-value of the interaction test: 0,267)					
<1 year	1/23 (4,3)	1/9 (11,1)	0,39 [0,03; 5,61]	0,36 [0,02; 6,53]	-6,76 [-28,92; 15,40]
				0,490	
≥1 to <5 years	9/104 (8,7)	0/44 (0,0)	8,14 [0,48; >100]	8,85 [0,50; >100]	8,65 [3,25; 14,06]
				0,058	
≥5 years	9/172 (5,2)	5/92 (5,4)	0,96 [0,33; 2,79]	0,96 [0,31; 2,96]	-0,20 [-5,91; 5,50]
				1,000	
Baseline disease location (p-value of the interaction test: 0,538)					
Colonic	6/120 (5,0)	2/59 (3,4)	1,48 [0,31; 7,09]	1,50 [0,29; 7,67]	1,61 [-4,43; 7,65]
				1,000	
Ileal	2/31 (6,5)	1/6 (16,7)	0,39 [0,04; 3,62]	0,34 [0,03; 4,56]	-10,22 [-41,26; 20,83]
				0,421	
Ileal-Colonic	11/148 (7,4)	3/80 (3,8)	1,98 [0,57; 6,90]	2,06 [0,56; 7,61]	3,68 [-2,25; 9,61]
				0,389	
Baseline fecal calprotectin (p-value of the interaction test: 0,487)					
≤250	4/38 (10,5)	2/15 (13,3)	0,79 [0,16; 3,87]	0,76 [0,12; 4,69]	-2,81 [-22,58; 16,97]
				1,000	
>250	13/208 (6,3)	4/93 (4,3)	1,45 [0,49; 4,34]	1,48 [0,47; 4,68]	1,95 [-3,33; 7,22]
				0,598	
Baseline CRP (p-value of the interaction test: 0,618)					
≤10	8/145 (5,5)	1/58 (1,7)	3,20 [0,41; 25,02]	3,33 [0,41; 27,23]	3,79 [-1,21; 8,80]
				0,451	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
>10	11/154 (7,1)	5/87 (5,7)	1,24 [0,45; 3,46]	1,26 [0,42; 3,76]	1,40 [-4,97; 7,76]
0,792					
Baseline SES-CD total score (p-value of the interaction test: 0,198)					
<12	7/142 (4,9)	4/66 (6,1)	0,81 [0,25; 2,68]	0,80 [0,23; 2,85]	-1,13 [-7,90; 5,64]
0,746					
≥12	12/157 (7,6)	2/79 (2,5)	3,02 [0,69; 13,16]	3,19 [0,70; 14,60]	5,11 [-0,30; 10,52]
0,150					
Baseline AP average (p-value of the interaction test: 0,176)					
<2	4/72 (5,6)	4/48 (8,3)	0,67 [0,18; 2,54]	0,65 [0,15; 2,72]	-2,78 [-12,22; 6,66]
0,712					
≥2	15/226 (6,6)	2/97 (2,1)	3,22 [0,75; 13,81]	3,38 [0,76; 15,06]	4,58 [0,27; 8,88]
0,108					
Baseline SF average (p-value of the interaction test: 0,292)					
<7	16/220 (7,3)	4/100 (4,0)	1,82 [0,62; 5,30]	1,88 [0,61; 5,78]	3,27 [-1,88; 8,42]
0,326					
≥7	2/76 (2,6)	2/45 (4,4)	0,59 [0,09; 4,06]	0,58 [0,08; 4,28]	-1,81 [-8,83; 5,20]
0,628					
Baseline CDAI 1 (p-value of the interaction test: 0,634)					
<300	6/109 (5,5)	3/59 (5,1)	1,08 [0,28; 4,17]	1,09 [0,26; 4,51]	0,42 [-6,63; 7,47]
1,000					
≥300	12/184 (6,5)	3/84 (3,6)	1,83 [0,53; 6,30]	1,88 [0,52; 6,86]	2,95 [-2,39; 8,29]
0,404					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline CDAI 2 (p-value of the interaction test: 0,645)					
<220	3/29 (10,3)	2/12 (16,7)	0,62 [0,12; 3,26]	0,58 [0,08; 3,98]	-6,32 [-30,14; 17,50]
			0,620		
≥220 and <450	14/244 (5,7)	4/119 (3,4)	1,71 [0,57; 5,07]	1,75 [0,56; 5,44]	2,38 [-1,98; 6,74]
			0,443		
≥450	1/20 (5,0)	0/12 (0,0)	1,86 [0,08; 42,27]	1,92 [0,07; 51,03]	5,00 [-4,55; 14,55]
			1,000		
OECD Country (p-value of the interaction test: 0,336)					
Yes	8/177 (4,5)	1/83 (1,2)	3,75 [0,48; 29,51]	3,88 [0,48; 31,56]	3,31 [-0,54; 7,17]
			0,279		
No	11/122 (9,0)	5/62 (8,1)	1,12 [0,41; 3,08]	1,13 [0,37; 3,41]	0,95 [-7,52; 9,42]
			1,000		
Datenschnitt: 23. August 2023; Biologic-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; SMQ: Standardised MedDRA Queries; TNF: Tumor Necrosis Factor. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher. The number and percentage of participants reporting hepatic events were assessed using the MedDRA PTs contained in 5 SMQs: broad and narrow terms in the Liver-related investigations, signs and symptoms SMQ (SMQ 20000008), broad and narrow terms in the Cholestasis and jaundice of hepatic origin SMQ (SMQ 20000009); broad and narrow terms in the Hepatitis non-infectious SMQ (SMQ 20000010); broad and narrow terms in the Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions SMQ (SMQ 20000013), and narrow terms in the Liver-related coagulation and bleeding disturbances SMQ (SMQ 20000015).					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_heaesins_sub_saftb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba

20DEC2024 / 04:00

Infektionen, inklusive opportunistischer Infektionen und schwerwiegender Infektionen

Subgruppen für Infections, including Opportunistic Infections and Serious Infections:

Gesamtrate in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B

(Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Age 1 (p-value of the interaction test: 0,636)					
<65 years	124/286 (43,4)	76/141 (53,9)	0,80 [0,66; 0,98]	0,65 [0,44; 0,98]	-10,54 [-20,58; -0,51]
				0,050	
≥65 years	6/13 (46,2)	3/4 (75,0)	0,62 [0,27; 1,39]	0,29 [0,02; 3,52]	-28,85 [-79,20; 21,50]
				0,576	
Age 2 (p-value of the interaction test: 0,060)					
<40 years	96/202 (47,5)	47/91 (51,6)	0,92 [0,72; 1,18]	0,85 [0,52; 1,39]	-4,12 [-16,49; 8,24]
				0,530	
≥40 years	34/97 (35,1)	32/54 (59,3)	0,59 [0,42; 0,84]	0,37 [0,19; 0,74]	-24,21 [-40,39; -8,02]
				0,006	
Sex (p-value of the interaction test: 0,301)					
Male	67/178 (37,6)	34/65 (52,3)	0,72 [0,53; 0,97]	0,55 [0,31; 0,98]	-14,67 [-28,74; -0,59]
				0,055	
Female	63/121 (52,1)	45/80 (56,3)	0,93 [0,72; 1,20]	0,84 [0,48; 1,49]	-4,18 [-18,23; 9,87]
				0,567	
Race (p-value of the interaction test: 0,795)					
Asian	43/100 (43,0)	31/56 (55,4)	0,78 [0,56; 1,08]	0,61 [0,31; 1,18]	-12,36 [-28,60; 3,88]
				0,181	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
White	79/179 (44,1)	44/82 (53,7)	0,82 [0,63; 1,07]	0,68 [0,40; 1,15]	-9,52 [-22,54; 3,49]
			0,182		
Other	4/13 (30,8)	4/7 (57,1)	0,54 [0,19; 1,52]	0,33 [0,05; 2,24]	-26,37 [-70,80; 18,05]
			0,356		
Geographic region 1 (p-value of the interaction test: 0,639)					
Europe	47/114 (41,2)	29/50 (58,0)	0,71 [0,52; 0,98]	0,51 [0,26; 1,00]	-16,77 [-33,17; -0,38]
			0,061		
North America	23/53 (43,4)	12/26 (46,2)	0,94 [0,56; 1,58]	0,89 [0,35; 2,30]	-2,76 [-26,11; 20,59]
			1,000		
Other	60/132 (45,5)	38/69 (55,1)	0,83 [0,62; 1,10]	0,68 [0,38; 1,22]	-9,62 [-24,11; 4,87]
			0,235		
Geographic region 2 (p-value of the interaction test: 0,846)					
Asia	47/105 (44,8)	31/56 (55,4)	0,81 [0,59; 1,11]	0,65 [0,34; 1,25]	-10,60 [-26,72; 5,53]
			0,247		
Central America/South America	11/24 (45,8)	7/13 (53,8)	0,85 [0,44; 1,66]	0,73 [0,19; 2,81]	-8,01 [-41,65; 25,63]
			0,737		
Europe and ROW	49/117 (41,9)	29/50 (58,0)	0,72 [0,53; 0,99]	0,52 [0,27; 1,02]	-16,12 [-32,46; 0,22]
			0,064		
North America	23/53 (43,4)	12/26 (46,2)	0,94 [0,56; 1,58]	0,89 [0,35; 2,30]	-2,76 [-26,11; 20,59]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Weight (p-value of the interaction test: 0,204)					
<100 kg	118/284 (41,5)	76/140 (54,3)	0,77 [0,62; 0,94]	0,60 [0,40; 0,90]	-12,74 [-22,78; -2,69]
				0,017	
≥100 kg	12/15 (80,0)	3/5 (60,0)	1,33 [0,62; 2,85]	2,67 [0,30; 23,86]	20,00 [-27,47; 67,47]
				0,560	
BMI (p-value of the interaction test: 0,358)					
Underweight (<18.5 kg/m ²)	25/54 (46,3)	16/32 (50,0)	0,93 [0,59; 1,45]	0,86 [0,36; 2,07]	-3,70 [-25,54; 18,14]
				0,825	
Normal (≥18.5 and <25 kg/m ²)	66/161 (41,0)	31/60 (51,7)	0,79 [0,58; 1,08]	0,65 [0,36; 1,18]	-10,67 [-25,42; 4,08]
				0,172	
Overweight (≥25 and <30 kg/m ²)	23/55 (41,8)	25/38 (65,8)	0,64 [0,43; 0,94]	0,37 [0,16; 0,88]	-23,97 [-43,91; -4,03]
				0,034	
Obese and Extreme obese (≥30 kg/m ²)	16/29 (55,2)	7/15 (46,7)	1,18 [0,63; 2,23]	1,41 [0,40; 4,91]	8,51 [-22,56; 39,57]
				0,752	
Tobacco use (p-value of the interaction test: 0,757)					
Current	22/52 (42,3)	14/29 (48,3)	0,88 [0,54; 1,43]	0,79 [0,32; 1,96]	-5,97 [-28,58; 16,64]
				0,646	
Former	23/49 (46,9)	14/21 (66,7)	0,70 [0,46; 1,08]	0,44 [0,15; 1,29]	-19,73 [-44,26; 4,80]
				0,192	
Never	85/198 (42,9)	51/95 (53,7)	0,80 [0,63; 1,02]	0,65 [0,40; 1,06]	-10,75 [-22,92; 1,41]
				0,104	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,437)					
Ever	121/279 (43,4)	75/140 (53,6)	0,81 [0,66; 0,99]	0,66 [0,44; 1,00]	-10,20 [-20,30; -0,10]
			0,050		
Never	9/20 (45,0)	4/5 (80,0)	0,56 [0,29; 1,08]	0,20 [0,02; 2,17]	-35,00 [-76,29; 6,29]
			0,322		
Prior anti-TNF failure (p-value of the interaction test: 0,821)					
Ever	122/281 (43,4)	76/139 (54,7)	0,79 [0,65; 0,97]	0,64 [0,42; 0,96]	-11,26 [-21,36; -1,16]
			0,038		
Never	8/18 (44,4)	3/6 (50,0)	0,89 [0,34; 2,30]	0,80 [0,13; 5,09]	-5,56 [-51,68; 40,57]
			1,000		
Prior anti-integrin failure (p-value of the interaction test: 0,556)					
Ever	35/71 (49,3)	17/31 (54,8)	0,90 [0,60; 1,34]	0,80 [0,34; 1,87]	-5,54 [-26,57; 15,48]
			0,670		
Never	95/228 (41,7)	62/114 (54,4)	0,77 [0,61; 0,96]	0,60 [0,38; 0,94]	-12,72 [-23,88; -1,56]
			0,029		
Baseline corticosteroid use (p-value of the interaction test: 0,114)					
Yes	37/76 (48,7)	18/39 (46,2)	1,05 [0,70; 1,59]	1,11 [0,51; 2,40]	2,53 [-16,73; 21,79]
			0,845		
No	93/223 (41,7)	61/106 (57,5)	0,72 [0,58; 0,91]	0,53 [0,33; 0,84]	-15,84 [-27,26; -4,42]
			0,009		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline immunomodulator use (p-value of the interaction test: 0,945)					
Yes	33/66 (50,0)	24/39 (61,5)	0,81 [0,57; 1,15]	0,63 [0,28; 1,40]	-11,54 [-31,00; 7,92]
				0,312	
No	97/233 (41,6)	55/106 (51,9)	0,80 [0,63; 1,02]	0,66 [0,42; 1,05]	-10,26 [-21,68; 1,17]
				0,099	
Duration of CD (p-value of the interaction test: 0,201)					
<1 year	9/23 (39,1)	8/9 (88,9)	0,44 [0,25; 0,77]	0,08 [0,01; 0,76]	-49,76 [-78,38; -21,13]
				0,018	
≥1 to <5 years	45/104 (43,3)	24/44 (54,5)	0,79 [0,56; 1,12]	0,64 [0,31; 1,29]	-11,28 [-28,80; 6,25]
				0,279	
≥5 years	76/172 (44,2)	47/92 (51,1)	0,86 [0,67; 1,12]	0,76 [0,46; 1,26]	-6,90 [-19,53; 5,73]
				0,302	
Baseline disease location (p-value of the interaction test: 0,563)					
Colonic	47/120 (39,2)	30/59 (50,8)	0,77 [0,55; 1,08]	0,62 [0,33; 1,17]	-11,68 [-27,14; 3,78]
				0,151	
Ileal	15/31 (48,4)	2/6 (33,3)	1,45 [0,44; 4,76]	1,88 [0,30; 11,78]	15,05 [-26,57; 56,67]
				0,667	
Ileal-Colonic	68/148 (45,9)	47/80 (58,8)	0,78 [0,61; 1,01]	0,60 [0,34; 1,03]	-12,80 [-26,25; 0,64]
				0,072	
Baseline fecal calprotectin (p-value of the interaction test: 0,181)					
≤250	18/38 (47,4)	6/15 (40,0)	1,18 [0,59; 2,40]	1,35 [0,40; 4,54]	7,37 [-22,07; 36,81]
				0,762	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
>250	90/208 (43,3)	54/93 (58,1)	0,75 [0,59; 0,94]	0,55 [0,34; 0,90]	-14,80 [-26,87; -2,72]
0,018					
Baseline CRP (p-value of the interaction test: 0,460)					
≤10	63/145 (43,4)	29/58 (50,0)	0,87 [0,63; 1,19]	0,77 [0,42; 1,41]	-6,55 [-21,74; 8,64]
0,437					
>10	67/154 (43,5)	50/87 (57,5)	0,76 [0,59; 0,98]	0,57 [0,34; 0,97]	-13,96 [-26,97; -0,96]
0,044					
Baseline SES-CD total score (p-value of the interaction test: 0,579)					
<12	64/142 (45,1)	35/66 (53,0)	0,85 [0,64; 1,14]	0,73 [0,40; 1,31]	-7,96 [-22,52; 6,60]
0,300					
≥12	66/157 (42,0)	44/79 (55,7)	0,75 [0,58; 0,99]	0,58 [0,33; 1,00]	-13,66 [-27,06; -0,26]
0,054					
Baseline AP average (p-value of the interaction test: 0,170)					
<2	33/72 (45,8)	32/48 (66,7)	0,69 [0,50; 0,95]	0,42 [0,20; 0,90]	-20,83 [-38,45; -3,22]
0,027					
≥2	96/226 (42,5)	47/97 (48,5)	0,88 [0,68; 1,13]	0,79 [0,49; 1,27]	-5,98 [-17,83; 5,88]
0,331					
Baseline SF average (p-value of the interaction test: 0,063)					
<7	96/220 (43,6)	48/100 (48,0)	0,91 [0,71; 1,17]	0,84 [0,52; 1,35]	-4,36 [-16,15; 7,42]
0,470					
≥7	33/76 (43,4)	31/45 (68,9)	0,63 [0,46; 0,87]	0,35 [0,16; 0,75]	-25,47 [-42,99; -7,94]
0,008					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Baseline CDAI 1 (p-value of the interaction test: 0,148)					
<300	41/109 (37,6)	34/59 (57,6)	0,65 [0,47; 0,90]	0,44 [0,23; 0,85]	-20,01 [-35,56; -4,47]
				0,015	
≥300	86/184 (46,7)	43/84 (51,2)	0,91 [0,70; 1,18]	0,84 [0,50; 1,40]	-4,45 [-17,34; 8,44]
				0,513	
Baseline CDAI 2 (p-value of the interaction test: 0,199)					
<220	11/29 (37,9)	5/12 (41,7)	0,91 [0,40; 2,06]	0,86 [0,22; 3,37]	-3,74 [-36,75; 29,28]
				1,000	
≥220 and <450	110/244 (45,1)	63/119 (52,9)	0,85 [0,68; 1,06]	0,73 [0,47; 1,13]	-7,86 [-18,79; 3,07]
				0,180	
≥450	6/20 (30,0)	9/12 (75,0)	0,40 [0,19; 0,84]	0,14 [0,03; 0,72]	-45,00 [-76,68; -13,32]
				0,027	
OECD Country (p-value of the interaction test: 0,374)					
Yes	78/177 (44,1)	49/83 (59,0)	0,75 [0,58; 0,95]	0,55 [0,32; 0,93]	-14,97 [-27,83; -2,11]
				0,033	
No	52/122 (42,6)	30/62 (48,4)	0,88 [0,63; 1,22]	0,79 [0,43; 1,46]	-5,76 [-20,99; 9,46]
				0,531	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis	Pat. mit Ereignis	RR	OR	RD
	n/N (%)	n/N (%)	[95% KI]	[95% KI]	[95% KI]
			p-Wert ^a		
Datenschnitt: 23. August 2023; Biologic-failed Safety Population.					
Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor.					
Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt.					
RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald.					
a: Exakter Test nach Fisher.					
Infections were defined using the PTs from the MedDRA Infections and Infestations SOC. The MedDRA terms used to identify infections considered to be opportunistic infections in participants with immune mediated inflammatory conditions treated with immunomodulatory drugs were based on Winthrop et al. (2015).					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_inaesi_sub_saftb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba

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Subgruppen für Infections, including Opportunistic Infections and Serious Infections: Nicht schwer in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,628)					
<65 years	115/286 (40,2)	71/141 (50,4)	0,80 [0,64; 0,99]	0,66 [0,44; 1,00]	-10,14 [-20,16; -0,12]
			0,049		
≥65 years	6/13 (46,2)	3/4 (75,0)	0,62 [0,27; 1,39]	0,29 [0,02; 3,52]	-28,85 [-79,20; 21,50]
			0,576		
Age 2 (p-value of the interaction test: 0,065)					
<40 years	88/202 (43,6)	43/91 (47,3)	0,92 [0,71; 1,21]	0,86 [0,52; 1,42]	-3,69 [-16,02; 8,64]
			0,612		
≥40 years	33/97 (34,0)	31/54 (57,4)	0,59 [0,41; 0,85]	0,38 [0,19; 0,76]	-23,39 [-39,60; -7,17]
			0,006		
Sex (p-value of the interaction test: 0,278)					
Male	60/178 (33,7)	31/65 (47,7)	0,71 [0,51; 0,98]	0,56 [0,31; 0,99]	-13,98 [-27,97; 0,00]
			0,052		
Female	61/121 (50,4)	43/80 (53,8)	0,94 [0,72; 1,23]	0,87 [0,50; 1,54]	-3,34 [-17,43; 10,76]
			0,668		
Race (p-value of the interaction test: 0,835)					
Asian	38/100 (38,0)	27/56 (48,2)	0,79 [0,54; 1,14]	0,66 [0,34; 1,28]	-10,21 [-26,39; 5,97]
			0,239		
White	75/179 (41,9)	43/82 (52,4)	0,80 [0,61; 1,05]	0,65 [0,39; 1,11]	-10,54 [-23,54; 2,46]
			0,140		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Other	4/13 (30,8)	4/7 (57,1)	0,54 [0,19; 1,52]	0,33 [0,05; 2,24]	-26,37 [-70,80; 18,05]
0,356					
Geographic region 1 (p-value of the interaction test: 0,533)					
Europe	45/114 (39,5)	29/50 (58,0)	0,68 [0,49; 0,94]	0,47 [0,24; 0,93]	-18,53 [-34,89; -2,17]
0,040					
North America	21/53 (39,6)	12/26 (46,2)	0,86 [0,50; 1,46]	0,77 [0,30; 1,97]	-6,53 [-29,78; 16,72]
0,632					
Other	55/132 (41,7)	33/69 (47,8)	0,87 [0,63; 1,20]	0,78 [0,43; 1,40]	-6,16 [-20,64; 8,32]
0,455					
Geographic region 2 (p-value of the interaction test: 0,787)					
Asia	42/105 (40,0)	26/56 (46,4)	0,86 [0,60; 1,24]	0,77 [0,40; 1,48]	-6,43 [-22,50; 9,65]
0,503					
Central America/South America	11/24 (45,8)	7/13 (53,8)	0,85 [0,44; 1,66]	0,73 [0,19; 2,81]	-8,01 [-41,65; 25,63]
0,737					
Europe and ROW	47/117 (40,2)	29/50 (58,0)	0,69 [0,50; 0,96]	0,49 [0,25; 0,95]	-17,83 [-34,14; -1,52]
0,042					
North America	21/53 (39,6)	12/26 (46,2)	0,86 [0,50; 1,46]	0,77 [0,30; 1,97]	-6,53 [-29,78; 16,72]
0,632					
Weight (p-value of the interaction test: 0,330)					
<100 kg	110/284 (38,7)	71/140 (50,7)	0,76 [0,61; 0,95]	0,61 [0,41; 0,92]	-11,98 [-22,02; -1,95]
0,022					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
≥100 kg	11/15 (73,3)	3/5 (60,0)	1,22 [0,56; 2,66]	1,83 [0,22; 15,33]	13,33 [-35,09; 61,76]
0,613					
BMI (p-value of the interaction test: 0,624)					
Underweight ($<18.5 \text{ kg/m}^2$)	21/54 (38,9)	14/32 (43,8)	0,89 [0,53; 1,49]	0,82 [0,34; 1,99]	-4,86 [-26,41; 16,69]
0,821					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	63/161 (39,1)	29/60 (48,3)	0,81 [0,59; 1,12]	0,69 [0,38; 1,25]	-9,20 [-23,92; 5,52]
0,224					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	23/55 (41,8)	24/38 (63,2)	0,66 [0,45; 0,98]	0,42 [0,18; 0,98]	-21,34 [-41,47; -1,21]
0,058					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	14/29 (48,3)	7/15 (46,7)	1,03 [0,54; 2,00]	1,07 [0,31; 3,72]	1,61 [-29,51; 32,72]
1,000					
Tobacco use (p-value of the interaction test: 0,694)					
Current	19/52 (36,5)	13/29 (44,8)	0,82 [0,48; 1,40]	0,71 [0,28; 1,79]	-8,29 [-30,63; 14,05]
0,486					
Former	22/49 (44,9)	14/21 (66,7)	0,67 [0,44; 1,04]	0,41 [0,14; 1,19]	-21,77 [-46,27; 2,74]
0,121					
Never	80/198 (40,4)	47/95 (49,5)	0,82 [0,63; 1,06]	0,69 [0,42; 1,13]	-9,07 [-21,23; 3,09]
0,166					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,612)					
Ever	114/279 (40,9)	71/140 (50,7)	0,81 [0,65; 1,00]	0,67 [0,45; 1,01]	-9,85 [-19,95; 0,24]
0,061					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Never	7/20 (35,0)	3/5 (60,0)	0,58 [0,23; 1,48]	0,36 [0,05; 2,68]	-25,00 [-72,76; 22,76]
0,358					
Prior anti-TNF failure (p-value of the interaction test: 0,829)					
Ever	113/281 (40,2)	71/139 (51,1)	0,79 [0,63; 0,98]	0,64 [0,43; 0,97]	-10,87 [-20,96; -0,77]
0,037					
Never	8/18 (44,4)	3/6 (50,0)	0,89 [0,34; 2,30]	0,80 [0,13; 5,09]	-5,56 [-51,68; 40,57]
1,000					
Prior anti-integrin failure (p-value of the interaction test: 0,794)					
Ever	33/71 (46,5)	17/31 (54,8)	0,85 [0,57; 1,27]	0,72 [0,31; 1,67]	-8,36 [-29,37; 12,65]
0,520					
Never	88/228 (38,6)	57/114 (50,0)	0,77 [0,60; 0,99]	0,63 [0,40; 0,99]	-11,40 [-22,55; -0,26]
0,049					
Baseline corticosteroid use (p-value of the interaction test: 0,218)					
Yes	35/76 (46,1)	18/39 (46,2)	1,00 [0,66; 1,51]	1,00 [0,46; 2,16]	-0,10 [-19,35; 19,14]
1,000					
No	86/223 (38,6)	56/106 (52,8)	0,73 [0,57; 0,93]	0,56 [0,35; 0,89]	-14,27 [-25,72; -2,81]
0,017					
Baseline immunomodulator use (p-value of the interaction test: 0,534)					
Yes	30/66 (45,5)	24/39 (61,5)	0,74 [0,51; 1,06]	0,52 [0,23; 1,17]	-16,08 [-35,51; 3,34]
0,157					
No	91/233 (39,1)	50/106 (47,2)	0,83 [0,64; 1,07]	0,72 [0,45; 1,14]	-8,11 [-19,50; 3,27]
0,191					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Duration of CD (p-value of the interaction test: 0,394)					
<1 year	9/23 (39,1)	7/9 (77,8)	0,50 [0,27; 0,93]	0,18 [0,03; 1,09]	-38,65 [-72,35; -4,95]
				0,113	
≥1 to <5 years	42/104 (40,4)	23/44 (52,3)	0,77 [0,54; 1,11]	0,62 [0,30; 1,26]	-11,89 [-29,40; 5,63]
				0,207	
≥5 years	70/172 (40,7)	44/92 (47,8)	0,85 [0,64; 1,13]	0,75 [0,45; 1,25]	-7,13 [-19,70; 5,45]
				0,298	
Baseline disease location (p-value of the interaction test: 0,551)					
Colonic	41/120 (34,2)	28/59 (47,5)	0,72 [0,50; 1,04]	0,57 [0,30; 1,08]	-13,29 [-28,60; 2,02]
				0,103	
Ileal	15/31 (48,4)	2/6 (33,3)	1,45 [0,44; 4,76]	1,88 [0,30; 11,78]	15,05 [-26,57; 56,67]
				0,667	
Ileal-Colonic	65/148 (43,9)	44/80 (55,0)	0,80 [0,61; 1,05]	0,64 [0,37; 1,11]	-11,08 [-24,60; 2,44]
				0,127	
Baseline fecal calprotectin (p-value of the interaction test: 0,235)					
≤250	18/38 (47,4)	6/15 (40,0)	1,18 [0,59; 2,40]	1,35 [0,40; 4,54]	7,37 [-22,07; 36,81]
				0,762	
>250	84/208 (40,4)	49/93 (52,7)	0,77 [0,59; 0,99]	0,61 [0,37; 1,00]	-12,30 [-24,45; -0,16]
				0,059	
Baseline CRP (p-value of the interaction test: 0,439)					
≤10	61/145 (42,1)	28/58 (48,3)	0,87 [0,63; 1,21]	0,78 [0,42; 1,43]	-6,21 [-21,37; 8,96]
				0,438	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
>10	60/154 (39,0)	46/87 (52,9)	0,74 [0,56; 0,98]	0,57 [0,33; 0,97]	-13,91 [-26,93; -0,90]
0,043					
Baseline SES-CD total score (p-value of the interaction test: 0,700)					
<12	59/142 (41,5)	33/66 (50,0)	0,83 [0,61; 1,13]	0,71 [0,40; 1,28]	-8,45 [-22,98; 6,08]
0,294					
≥12	62/157 (39,5)	41/79 (51,9)	0,76 [0,57; 1,01]	0,60 [0,35; 1,04]	-12,41 [-25,82; 1,00]
0,073					
Baseline AP average (p-value of the interaction test: 0,485)					
<2	31/72 (43,1)	28/48 (58,3)	0,74 [0,52; 1,06]	0,54 [0,26; 1,13]	-15,28 [-33,31; 2,76]
0,136					
≥2	90/226 (39,8)	46/97 (47,4)	0,84 [0,65; 1,09]	0,73 [0,45; 1,18]	-7,60 [-19,41; 4,21]
0,220					
Baseline SF average (p-value of the interaction test: 0,073)					
<7	88/220 (40,0)	44/100 (44,0)	0,91 [0,69; 1,20]	0,85 [0,53; 1,37]	-4,00 [-15,69; 7,69]
0,541					
≥7	32/76 (42,1)	30/45 (66,7)	0,63 [0,45; 0,88]	0,36 [0,17; 0,78]	-24,56 [-42,25; -6,87]
0,014					
Baseline CDAI 1 (p-value of the interaction test: 0,265)					
<300	39/109 (35,8)	31/59 (52,5)	0,68 [0,48; 0,97]	0,50 [0,26; 0,96]	-16,76 [-32,36; -1,16]
0,049					
≥300	81/184 (44,0)	41/84 (48,8)	0,90 [0,69; 1,18]	0,82 [0,49; 1,38]	-4,79 [-17,66; 8,09]
0,509					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline CDAI 2 (p-value of the interaction test: 0,063)					
<220	11/29 (37,9)	3/12 (25,0)	1,52 [0,51; 4,49]	1,83 [0,41; 8,27]	12,93 [-17,27; 43,13]
				0,494	
≥220 and <450	104/244 (42,6)	60/119 (50,4)	0,85 [0,67; 1,06]	0,73 [0,47; 1,13]	-7,80 [-18,72; 3,12]
				0,178	
≥450	5/20 (25,0)	9/12 (75,0)	0,33 [0,15; 0,76]	0,11 [0,02; 0,58]	-50,00 [-80,99; -19,01]
				0,010	
OECD Country (p-value of the interaction test: 0,287)					
Yes	73/177 (41,2)	47/83 (56,6)	0,73 [0,56; 0,94]	0,54 [0,32; 0,91]	-15,38 [-28,28; -2,49]
				0,024	
No	48/122 (39,3)	27/62 (43,5)	0,90 [0,63; 1,29]	0,84 [0,45; 1,56]	-4,20 [-19,29; 10,88]
				0,635	
Datenschnitt: 23. August 2023; Biologic-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. a: Exakter Test nach Fisher. Infections were defined using the PTs from the MedDRA Infections and Infestations SOC. The MedDRA terms used to identify infections considered to be opportunistic infections in participants with immune mediated inflammatory conditions treated with immunomodulatory drugs were based on Winthrop et al. (2015).					

Program Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_inaesins_sub_safb_a.rtf

Dataset Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
20DEC2024 / 04:00

Subgruppen für Infections, including Opportunistic Infections and Serious Infections: Schwer in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,689)					
<65 years	9/286 (3,1)	5/141 (3,5)	0,89 [0,30; 2,60]	0,88 [0,29; 2,69]	-0,40 [-4,06; 3,26]
			0,781		
≥65 years	0/13 (0,0)	0/4 (0,0)	NB	NB	NB
			NB		
Age 2 (p-value of the interaction test: 0,734)					
<40 years	8/202 (4,0)	4/91 (4,4)	0,90 [0,28; 2,92]	0,90 [0,26; 3,06]	-0,44 [-5,43; 4,56]
			1,000		
≥40 years	1/97 (1,0)	1/54 (1,9)	0,56 [0,04; 8,72]	0,55 [0,03; 9,01]	-0,82 [-4,94; 3,30]
			1,000		
Sex (p-value of the interaction test: 0,879)					
Male	7/178 (3,9)	3/65 (4,6)	0,85 [0,23; 3,20]	0,85 [0,21; 3,37]	-0,68 [-6,53; 5,16]
			0,730		
Female	2/121 (1,7)	2/80 (2,5)	0,66 [0,10; 4,60]	0,66 [0,09; 4,75]	-0,85 [-4,95; 3,26]
			0,651		
Geographic region 1 (p-value of the interaction test: 0,457)					
Europe	2/114 (1,8)	0/50 (0,0)	2,22 [0,11; 45,36]	2,24 [0,11; 47,60]	1,75 [-0,66; 4,16]
			1,000		
North America	2/53 (3,8)	0/26 (0,0)	2,50 [0,12; 50,26]	2,57 [0,12; 55,55]	3,77 [-1,36; 8,90]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Other	5/132 (3,8)	5/69 (7,2)	0,52 [0,16; 1,74]	0,50 [0,14; 1,80]	-3,46 [-10,39; 3,47]
0,316					
Geographic region 2 (p-value of the interaction test: 0,675)					
Asia	5/105 (4,8)	5/56 (8,9)	0,53 [0,16; 1,76]	0,51 [0,14; 1,84]	-4,17 [-12,67; 4,34]
0,319					
Central America/South America	0/24 (0,0)	0/13 (0,0)	NB	NB	NB
NB					
Europe and ROW	2/117 (1,7)	0/50 (0,0)	2,16 [0,11; 44,22]	2,19 [0,10; 46,36]	1,71 [-0,64; 4,06]
1,000					
North America	2/53 (3,8)	0/26 (0,0)	2,50 [0,12; 50,26]	2,57 [0,12; 55,55]	3,77 [-1,36; 8,90]
1,000					
Weight (p-value of the interaction test: 0,829)					
<100 kg	8/284 (2,8)	5/140 (3,6)	0,79 [0,26; 2,37]	0,78 [0,25; 2,44]	-0,75 [-4,38; 2,87]
0,766					
≥100 kg	1/15 (6,7)	0/5 (0,0)	1,13 [0,05; 23,99]	1,14 [0,04; 32,36]	6,67 [-5,96; 19,29]
1,000					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,579)					
Ever	7/279 (2,5)	4/140 (2,9)	0,88 [0,26; 2,95]	0,88 [0,25; 3,04]	-0,35 [-3,66; 2,97]
1,000					
Never	2/20 (10,0)	1/5 (20,0)	0,50 [0,06; 4,47]	0,44 [0,03; 6,19]	-10,00 [-47,45; 27,45]
0,504					
Prior anti-TNF failure (p-value of the interaction test: 0,686)					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Ever	9/281 (3,2)	5/139 (3,6)	0,89 [0,30; 2,61]	0,89 [0,29; 2,70]	-0,39 [-4,11; 3,32]
			0,781		
Never	0/18 (0,0)	0/6 (0,0)	NB	NB	NB
			NB		
Prior anti-integrin failure (p-value of the interaction test: 0,454)					
Ever	2/71 (2,8)	0/31 (0,0)	2,22 [0,11; 44,98]	2,27 [0,11; 48,59]	2,82 [-1,03; 6,67]
			1,000		
Never	7/228 (3,1)	5/114 (4,4)	0,70 [0,23; 2,16]	0,69 [0,21; 2,23]	-1,32 [-5,69; 3,06]
			0,543		
Baseline corticosteroid use (p-value of the interaction test: 0,388)					
Yes	2/76 (2,6)	0/39 (0,0)	2,60 [0,13; 52,81]	2,65 [0,12; 56,58]	2,63 [-0,97; 6,23]
			0,548		
No	7/223 (3,1)	5/106 (4,7)	0,67 [0,22; 2,05]	0,65 [0,20; 2,11]	-1,58 [-6,22; 3,06]
			0,533		
Baseline immunomodulator use (p-value of the interaction test: 0,185)					
Yes	3/66 (4,5)	0/39 (0,0)	4,18 [0,22; 78,83]	4,35 [0,22; 86,56]	4,55 [-0,48; 9,57]
			0,293		
No	6/233 (2,6)	5/106 (4,7)	0,55 [0,17; 1,75]	0,53 [0,16; 1,79]	-2,14 [-6,66; 2,38]
			0,329		
Baseline fecal calprotectin (p-value of the interaction test: 0,908)					
≤250	0/38 (0,0)	0/15 (0,0)	NB	NB	NB
			NB		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
>250	6/208 (2,9)	5/93 (5,4)	0,54 [0,17; 1,71]	0,52 [0,16; 1,76]	-2,49 [-7,61; 2,63]
0,324					
Baseline CRP (p-value of the interaction test: 0,770)					
≤10	2/145 (1,4)	1/58 (1,7)	0,80 [0,07; 8,65]	0,80 [0,07; 8,97]	-0,34 [-4,20; 3,51]
1,000					
>10	7/154 (4,5)	4/87 (4,6)	0,99 [0,30; 3,28]	0,99 [0,28; 3,48]	-0,05 [-5,55; 5,44]
1,000					
Baseline SF average (p-value of the interaction test: 0,784)					
<7	8/220 (3,6)	4/100 (4,0)	0,91 [0,28; 2,95]	0,91 [0,27; 3,08]	-0,36 [-4,93; 4,20]
1,000					
≥7	1/76 (1,3)	1/45 (2,2)	0,59 [0,04; 9,24]	0,59 [0,04; 9,62]	-0,91 [-5,92; 4,10]
1,000					
Datenschnitt: 23. August 2023; Biologic-failed Safety Population. Abkürzungen: CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OR: Odds Ratio; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SF: Stool Frequency; TNF: Tumor Necrosis Factor. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher. Infections were defined using the PTs from the MedDRA Infections and Infestations SOC. The MedDRA terms used to identify infections considered to be opportunistic infections in participants with immune mediated inflammatory conditions treated with immunomodulatory drugs were based on Winthrop et al. (2015).					

Program Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_inaesise_sub_safb_a.rtf

Dataset Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
20DEC2024 / 04:00

Subgruppen für Infections, including Opportunistic Infections and Serious Infections: Schwerwiegend in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,899)					
<65 years	8/286 (2,8)	5/141 (3,5)	0,79 [0,26; 2,37]	0,78 [0,25; 2,44]	-0,75 [-4,35; 2,85]
			0,766		
≥65 years	1/13 (7,7)	0/4 (0,0)	1,07 [0,05; 22,25]	1,08 [0,04; 31,63]	7,69 [-6,79; 22,18]
			1,000		
Age 2 (p-value of the interaction test: 0,608)					
<40 years	7/202 (3,5)	3/91 (3,3)	1,05 [0,28; 3,97]	1,05 [0,27; 4,17]	0,17 [-4,28; 4,62]
			1,000		
≥40 years	2/97 (2,1)	2/54 (3,7)	0,56 [0,08; 3,84]	0,55 [0,07; 4,00]	-1,64 [-7,42; 4,13]
			0,617		
Weight (p-value of the interaction test: 0,652)					
<100 kg	9/284 (3,2)	5/140 (3,6)	0,89 [0,30; 2,60]	0,88 [0,29; 2,69]	-0,40 [-4,09; 3,29]
			0,781		
≥100 kg	0/15 (0,0)	0/5 (0,0)	NB	NB	NB
			NB		
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,562)					
Ever	7/279 (2,5)	4/140 (2,9)	0,88 [0,26; 2,95]	0,88 [0,25; 3,04]	-0,35 [-3,66; 2,97]
			1,000		
Never	2/20 (10,0)	1/5 (20,0)	0,50 [0,06; 4,47]	0,44 [0,03; 6,19]	-10,00 [-47,45; 27,45]
			0,504		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Prior anti-TNF failure (p-value of the interaction test: 0,645)					
Ever	9/281 (3,2)	5/139 (3,6)	0,89 [0,30; 2,61]	0,89 [0,29; 2,70]	-0,39 [-4,11; 3,32]
			0,781		
Never	0/18 (0,0)	0/6 (0,0)	NB	NB	NB
			NB		
Prior anti-integrin failure (p-value of the interaction test: 0,294)					
Ever	3/71 (4,2)	0/31 (0,0)	3,11 [0,17; 58,48]	3,22 [0,16; 64,21]	4,23 [-0,45; 8,90]
			0,551		
Never	6/228 (2,6)	5/114 (4,4)	0,60 [0,19; 1,92]	0,59 [0,18; 1,97]	-1,75 [-6,05; 2,54]
			0,516		
Baseline corticosteroid use (p-value of the interaction test: 0,654)					
Yes	1/76 (1,3)	0/39 (0,0)	1,56 [0,06; 37,39]	1,57 [0,06; 39,43]	1,32 [-1,25; 3,88]
			1,000		
No	8/223 (3,6)	5/106 (4,7)	0,76 [0,25; 2,27]	0,75 [0,24; 2,36]	-1,13 [-5,85; 3,59]
			0,763		
Baseline immunomodulator use (p-value of the interaction test: 0,164)					
Yes	3/66 (4,5)	0/39 (0,0)	4,18 [0,22; 78,83]	4,35 [0,22; 86,56]	4,55 [-0,48; 9,57]
			0,293		
No	6/233 (2,6)	5/106 (4,7)	0,55 [0,17; 1,75]	0,53 [0,16; 1,79]	-2,14 [-6,66; 2,38]
			0,329		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Duration of CD (p-value of the interaction test: 0,450)					
<1 year	0/23 (0,0)	1/9 (11,1)	0,14 [0,01; 3,13]	0,12 [0,00; 3,25]	-11,11 [-31,64; 9,42]
			0,281		
≥1 to <5 years	2/104 (1,9)	1/44 (2,3)	0,85 [0,08; 9,09]	0,84 [0,07; 9,55]	-0,35 [-5,48; 4,78]
			1,000		
≥5 years	7/172 (4,1)	3/92 (3,3)	1,25 [0,33; 4,71]	1,26 [0,32; 4,99]	0,81 [-3,87; 5,49]
			1,000		
Baseline fecal calprotectin (p-value of the interaction test: 0,757)					
≤250	0/38 (0,0)	0/15 (0,0)	NB	NB	NB
			NB		
>250	7/208 (3,4)	4/93 (4,3)	0,78 [0,23; 2,61]	0,77 [0,22; 2,71]	-0,94 [-5,73; 3,86]
			0,743		
Baseline SF average (p-value of the interaction test: 0,673)					
<7	7/220 (3,2)	3/100 (3,0)	1,06 [0,28; 4,02]	1,06 [0,27; 4,20]	0,18 [-3,89; 4,25]
			1,000		
≥7	2/76 (2,6)	2/45 (4,4)	0,59 [0,09; 4,06]	0,58 [0,08; 4,28]	-1,81 [-8,83; 5,20]
			0,628		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Datenschnitt: 23. August 2023; Biologic-failed Safety Population. Abkürzungen: CD: Crohn’s Disease; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OR: Odds Ratio; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; RR: relatives Risiko; SF: Stool Frequency; TNF: Tumor Necrosis Factor. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher. Infections were defined using the PTs from the MedDRA Infections and Infestations SOC. The MedDRA terms used to identify infections considered to be opportunistic infections in participants with immune mediated inflammatory conditions treated with immunomodulatory drugs were based on Winthrop et al. (2015).					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_insaesi_sub_safb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba

20DEC2024 / 04:00

Überempfindlichkeitsreaktionen, inklusive Anaphylaxie

Subgruppen für Hypersensitivity Reactions: Gesamtrate in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,608)					
<65 years	38/286 (13,3)	15/141 (10,6)	1,25 [0,71; 2,19]	1,29 [0,68; 2,43]	2,65 [-3,78; 9,08]
			0,533		
≥65 years	0/13 (0,0)	0/4 (0,0)	NB	NB	NB
			NB		
Age 2 (p-value of the interaction test: 0,636)					
<40 years	29/202 (14,4)	10/91 (11,0)	1,31 [0,67; 2,57]	1,36 [0,63; 2,92]	3,37 [-4,67; 11,41]
			0,577		
≥40 years	9/97 (9,3)	5/54 (9,3)	1,00 [0,35; 2,84]	1,00 [0,32; 3,16]	0,02 [-9,63; 9,67]
			1,000		
Sex (p-value of the interaction test: 0,088)					
Male	14/178 (7,9)	7/65 (10,8)	0,73 [0,31; 1,73]	0,71 [0,27; 1,84]	-2,90 [-11,41; 5,61]
			0,451		
Female	24/121 (19,8)	8/80 (10,0)	1,98 [0,94; 4,19]	2,23 [0,95; 5,24]	9,83 [0,15; 19,51]
			0,077		
Race (p-value of the interaction test: 0,678)					
Asian	11/100 (11,0)	7/56 (12,5)	0,88 [0,36; 2,14]	0,87 [0,32; 2,37]	-1,50 [-12,11; 9,11]
			0,798		
White	22/179 (12,3)	8/82 (9,8)	1,26 [0,59; 2,71]	1,30 [0,55; 3,05]	2,53 [-5,49; 10,56]
			0,677		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Other	2/13 (15,4)	0/7 (0,0)	2,86 [0,16; 52,42]	3,26 [0,14; 77,84]	15,38 [-4,23; 35,00]
0,521					
Geographic region 1 (p-value of the interaction test: 0,894)					
Europe	14/114 (12,3)	4/50 (8,0)	1,54 [0,53; 4,43]	1,61 [0,50; 5,16]	4,28 [-5,35; 13,92]
0,589					
North America	6/53 (11,3)	3/26 (11,5)	0,98 [0,27; 3,61]	0,98 [0,22; 4,27]	-0,22 [-15,17; 14,73]
1,000					
Other	18/132 (13,6)	8/69 (11,6)	1,18 [0,54; 2,57]	1,20 [0,49; 2,93]	2,04 [-7,51; 11,60]
0,826					
Geographic region 2 (p-value of the interaction test: 0,670)					
Asia	11/105 (10,5)	7/56 (12,5)	0,84 [0,34; 2,04]	0,82 [0,30; 2,25]	-2,02 [-12,48; 8,43]
0,794					
Central America/South America	6/24 (25,0)	1/13 (7,7)	3,25 [0,44; 24,17]	4,00 [0,43; 37,55]	17,31 [-5,27; 39,89]
0,383					
Europe and ROW	15/117 (12,8)	4/50 (8,0)	1,60 [0,56; 4,59]	1,69 [0,53; 5,38]	4,82 [-4,84; 14,48]
0,437					
North America	6/53 (11,3)	3/26 (11,5)	0,98 [0,27; 3,61]	0,98 [0,22; 4,27]	-0,22 [-15,17; 14,73]
1,000					
Weight (p-value of the interaction test: 0,821)					
<100 kg	35/284 (12,3)	14/140 (10,0)	1,23 [0,69; 2,21]	1,27 [0,66; 2,44]	2,32 [-3,95; 8,59]
0,522					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
≥100 kg	3/15 (20,0)	1/5 (20,0)	1,00 [0,13; 7,57]	1,00 [0,08; 12,56]	0,00 [-40,48; 40,48]
1,000					
BMI (p-value of the interaction test: 0,908)					
Underweight ($<18.5 \text{ kg/m}^2$)	8/54 (14,8)	4/32 (12,5)	1,19 [0,39; 3,62]	1,22 [0,34; 4,42]	2,31 [-12,55; 17,18]
1,000					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	21/161 (13,0)	8/60 (13,3)	0,98 [0,46; 2,09]	0,98 [0,41; 2,34]	-0,29 [-10,34; 9,76]
1,000					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	4/55 (7,3)	1/38 (2,6)	2,76 [0,32; 23,77]	2,90 [0,31; 27,04]	4,64 [-3,90; 13,19]
0,645					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	5/29 (17,2)	2/15 (13,3)	1,29 [0,28; 5,89]	1,35 [0,23; 7,98]	3,91 [-18,11; 25,93]
1,000					
Tobacco use (p-value of the interaction test: 0,630)					
Current	8/52 (15,4)	2/29 (6,9)	2,23 [0,51; 9,81]	2,45 [0,48; 12,43]	8,49 [-4,97; 21,95]
0,318					
Former	7/49 (14,3)	3/21 (14,3)	1,00 [0,29; 3,50]	1,00 [0,23; 4,31]	0,00 [-17,89; 17,89]
1,000					
Never	23/198 (11,6)	10/95 (10,5)	1,10 [0,55; 2,22]	1,12 [0,51; 2,45]	1,09 [-6,53; 8,71]
0,846					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,189)					
Ever	37/279 (13,3)	14/140 (10,0)	1,33 [0,74; 2,37]	1,38 [0,72; 2,64]	3,26 [-3,10; 9,63]
0,428					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Never	1/20 (5,0)	1/5 (20,0)	0,25 [0,02; 3,34]	0,21 [0,01; 4,12]	-15,00 [-51,34; 21,34]
0,367					
Prior anti-TNF failure (p-value of the interaction test: 0,321)					
Ever	37/281 (13,2)	14/139 (10,1)	1,31 [0,73; 2,34]	1,35 [0,71; 2,60]	3,10 [-3,28; 9,47]
0,429					
Never	1/18 (5,6)	1/6 (16,7)	0,33 [0,02; 4,55]	0,29 [0,02; 5,60]	-11,11 [-42,75; 20,53]
0,446					
Prior anti-integrin failure (p-value of the interaction test: 0,107)					
Ever	6/71 (8,5)	5/31 (16,1)	0,52 [0,17; 1,59]	0,48 [0,13; 1,71]	-7,68 [-22,15; 6,80]
0,302					
Never	32/228 (14,0)	10/114 (8,8)	1,60 [0,82; 3,14]	1,70 [0,80; 3,59]	5,26 [-1,61; 12,14]
0,221					
Baseline corticosteroid use (p-value of the interaction test: 0,936)					
Yes	15/76 (19,7)	6/39 (15,4)	1,28 [0,54; 3,05]	1,35 [0,48; 3,82]	4,35 [-10,08; 18,78]
0,621					
No	23/223 (10,3)	9/106 (8,5)	1,21 [0,58; 2,53]	1,24 [0,55; 2,78]	1,82 [-4,82; 8,46]
0,693					
Baseline immunomodulator use (p-value of the interaction test: 0,828)					
Yes	8/66 (12,1)	4/39 (10,3)	1,18 [0,38; 3,67]	1,21 [0,34; 4,30]	1,86 [-10,49; 14,22]
1,000					
No	30/233 (12,9)	11/106 (10,4)	1,24 [0,65; 2,38]	1,28 [0,61; 2,66]	2,50 [-4,73; 9,72]
0,592					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Duration of CD (p-value of the interaction test: 0,684)					
<1 year	5/23 (21,7)	2/9 (22,2)	0,98 [0,23; 4,16]	0,97 [0,15; 6,23]	-0,48 [-32,45; 31,48]
				1,000	
≥1 to <5 years	14/104 (13,5)	3/44 (6,8)	1,97 [0,60; 6,53]	2,13 [0,58; 7,80]	6,64 [-3,28; 16,57]
				0,397	
≥5 years	19/172 (11,0)	10/92 (10,9)	1,02 [0,49; 2,09]	1,02 [0,45; 2,29]	0,18 [-7,72; 8,08]
				1,000	
Baseline disease location (p-value of the interaction test: 0,259)					
Colonic	17/120 (14,2)	5/59 (8,5)	1,67 [0,65; 4,31]	1,78 [0,62; 5,09]	5,69 [-3,76; 15,15]
				0,339	
Ileal	3/31 (9,7)	2/6 (33,3)	0,29 [0,06; 1,38]	0,21 [0,03; 1,70]	-23,66 [-62,78; 15,47]
				0,177	
Ileal-Colonic	18/148 (12,2)	8/80 (10,0)	1,22 [0,55; 2,67]	1,25 [0,52; 3,01]	2,16 [-6,26; 10,59]
				0,670	
Baseline fecal calprotectin (p-value of the interaction test: 0,869)					
≤250	4/38 (10,5)	1/15 (6,7)	1,58 [0,19; 13,00]	1,65 [0,17; 16,07]	3,86 [-12,10; 19,81]
				1,000	
>250	25/208 (12,0)	8/93 (8,6)	1,40 [0,65; 2,98]	1,45 [0,63; 3,35]	3,42 [-3,79; 10,63]
				0,431	
Baseline CRP (p-value of the interaction test: 0,680)					
≤10	19/145 (13,1)	5/58 (8,6)	1,52 [0,60; 3,88]	1,60 [0,57; 4,50]	4,48 [-4,59; 13,56]
				0,474	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
>10	19/154 (12,3)	10/87 (11,5)	1,07 [0,52; 2,20]	1,08 [0,48; 2,45]	0,84 [-7,64; 9,32]
1,000					
Baseline SES-CD total score (p-value of the interaction test: 0,376)					
<12	16/142 (11,3)	8/66 (12,1)	0,93 [0,42; 2,06]	0,92 [0,37; 2,27]	-0,85 [-10,29; 8,58]
0,820					
≥12	22/157 (14,0)	7/79 (8,9)	1,58 [0,71; 3,54]	1,68 [0,68; 4,11]	5,15 [-3,14; 13,44]
0,299					
Baseline SF average (p-value of the interaction test: 0,686)					
<7	29/220 (13,2)	12/100 (12,0)	1,10 [0,59; 2,06]	1,11 [0,54; 2,28]	1,18 [-6,60; 8,96]
0,858					
≥7	8/76 (10,5)	3/45 (6,7)	1,58 [0,44; 5,65]	1,65 [0,41; 6,56]	3,86 [-6,18; 13,90]
0,745					
Baseline CDAI 1 (p-value of the interaction test: 0,188)					
<300	19/109 (17,4)	5/59 (8,5)	2,06 [0,81; 5,23]	2,28 [0,80; 6,46]	8,96 [-1,10; 19,02]
0,165					
≥300	18/184 (9,8)	9/84 (10,7)	0,91 [0,43; 1,95]	0,90 [0,39; 2,10]	-0,93 [-8,82; 6,95]
0,829					
Baseline CDAI 2 (p-value of the interaction test: 0,382)					
<220	7/29 (24,1)	0/12 (0,0)	6,50 [0,40; >100]	8,33 [0,44; >100]	24,14 [8,56; 39,71]
0,085					
≥220 and <450	29/244 (11,9)	14/119 (11,8)	1,01 [0,55; 1,84]	1,01 [0,51; 2,00]	0,12 [-6,95; 7,19]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
≥450	1/20 (5,0)	0/12 (0,0)	1,86 [0,08; 42,27]	1,92 [0,07; 51,03]	5,00 [-4,55; 14,55]
1,000					
OECD Country (p-value of the interaction test: 0,449)					
Yes	24/177 (13,6)	11/83 (13,3)	1,02 [0,53; 1,99]	1,03 [0,48; 2,21]	0,31 [-8,56; 9,17]
1,000					
No	14/122 (11,5)	4/62 (6,5)	1,78 [0,61; 5,18]	1,88 [0,59; 5,97]	5,02 [-3,31; 13,35]
0,431					
Datenschnitt: 23. August 2023; Biologic-failed Safety Population. Abkürzungen: BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher. The TEAEs were summarized using all narrow or algorithm terms in the Anaphylatic reaction, Angioedema, or Hypersensitivity SMQs.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_hyaesi_sub_saftb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
20DEC2024 / 04:00

Subgruppen für Hypersensitivity Reactions: Nicht schwer in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,580)					
<65 years	38/286 (13,3)	14/141 (9,9)	1,34 [0,75; 2,39]	1,39 [0,73; 2,66]	3,36 [-2,95; 9,67]
			0,349		
≥65 years	0/13 (0,0)	0/4 (0,0)	NB	NB	NB
			NB		
Age 2 (p-value of the interaction test: 0,887)					
<40 years	29/202 (14,4)	10/91 (11,0)	1,31 [0,67; 2,57]	1,36 [0,63; 2,92]	3,37 [-4,67; 11,41]
			0,577		
≥40 years	9/97 (9,3)	4/54 (7,4)	1,25 [0,40; 3,88]	1,28 [0,37; 4,36]	1,87 [-7,19; 10,93]
			0,772		
Sex (p-value of the interaction test: 0,058)					
Male	14/178 (7,9)	7/65 (10,8)	0,73 [0,31; 1,73]	0,71 [0,27; 1,84]	-2,90 [-11,41; 5,61]
			0,451		
Female	24/121 (19,8)	7/80 (8,8)	2,27 [1,03; 5,01]	2,58 [1,05; 6,31]	11,08 [1,66; 20,51]
			0,045		
Race (p-value of the interaction test: 0,607)					
Asian	11/100 (11,0)	7/56 (12,5)	0,88 [0,36; 2,14]	0,87 [0,32; 2,37]	-1,50 [-12,11; 9,11]
			0,798		
White	22/179 (12,3)	7/82 (8,5)	1,44 [0,64; 3,23]	1,50 [0,61; 3,67]	3,75 [-3,97; 11,48]
			0,525		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Other	2/13 (15,4)	0/7 (0,0)	2,86 [0,16; 52,42]	3,26 [0,14; 77,84]	15,38 [-4,23; 35,00]
0,521					
Geographic region 1 (p-value of the interaction test: 0,950)					
Europe	14/114 (12,3)	4/50 (8,0)	1,54 [0,53; 4,43]	1,61 [0,50; 5,16]	4,28 [-5,35; 13,92]
0,589					
North America	6/53 (11,3)	2/26 (7,7)	1,47 [0,32; 6,80]	1,53 [0,29; 8,17]	3,63 [-9,70; 16,96]
1,000					
Other	18/132 (13,6)	8/69 (11,6)	1,18 [0,54; 2,57]	1,20 [0,49; 2,93]	2,04 [-7,51; 11,60]
0,826					
Geographic region 2 (p-value of the interaction test: 0,681)					
Asia	11/105 (10,5)	7/56 (12,5)	0,84 [0,34; 2,04]	0,82 [0,30; 2,25]	-2,02 [-12,48; 8,43]
0,794					
Central America/South America	6/24 (25,0)	1/13 (7,7)	3,25 [0,44; 24,17]	4,00 [0,43; 37,55]	17,31 [-5,27; 39,89]
0,383					
Europe and ROW	15/117 (12,8)	4/50 (8,0)	1,60 [0,56; 4,59]	1,69 [0,53; 5,38]	4,82 [-4,84; 14,48]
0,437					
North America	6/53 (11,3)	2/26 (7,7)	1,47 [0,32; 6,80]	1,53 [0,29; 8,17]	3,63 [-9,70; 16,96]
1,000					
Weight (p-value of the interaction test: 0,773)					
<100 kg	35/284 (12,3)	13/140 (9,3)	1,33 [0,73; 2,43]	1,37 [0,70; 2,69]	3,04 [-3,10; 9,18]
0,417					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
≥100 kg	3/15 (20,0)	1/5 (20,0)	1,00 [0,13; 7,57]	1,00 [0,08; 12,56]	0,00 [-40,48; 40,48]
1,000					
BMI (p-value of the interaction test: 0,951)					
Underweight ($<18.5 \text{ kg/m}^2$)	8/54 (14,8)	4/32 (12,5)	1,19 [0,39; 3,62]	1,22 [0,34; 4,42]	2,31 [-12,55; 17,18]
1,000					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	21/161 (13,0)	7/60 (11,7)	1,12 [0,50; 2,49]	1,14 [0,46; 2,83]	1,38 [-8,27; 11,02]
1,000					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	4/55 (7,3)	1/38 (2,6)	2,76 [0,32; 23,77]	2,90 [0,31; 27,04]	4,64 [-3,90; 13,19]
0,645					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	5/29 (17,2)	2/15 (13,3)	1,29 [0,28; 5,89]	1,35 [0,23; 7,98]	3,91 [-18,11; 25,93]
1,000					
Tobacco use (p-value of the interaction test: 0,666)					
Current	8/52 (15,4)	2/29 (6,9)	2,23 [0,51; 9,81]	2,45 [0,48; 12,43]	8,49 [-4,97; 21,95]
0,318					
Former	7/49 (14,3)	3/21 (14,3)	1,00 [0,29; 3,50]	1,00 [0,23; 4,31]	0,00 [-17,89; 17,89]
1,000					
Never	23/198 (11,6)	9/95 (9,5)	1,23 [0,59; 2,55]	1,26 [0,56; 2,83]	2,14 [-5,25; 9,53]
0,691					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,176)					
Ever	37/279 (13,3)	13/140 (9,3)	1,43 [0,79; 2,60]	1,49 [0,77; 2,91]	3,98 [-2,27; 10,22]
0,266					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert ^a					
Never	1/20 (5,0)	1/5 (20,0)	0,25 [0,02; 3,34]	0,21 [0,01; 4,12]	-15,00 [-51,34; 21,34]
0,367					
Prior anti-TNF failure (p-value of the interaction test: 0,297)					
Ever	37/281 (13,2)	13/139 (9,4)	1,41 [0,77; 2,56]	1,47 [0,75; 2,87]	3,81 [-2,44; 10,06]
0,337					
Never	1/18 (5,6)	1/6 (16,7)	0,33 [0,02; 4,55]	0,29 [0,02; 5,60]	-11,11 [-42,75; 20,53]
0,446					
Prior anti-integrin failure (p-value of the interaction test: 0,079)					
Ever	6/71 (8,5)	5/31 (16,1)	0,52 [0,17; 1,59]	0,48 [0,13; 1,71]	-7,68 [-22,15; 6,80]
0,302					
Never	32/228 (14,0)	9/114 (7,9)	1,78 [0,88; 3,60]	1,90 [0,88; 4,14]	6,14 [-0,56; 12,84]
0,114					
Baseline corticosteroid use (p-value of the interaction test: 0,707)					
Yes	15/76 (19,7)	5/39 (12,8)	1,54 [0,60; 3,92]	1,67 [0,56; 5,00]	6,92 [-6,87; 20,71]
0,442					
No	23/223 (10,3)	9/106 (8,5)	1,21 [0,58; 2,53]	1,24 [0,55; 2,78]	1,82 [-4,82; 8,46]
0,693					
Baseline immunomodulator use (p-value of the interaction test: 0,721)					
Yes	8/66 (12,1)	4/39 (10,3)	1,18 [0,38; 3,67]	1,21 [0,34; 4,30]	1,86 [-10,49; 14,22]
1,000					
No	30/233 (12,9)	10/106 (9,4)	1,36 [0,69; 2,69]	1,42 [0,67; 3,02]	3,44 [-3,59; 10,47]
0,468					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Duration of CD (p-value of the interaction test: 0,756)					
<1 year	5/23 (21,7)	2/9 (22,2)	0,98 [0,23; 4,16]	0,97 [0,15; 6,23]	-0,48 [-32,45; 31,48]
			1,000		
≥1 to <5 years	14/104 (13,5)	3/44 (6,8)	1,97 [0,60; 6,53]	2,13 [0,58; 7,80]	6,64 [-3,28; 16,57]
			0,397		
≥5 years	19/172 (11,0)	9/92 (9,8)	1,13 [0,53; 2,39]	1,15 [0,50; 2,64]	1,26 [-6,40; 8,93]
			0,836		
Baseline disease location (p-value of the interaction test: 0,633)					
Colonic	17/120 (14,2)	5/59 (8,5)	1,67 [0,65; 4,31]	1,78 [0,62; 5,09]	5,69 [-3,76; 15,15]
			0,339		
Ileal	3/31 (9,7)	1/6 (16,7)	0,58 [0,07; 4,68]	0,54 [0,05; 6,24]	-6,99 [-38,57; 24,59]
			0,524		
Ileal-Colonic	18/148 (12,2)	8/80 (10,0)	1,22 [0,55; 2,67]	1,25 [0,52; 3,01]	2,16 [-6,26; 10,59]
			0,670		
Baseline fecal calprotectin (p-value of the interaction test: 0,869)					
≤250	4/38 (10,5)	1/15 (6,7)	1,58 [0,19; 13,00]	1,65 [0,17; 16,07]	3,86 [-12,10; 19,81]
			1,000		
>250	25/208 (12,0)	8/93 (8,6)	1,40 [0,65; 2,98]	1,45 [0,63; 3,35]	3,42 [-3,79; 10,63]
			0,431		
Baseline CRP (p-value of the interaction test: 0,810)					
≤10	19/145 (13,1)	5/58 (8,6)	1,52 [0,60; 3,88]	1,60 [0,57; 4,50]	4,48 [-4,59; 13,56]
			0,474		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
>10	19/154 (12,3)	9/87 (10,3)	1,19 [0,56; 2,52]	1,22 [0,53; 2,83]	1,99 [-6,25; 10,23]
0,682					
Baseline SES-CD total score (p-value of the interaction test: 0,515)					
<12	16/142 (11,3)	7/66 (10,6)	1,06 [0,46; 2,46]	1,07 [0,42; 2,74]	0,66 [-8,41; 9,73]
1,000					
≥12	22/157 (14,0)	7/79 (8,9)	1,58 [0,71; 3,54]	1,68 [0,68; 4,11]	5,15 [-3,14; 13,44]
0,299					
Baseline AP average (p-value of the interaction test: 0,059)					
<2	17/72 (23,6)	4/48 (8,3)	2,83 [1,02; 7,91]	3,40 [1,07; 10,84]	15,28 [2,73; 27,82]
0,048					
≥2	21/226 (9,3)	10/97 (10,3)	0,90 [0,44; 1,84]	0,89 [0,40; 1,97]	-1,02 [-8,15; 6,12]
0,837					
Baseline SF average (p-value of the interaction test: 0,783)					
<7	29/220 (13,2)	11/100 (11,0)	1,20 [0,62; 2,30]	1,23 [0,59; 2,57]	2,18 [-5,41; 9,77]
0,716					
≥7	8/76 (10,5)	3/45 (6,7)	1,58 [0,44; 5,65]	1,65 [0,41; 6,56]	3,86 [-6,18; 13,90]
0,745					
Baseline CDAI 1 (p-value of the interaction test: 0,277)					
<300	19/109 (17,4)	5/59 (8,5)	2,06 [0,81; 5,23]	2,28 [0,80; 6,46]	8,96 [-1,10; 19,02]
0,165					
≥300	18/184 (9,8)	8/84 (9,5)	1,03 [0,47; 2,27]	1,03 [0,43; 2,47]	0,26 [-7,35; 7,86]
1,000					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline CDAI 2 (p-value of the interaction test: 0,415)					
<220	7/29 (24,1)	0/12 (0,0)	6,50 [0,40; >100]	8,33 [0,44; >100]	24,14 [8,56; 39,71]
				0,085	
≥220 and <450	29/244 (11,9)	13/119 (10,9)	1,09 [0,59; 2,02]	1,10 [0,55; 2,20]	0,96 [-5,96; 7,88]
				0,862	
≥450	1/20 (5,0)	0/12 (0,0)	1,86 [0,08; 42,27]	1,92 [0,07; 51,03]	5,00 [-4,55; 14,55]
				1,000	
OECD Country (p-value of the interaction test: 0,548)					
Yes	24/177 (13,6)	10/83 (12,0)	1,13 [0,56; 2,24]	1,15 [0,52; 2,52]	1,51 [-7,12; 10,14]
				0,845	
No	14/122 (11,5)	4/62 (6,5)	1,78 [0,61; 5,18]	1,88 [0,59; 5,97]	5,02 [-3,31; 13,35]
				0,431	
Datenschnitt: 23. August 2023; Biologic-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher. The TEAEs were summarized using all narrow or algorithm terms in the Anaphylatic reaction, Angioedema, or Hypersensitivity SMQs.					

Program Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_sub.sas

Output Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_hyaesins_sub_safb_a.rtf

Dataset Location: /lilly/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
20DEC2024 / 04:00

Reaktionen an der Injektions-/Infusionsstelle

Subgruppen für Infusion and Injection Site Reactions: Gesamtrate in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,838)					
<65 years	41/286 (14,3)	11/141 (7,8)	1,84 [0,97; 3,46]	1,98 [0,98; 3,98]	6,53 [0,53; 12,54]
			0,059		
≥65 years	1/13 (7,7)	0/4 (0,0)	1,07 [0,05; 22,25]	1,08 [0,04; 31,63]	7,69 [-6,79; 22,18]
			1,000		
Age 2 (p-value of the interaction test: 0,929)					
<40 years	32/202 (15,8)	8/91 (8,8)	1,80 [0,86; 3,75]	1,95 [0,86; 4,43]	7,05 [-0,64; 14,74]
			0,140		
≥40 years	10/97 (10,3)	3/54 (5,6)	1,86 [0,53; 6,45]	1,95 [0,51; 7,43]	4,75 [-3,85; 13,35]
			0,380		
Sex (p-value of the interaction test: 0,652)					
Male	15/178 (8,4)	3/65 (4,6)	1,83 [0,55; 6,10]	1,90 [0,53; 6,80]	3,81 [-2,72; 10,34]
			0,414		
Female	27/121 (22,3)	8/80 (10,0)	2,23 [1,07; 4,66]	2,59 [1,11; 6,03]	12,31 [2,40; 22,23]
			0,035		
Race (p-value of the interaction test: 0,485)					
Asian	7/100 (7,0)	1/56 (1,8)	3,92 [0,49; 31,05]	4,14 [0,50; 34,55]	5,21 [-0,87; 11,30]
			0,260		
White	30/179 (16,8)	8/82 (9,8)	1,72 [0,82; 3,58]	1,86 [0,81; 4,26]	7,00 [-1,43; 15,44]
			0,185		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Other	2/13 (15,4)	2/7 (28,6)	0,54 [0,10; 3,04]	0,45 [0,05; 4,21]	-13,19 [-51,98; 25,60]
0,587					
Geographic region 1 (p-value of the interaction test: 0,893)					
Europe	13/114 (11,4)	2/50 (4,0)	2,85 [0,67; 12,17]	3,09 [0,67; 14,24]	7,40 [-0,57; 15,38]
0,154					
North America	15/53 (28,3)	5/26 (19,2)	1,47 [0,60; 3,61]	1,66 [0,53; 5,20]	9,07 [-10,33; 28,48]
0,425					
Other	14/132 (10,6)	4/69 (5,8)	1,83 [0,63; 5,35]	1,93 [0,61; 6,10]	4,81 [-2,81; 12,42]
0,308					
Geographic region 2 (p-value of the interaction test: 0,920)					
Asia	8/105 (7,6)	2/56 (3,6)	2,13 [0,47; 9,71]	2,23 [0,46; 10,86]	4,05 [-2,98; 11,07]
0,496					
Central America/South America	5/24 (20,8)	2/13 (15,4)	1,35 [0,30; 6,04]	1,45 [0,24; 8,76]	5,45 [-20,02; 30,92]
1,000					
Europe and ROW	14/117 (12,0)	2/50 (4,0)	2,99 [0,71; 12,68]	3,26 [0,71; 14,93]	7,97 [-0,04; 15,97]
0,153					
North America	15/53 (28,3)	5/26 (19,2)	1,47 [0,60; 3,61]	1,66 [0,53; 5,20]	9,07 [-10,33; 28,48]
0,425					
Weight (p-value of the interaction test: 0,559)					
<100 kg	38/284 (13,4)	11/140 (7,9)	1,70 [0,90; 3,23]	1,81 [0,90; 3,66]	5,52 [-0,44; 11,48]
0,107					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
≥100 kg	4/15 (26,7)	0/5 (0,0)	3,38 [0,21; 53,70]	4,30 [0,20; 94,92]	26,67 [4,29; 49,05]
0,530					
BMI (p-value of the interaction test: 0,985)					
Underweight ($<18.5 \text{ kg/m}^2$)	8/54 (14,8)	3/32 (9,4)	1,58 [0,45; 5,53]	1,68 [0,41; 6,86]	5,44 [-8,41; 19,29]
0,527					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	22/161 (13,7)	5/60 (8,3)	1,64 [0,65; 4,13]	1,74 [0,63; 4,83]	5,33 [-3,45; 14,11]
0,359					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	7/55 (12,7)	2/38 (5,3)	2,42 [0,53; 11,01]	2,63 [0,51; 13,39]	7,46 [-3,85; 18,78]
0,301					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	5/29 (17,2)	1/15 (6,7)	2,59 [0,33; 20,18]	2,92 [0,31; 27,56]	10,57 [-8,09; 29,24]
0,647					
Tobacco use (p-value of the interaction test: 0,682)					
Current	7/52 (13,5)	1/29 (3,4)	3,90 [0,50; 30,19]	4,36 [0,51; 37,31]	10,01 [-1,40; 21,42]
0,248					
Former	9/49 (18,4)	3/21 (14,3)	1,29 [0,39; 4,28]	1,35 [0,33; 5,59]	4,08 [-14,40; 22,56]
1,000					
Never	26/198 (13,1)	7/95 (7,4)	1,78 [0,80; 3,96]	1,90 [0,79; 4,55]	5,76 [-1,29; 12,81]
0,170					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,771)					
Ever	38/279 (13,6)	11/140 (7,9)	1,73 [0,91; 3,29]	1,85 [0,91; 3,74]	5,76 [-0,24; 11,77]
0,106					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Never	4/20 (20,0)	0/5 (0,0)	2,57 [0,16; 41,34]	3,00 [0,14; 65,08]	20,00 [2,47; 37,53]
0,549					
Prior anti-TNF failure (p-value of the interaction test: 0,582)					
Ever	38/281 (13,5)	11/139 (7,9)	1,71 [0,90; 3,24]	1,82 [0,90; 3,68]	5,61 [-0,40; 11,62]
0,107					
Never	4/18 (22,2)	0/6 (0,0)	3,32 [0,20; 54,00]	4,03 [0,19; 86,45]	22,22 [3,02; 41,43]
0,539					
Prior anti-integrin failure (p-value of the interaction test: 0,995)					
Ever	9/71 (12,7)	2/31 (6,5)	1,96 [0,45; 8,57]	2,10 [0,43; 10,37]	6,22 [-5,38; 17,83]
0,497					
Never	33/228 (14,5)	9/114 (7,9)	1,83 [0,91; 3,70]	1,97 [0,91; 4,28]	6,58 [-0,16; 13,31]
0,084					
Baseline corticosteroid use (p-value of the interaction test: 0,686)					
Yes	17/76 (22,4)	4/39 (10,3)	2,18 [0,79; 6,04]	2,52 [0,79; 8,10]	12,11 [-1,25; 25,47]
0,132					
No	25/223 (11,2)	7/106 (6,6)	1,70 [0,76; 3,80]	1,79 [0,75; 4,27]	4,61 [-1,68; 10,89]
0,234					
Baseline immunomodulator use (p-value of the interaction test: 0,771)					
Yes	6/66 (9,1)	2/39 (5,1)	1,77 [0,38; 8,36]	1,85 [0,35; 9,65]	3,96 [-5,84; 13,76]
0,707					
No	36/233 (15,5)	9/106 (8,5)	1,82 [0,91; 3,64]	1,97 [0,91; 4,25]	6,96 [-0,09; 14,01]
0,086					

	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Subgruppe			p-Wert ^a		
Duration of CD (p-value of the interaction test: 0,880)					
<1 year	4/23 (17,4)	1/9 (11,1)	1,57 [0,20; 12,17]	1,68 [0,16; 17,52]	6,28 [-19,44; 32,00]
			1,000		
≥1 to <5 years	17/104 (16,3)	3/44 (6,8)	2,40 [0,74; 7,77]	2,67 [0,74; 9,63]	9,53 [-0,77; 19,82]
			0,187		
≥5 years	21/172 (12,2)	7/92 (7,6)	1,60 [0,71; 3,63]	1,69 [0,69; 4,14]	4,60 [-2,70; 11,90]
			0,298		
Baseline disease location (p-value of the interaction test: 0,543)					
Colonic	17/120 (14,2)	3/59 (5,1)	2,79 [0,85; 9,13]	3,08 [0,87; 10,97]	9,08 [0,69; 17,47]
			0,081		
Ileal	4/31 (12,9)	1/6 (16,7)	0,77 [0,10; 5,77]	0,74 [0,07; 8,08]	-3,76 [-35,83; 28,31]
			1,000		
Ileal-Colonic	21/148 (14,2)	7/80 (8,8)	1,62 [0,72; 3,65]	1,72 [0,70; 4,25]	5,44 [-2,92; 13,80]
			0,293		
Baseline fecal calprotectin (p-value of the interaction test: 0,981)					
≤250	5/38 (13,2)	1/15 (6,7)	1,97 [0,25; 15,52]	2,12 [0,23; 19,85]	6,49 [-10,09; 23,07]
			0,662		
>250	27/208 (13,0)	8/93 (8,6)	1,51 [0,71; 3,19]	1,58 [0,69; 3,63]	4,38 [-2,92; 11,68]
			0,333		
Baseline CRP (p-value of the interaction test: 0,483)					
≤10	21/145 (14,5)	3/58 (5,2)	2,80 [0,87; 9,03]	3,10 [0,89; 10,84]	9,31 [1,23; 17,39]
			0,090		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
>10	21/154 (13,6)	8/87 (9,2)	1,48 [0,69; 3,21]	1,56 [0,66; 3,69]	4,44 [-3,70; 12,58]
0,410					
Baseline SES-CD total score (p-value of the interaction test: 0,768)					
<12	18/142 (12,7)	5/66 (7,6)	1,67 [0,65; 4,31]	1,77 [0,63; 5,00]	5,10 [-3,31; 13,51]
0,347					
≥12	24/157 (15,3)	6/79 (7,6)	2,01 [0,86; 4,72]	2,20 [0,86; 5,62]	7,69 [-0,42; 15,80]
0,102					
Baseline AP average (p-value of the interaction test: 0,981)					
<2	11/72 (15,3)	4/48 (8,3)	1,83 [0,62; 5,42]	1,98 [0,59; 6,64]	6,94 [-4,47; 18,35]
0,399					
≥2	31/226 (13,7)	7/97 (7,2)	1,90 [0,87; 4,17]	2,04 [0,87; 4,82]	6,50 [-0,33; 13,33]
0,131					
Baseline SF average (p-value of the interaction test: 0,860)					
<7	31/220 (14,1)	8/100 (8,0)	1,76 [0,84; 3,69]	1,89 [0,83; 4,27]	6,09 [-0,94; 13,12]
0,142					
≥7	11/76 (14,5)	3/45 (6,7)	2,17 [0,64; 7,37]	2,37 [0,62; 9,00]	7,81 [-2,95; 18,56]
0,248					
Baseline CDAI 1 (p-value of the interaction test: 0,432)					
<300	19/109 (17,4)	7/59 (11,9)	1,47 [0,66; 3,29]	1,57 [0,62; 3,98]	5,57 [-5,33; 16,47]
0,381					
≥300	23/184 (12,5)	4/84 (4,8)	2,63 [0,94; 7,35]	2,86 [0,96; 8,54]	7,74 [1,14; 14,34]
0,052					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline CDAI 2 (p-value of the interaction test: 0,501)					
<220	7/29 (24,1)	3/12 (25,0)	0,97 [0,30; 3,12]	0,95 [0,20; 4,54]	-0,86 [-29,89; 28,17]
			1,000		
≥220 and <450	33/244 (13,5)	7/119 (5,9)	2,30 [1,05; 5,04]	2,50 [1,07; 5,84]	7,64 [1,62; 13,67]
			0,032		
≥450	2/20 (10,0)	1/12 (8,3)	1,20 [0,12; 11,87]	1,22 [0,10; 15,11]	1,67 [-18,76; 22,10]
			1,000		
OECD Country (p-value of the interaction test: 0,851)					
Yes	29/177 (16,4)	8/83 (9,6)	1,70 [0,81; 3,56]	1,84 [0,80; 4,22]	6,75 [-1,62; 15,11]
			0,183		
No	13/122 (10,7)	3/62 (4,8)	2,20 [0,65; 7,44]	2,35 [0,64; 8,56]	5,82 [-1,83; 13,47]
			0,270		
Datenschnitt: 23. August 2023; Biologic-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher. The TEAEs were summarized using the MedDRA HLT Injection site reactions excluding certain PTs (e.g., those PTs related to joint) and the MedDRA HLT Infusion site reactions.					

Program Location: /lilyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lilyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_iaesi_sub_safb_a.rtf

Dataset Location: /lilyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
20DEC2024 / 04:00

Subgruppen für Infusion and Injection Site Reactions: Nicht schwer in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,838)					
<65 years	41/286 (14,3)	11/141 (7,8)	1,84 [0,97; 3,46]	1,98 [0,98; 3,98]	6,53 [0,53; 12,54]
			0,059		
≥65 years	1/13 (7,7)	0/4 (0,0)	1,07 [0,05; 22,25]	1,08 [0,04; 31,63]	7,69 [-6,79; 22,18]
			1,000		
Age 2 (p-value of the interaction test: 0,929)					
<40 years	32/202 (15,8)	8/91 (8,8)	1,80 [0,86; 3,75]	1,95 [0,86; 4,43]	7,05 [-0,64; 14,74]
			0,140		
≥40 years	10/97 (10,3)	3/54 (5,6)	1,86 [0,53; 6,45]	1,95 [0,51; 7,43]	4,75 [-3,85; 13,35]
			0,380		
Sex (p-value of the interaction test: 0,652)					
Male	15/178 (8,4)	3/65 (4,6)	1,83 [0,55; 6,10]	1,90 [0,53; 6,80]	3,81 [-2,72; 10,34]
			0,414		
Female	27/121 (22,3)	8/80 (10,0)	2,23 [1,07; 4,66]	2,59 [1,11; 6,03]	12,31 [2,40; 22,23]
			0,035		
Race (p-value of the interaction test: 0,485)					
Asian	7/100 (7,0)	1/56 (1,8)	3,92 [0,49; 31,05]	4,14 [0,50; 34,55]	5,21 [-0,87; 11,30]
			0,260		
White	30/179 (16,8)	8/82 (9,8)	1,72 [0,82; 3,58]	1,86 [0,81; 4,26]	7,00 [-1,43; 15,44]
			0,185		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Other	2/13 (15,4)	2/7 (28,6)	0,54 [0,10; 3,04]	0,45 [0,05; 4,21]	-13,19 [-51,98; 25,60]
0,587					
Geographic region 1 (p-value of the interaction test: 0,893)					
Europe	13/114 (11,4)	2/50 (4,0)	2,85 [0,67; 12,17]	3,09 [0,67; 14,24]	7,40 [-0,57; 15,38]
0,154					
North America	15/53 (28,3)	5/26 (19,2)	1,47 [0,60; 3,61]	1,66 [0,53; 5,20]	9,07 [-10,33; 28,48]
0,425					
Other	14/132 (10,6)	4/69 (5,8)	1,83 [0,63; 5,35]	1,93 [0,61; 6,10]	4,81 [-2,81; 12,42]
0,308					
Geographic region 2 (p-value of the interaction test: 0,920)					
Asia	8/105 (7,6)	2/56 (3,6)	2,13 [0,47; 9,71]	2,23 [0,46; 10,86]	4,05 [-2,98; 11,07]
0,496					
Central America/South America	5/24 (20,8)	2/13 (15,4)	1,35 [0,30; 6,04]	1,45 [0,24; 8,76]	5,45 [-20,02; 30,92]
1,000					
Europe and ROW	14/117 (12,0)	2/50 (4,0)	2,99 [0,71; 12,68]	3,26 [0,71; 14,93]	7,97 [-0,04; 15,97]
0,153					
North America	15/53 (28,3)	5/26 (19,2)	1,47 [0,60; 3,61]	1,66 [0,53; 5,20]	9,07 [-10,33; 28,48]
0,425					
Weight (p-value of the interaction test: 0,559)					
<100 kg	38/284 (13,4)	11/140 (7,9)	1,70 [0,90; 3,23]	1,81 [0,90; 3,66]	5,52 [-0,44; 11,48]
0,107					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
≥100 kg	4/15 (26,7)	0/5 (0,0)	3,38 [0,21; 53,70]	4,30 [0,20; 94,92]	26,67 [4,29; 49,05]
0,530					
BMI (p-value of the interaction test: 0,985)					
Underweight ($<18.5 \text{ kg/m}^2$)	8/54 (14,8)	3/32 (9,4)	1,58 [0,45; 5,53]	1,68 [0,41; 6,86]	5,44 [-8,41; 19,29]
0,527					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	22/161 (13,7)	5/60 (8,3)	1,64 [0,65; 4,13]	1,74 [0,63; 4,83]	5,33 [-3,45; 14,11]
0,359					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	7/55 (12,7)	2/38 (5,3)	2,42 [0,53; 11,01]	2,63 [0,51; 13,39]	7,46 [-3,85; 18,78]
0,301					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	5/29 (17,2)	1/15 (6,7)	2,59 [0,33; 20,18]	2,92 [0,31; 27,56]	10,57 [-8,09; 29,24]
0,647					
Tobacco use (p-value of the interaction test: 0,682)					
Current	7/52 (13,5)	1/29 (3,4)	3,90 [0,50; 30,19]	4,36 [0,51; 37,31]	10,01 [-1,40; 21,42]
0,248					
Former	9/49 (18,4)	3/21 (14,3)	1,29 [0,39; 4,28]	1,35 [0,33; 5,59]	4,08 [-14,40; 22,56]
1,000					
Never	26/198 (13,1)	7/95 (7,4)	1,78 [0,80; 3,96]	1,90 [0,79; 4,55]	5,76 [-1,29; 12,81]
0,170					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,771)					
Ever	38/279 (13,6)	11/140 (7,9)	1,73 [0,91; 3,29]	1,85 [0,91; 3,74]	5,76 [-0,24; 11,77]
0,106					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
	p-Wert ^a				
Never	4/20 (20,0)	0/5 (0,0)	2,57 [0,16; 41,34]	3,00 [0,14; 65,08]	20,00 [2,47; 37,53]
0,549					
Prior anti-TNF failure (p-value of the interaction test: 0,582)					
Ever	38/281 (13,5)	11/139 (7,9)	1,71 [0,90; 3,24]	1,82 [0,90; 3,68]	5,61 [-0,40; 11,62]
0,107					
Never	4/18 (22,2)	0/6 (0,0)	3,32 [0,20; 54,00]	4,03 [0,19; 86,45]	22,22 [3,02; 41,43]
0,539					
Prior anti-integrin failure (p-value of the interaction test: 0,995)					
Ever	9/71 (12,7)	2/31 (6,5)	1,96 [0,45; 8,57]	2,10 [0,43; 10,37]	6,22 [-5,38; 17,83]
0,497					
Never	33/228 (14,5)	9/114 (7,9)	1,83 [0,91; 3,70]	1,97 [0,91; 4,28]	6,58 [-0,16; 13,31]
0,084					
Baseline corticosteroid use (p-value of the interaction test: 0,686)					
Yes	17/76 (22,4)	4/39 (10,3)	2,18 [0,79; 6,04]	2,52 [0,79; 8,10]	12,11 [-1,25; 25,47]
0,132					
No	25/223 (11,2)	7/106 (6,6)	1,70 [0,76; 3,80]	1,79 [0,75; 4,27]	4,61 [-1,68; 10,89]
0,234					
Baseline immunomodulator use (p-value of the interaction test: 0,771)					
Yes	6/66 (9,1)	2/39 (5,1)	1,77 [0,38; 8,36]	1,85 [0,35; 9,65]	3,96 [-5,84; 13,76]
0,707					
No	36/233 (15,5)	9/106 (8,5)	1,82 [0,91; 3,64]	1,97 [0,91; 4,25]	6,96 [-0,09; 14,01]
0,086					

	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
Subgruppe			p-Wert ^a		
Duration of CD (p-value of the interaction test: 0,880)					
<1 year	4/23 (17,4)	1/9 (11,1)	1,57 [0,20; 12,17]	1,68 [0,16; 17,52]	6,28 [-19,44; 32,00]
			1,000		
≥1 to <5 years	17/104 (16,3)	3/44 (6,8)	2,40 [0,74; 7,77]	2,67 [0,74; 9,63]	9,53 [-0,77; 19,82]
			0,187		
≥5 years	21/172 (12,2)	7/92 (7,6)	1,60 [0,71; 3,63]	1,69 [0,69; 4,14]	4,60 [-2,70; 11,90]
			0,298		
Baseline disease location (p-value of the interaction test: 0,543)					
Colonic	17/120 (14,2)	3/59 (5,1)	2,79 [0,85; 9,13]	3,08 [0,87; 10,97]	9,08 [0,69; 17,47]
			0,081		
Ileal	4/31 (12,9)	1/6 (16,7)	0,77 [0,10; 5,77]	0,74 [0,07; 8,08]	-3,76 [-35,83; 28,31]
			1,000		
Ileal-Colonic	21/148 (14,2)	7/80 (8,8)	1,62 [0,72; 3,65]	1,72 [0,70; 4,25]	5,44 [-2,92; 13,80]
			0,293		
Baseline fecal calprotectin (p-value of the interaction test: 0,981)					
≤250	5/38 (13,2)	1/15 (6,7)	1,97 [0,25; 15,52]	2,12 [0,23; 19,85]	6,49 [-10,09; 23,07]
			0,662		
>250	27/208 (13,0)	8/93 (8,6)	1,51 [0,71; 3,19]	1,58 [0,69; 3,63]	4,38 [-2,92; 11,68]
			0,333		
Baseline CRP (p-value of the interaction test: 0,483)					
≤10	21/145 (14,5)	3/58 (5,2)	2,80 [0,87; 9,03]	3,10 [0,89; 10,84]	9,31 [1,23; 17,39]
			0,090		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
>10	21/154 (13,6)	8/87 (9,2)	1,48 [0,69; 3,21]	1,56 [0,66; 3,69]	4,44 [-3,70; 12,58]
0,410					
Baseline SES-CD total score (p-value of the interaction test: 0,768)					
<12	18/142 (12,7)	5/66 (7,6)	1,67 [0,65; 4,31]	1,77 [0,63; 5,00]	5,10 [-3,31; 13,51]
0,347					
≥12	24/157 (15,3)	6/79 (7,6)	2,01 [0,86; 4,72]	2,20 [0,86; 5,62]	7,69 [-0,42; 15,80]
0,102					
Baseline AP average (p-value of the interaction test: 0,981)					
<2	11/72 (15,3)	4/48 (8,3)	1,83 [0,62; 5,42]	1,98 [0,59; 6,64]	6,94 [-4,47; 18,35]
0,399					
≥2	31/226 (13,7)	7/97 (7,2)	1,90 [0,87; 4,17]	2,04 [0,87; 4,82]	6,50 [-0,33; 13,33]
0,131					
Baseline SF average (p-value of the interaction test: 0,860)					
<7	31/220 (14,1)	8/100 (8,0)	1,76 [0,84; 3,69]	1,89 [0,83; 4,27]	6,09 [-0,94; 13,12]
0,142					
≥7	11/76 (14,5)	3/45 (6,7)	2,17 [0,64; 7,37]	2,37 [0,62; 9,00]	7,81 [-2,95; 18,56]
0,248					
Baseline CDAI 1 (p-value of the interaction test: 0,432)					
<300	19/109 (17,4)	7/59 (11,9)	1,47 [0,66; 3,29]	1,57 [0,62; 3,98]	5,57 [-5,33; 16,47]
0,381					
≥300	23/184 (12,5)	4/84 (4,8)	2,63 [0,94; 7,35]	2,86 [0,96; 8,54]	7,74 [1,14; 14,34]
0,052					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline CDAI 2 (p-value of the interaction test: 0,501)					
<220	7/29 (24,1)	3/12 (25,0)	0,97 [0,30; 3,12]	0,95 [0,20; 4,54]	-0,86 [-29,89; 28,17]
1,000					
≥220 and <450	33/244 (13,5)	7/119 (5,9)	2,30 [1,05; 5,04]	2,50 [1,07; 5,84]	7,64 [1,62; 13,67]
0,032					
≥450	2/20 (10,0)	1/12 (8,3)	1,20 [0,12; 11,87]	1,22 [0,10; 15,11]	1,67 [-18,76; 22,10]
1,000					
OECD Country (p-value of the interaction test: 0,851)					
Yes	29/177 (16,4)	8/83 (9,6)	1,70 [0,81; 3,56]	1,84 [0,80; 4,22]	6,75 [-1,62; 15,11]
0,183					
No	13/122 (10,7)	3/62 (4,8)	2,20 [0,65; 7,44]	2,35 [0,64; 8,56]	5,82 [-1,83; 13,47]
0,270					
Datenschnitt: 23. August 2023; Biologic-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher. The TEAEs were summarized using the MedDRA HLT Injection site reactions excluding certain PTs (e.g., those PTs related to joint) and the MedDRA HLT Infusion site reactions.					

Program Location: /lilyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effresp_sub.sas

Output Location: /lilyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_iaesins_sub_safb_a.rtf

Dataset Location: /lilyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
20DEC2024 / 04:00

Anhang 4-G.4.6.3.3 Unerwünschte Ereignisse (UE) nach SOC/PT

Subgruppen für TEAE (PT): General disorders and administration site conditions/Injection site reaction - in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,196)					
<65 years	18/286 (6,3)	1/141 (0,7)	8,87 [1,20; 65,80]	9,40 [1,24; 71,17]	5,58 [2,45; 8,72]
			0,006		
≥65 years	0/13 (0,0)	0/4 (0,0)	NB	NB	NB
			NB		
Age 2 (p-value of the interaction test: 0,944)					
<40 years	14/202 (6,9)	1/91 (1,1)	6,31 [0,84; 47,24]	6,70 [0,87; 51,76]	5,83 [1,73; 9,94]
			0,043		
≥40 years	4/97 (4,1)	0/54 (0,0)	5,05 [0,28; 92,08]	5,25 [0,28; 99,31]	4,12 [0,17; 8,08]
			0,297		
Sex (p-value of the interaction test: 0,657)					
Male	4/178 (2,2)	0/65 (0,0)	3,32 [0,18; 60,80]	3,38 [0,18; 63,62]	2,25 [0,07; 4,42]
			0,576		
Female	14/121 (11,6)	1/80 (1,3)	9,26 [1,24; 69,01]	10,34 [1,33; 80,25]	10,32 [4,12; 16,52]
			0,005		
Race (p-value of the interaction test: 0,883)					
Asian	1/100 (1,0)	0/56 (0,0)	1,69 [0,07; 40,88]	1,70 [0,07; 42,52]	1,00 [-0,95; 2,95]
			1,000		
White	12/179 (6,7)	1/82 (1,2)	5,50 [0,73; 41,57]	5,82 [0,74; 45,54]	5,48 [1,12; 9,85]
			0,069		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Other	2/13 (15,4)	0/7 (0,0)	2,86 [0,16; 52,42]	3,26 [0,14; 77,84]	15,38 [-4,23; 35,00]
0,521					
Weight (p-value of the interaction test: 0,728)					
<100 kg	15/284 (5,3)	1/140 (0,7)	7,39 [0,99; 55,41]	7,75 [1,01; 59,29]	4,57 [1,62; 7,52]
0,027					
≥100 kg	3/15 (20,0)	0/5 (0,0)	2,63 [0,16; 43,63]	3,08 [0,13; 70,33]	20,00 [-0,24; 40,24]
0,539					
BMI (p-value of the interaction test: 0,966)					
Underweight (<18.5 kg/m ²)	3/54 (5,6)	0/32 (0,0)	4,20 [0,22; 78,78]	4,42 [0,22; 88,33]	5,56 [-0,55; 11,67]
0,291					
Normal (≥18.5 and <25 kg/m ²)	9/161 (5,6)	1/60 (1,7)	3,35 [0,43; 25,91]	3,49 [0,43; 28,18]	3,92 [-0,88; 8,73]
0,293					
Overweight (≥25 and <30 kg/m ²)	3/55 (5,5)	0/38 (0,0)	4,88 [0,26; 91,74]	5,13 [0,26; >100]	5,45 [-0,55; 11,46]
0,267					
Obese and Extreme obese (≥30 kg/m ²)	3/29 (10,3)	0/15 (0,0)	3,73 [0,21; 67,88]	4,09 [0,20; 84,63]	10,34 [-0,74; 21,43]
0,540					
Tobacco use (p-value of the interaction test: 0,929)					
Current	3/52 (5,8)	0/29 (0,0)	3,96 [0,21; 74,14]	4,17 [0,21; 83,63]	5,77 [-0,57; 12,11]
0,549					
Former	6/49 (12,2)	0/21 (0,0)	5,72 [0,34; 97,16]	6,43 [0,35; >100]	12,24 [3,07; 21,42]
0,168					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Never	9/198 (4,5)	1/95 (1,1)	4,32 [0,56; 33,59]	4,48 [0,56; 35,86]	3,49 [-0,06; 7,05]
0,175					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,301)					
Ever	17/279 (6,1)	1/140 (0,7)	8,53 [1,15; 63,45]	9,02 [1,19; 68,48]	5,38 [2,24; 8,51]
0,009					
Never	1/20 (5,0)	0/5 (0,0)	0,86 [0,04; 18,45]	0,85 [0,03; 23,82]	5,00 [-4,55; 14,55]
1,000					
Prior anti-TNF failure (p-value of the interaction test: 0,528)					
Ever	16/281 (5,7)	1/139 (0,7)	7,91 [1,06; 59,07]	8,33 [1,09; 63,49]	4,97 [1,92; 8,03]
0,016					
Never	2/18 (11,1)	0/6 (0,0)	1,84 [0,10; 33,82]	1,97 [0,08; 46,85]	11,11 [-3,41; 25,63]
1,000					
Prior anti-integrin failure (p-value of the interaction test: 0,907)					
Ever	4/71 (5,6)	0/31 (0,0)	4,00 [0,22; 72,11]	4,20 [0,22; 80,42]	5,63 [0,27; 11,00]
0,311					
Never	14/228 (6,1)	1/114 (0,9)	7,00 [0,93; 52,57]	7,39 [0,96; 56,94]	5,26 [1,71; 8,82]
0,025					
Baseline corticosteroid use (p-value of the interaction test: 0,748)					
Yes	6/76 (7,9)	0/39 (0,0)	6,75 [0,39; >100]	7,28 [0,40; >100]	7,89 [1,83; 13,96]
0,094					
No	12/223 (5,4)	1/106 (0,9)	5,70 [0,75; 43,29]	5,97 [0,77; 46,54]	4,44 [0,95; 7,92]
0,068					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline immunomodulator use (p-value of the interaction test: 0,986)					
Yes	3/66 (4,5)	0/39 (0,0)	4,18 [0,22; 78,83]	4,35 [0,22; 86,56]	4,55 [-0,48; 9,57]
			0,293		
No	15/233 (6,4)	1/106 (0,9)	6,82 [0,91; 50,99]	7,22 [0,94; 55,43]	5,49 [1,85; 9,14]
			0,027		
Duration of CD (p-value of the interaction test: 0,720)					
<1 year	1/23 (4,3)	0/9 (0,0)	1,25 [0,06; 28,15]	1,27 [0,05; 33,97]	4,35 [-3,99; 12,68]
			1,000		
≥1 to <5 years	7/104 (6,7)	0/44 (0,0)	6,43 [0,38; >100]	6,85 [0,38; >100]	6,73 [1,92; 11,55]
			0,104		
≥5 years	10/172 (5,8)	1/92 (1,1)	5,35 [0,70; 41,13]	5,62 [0,71; 44,59]	4,73 [0,64; 8,82]
			0,103		
Baseline fecal calprotectin (p-value of the interaction test: 0,973)					
≤250	3/38 (7,9)	0/15 (0,0)	2,87 [0,16; 52,48]	3,06 [0,15; 62,80]	7,89 [-0,68; 16,47]
			0,550		
>250	10/208 (4,8)	1/93 (1,1)	4,47 [0,58; 34,42]	4,65 [0,59; 36,84]	3,73 [0,15; 7,32]
			0,182		
Baseline CRP (p-value of the interaction test: 0,944)					
≤10	6/145 (4,1)	0/58 (0,0)	5,25 [0,30; 91,78]	5,45 [0,30; 98,35]	4,14 [0,90; 7,38]
			0,186		
>10	12/154 (7,8)	1/87 (1,1)	6,78 [0,90; 51,26]	7,27 [0,93; 56,88]	6,64 [1,85; 11,43]
			0,035		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline SES-CD total score (p-value of the interaction test: 0,568)					
<12	10/142 (7,0)	1/66 (1,5)	4,65 [0,61; 35,56]	4,92 [0,62; 39,30]	5,53 [0,39; 10,66]
			0,179		
≥12	8/157 (5,1)	0/79 (0,0)	8,61 [0,50; >100]	9,04 [0,52; >100]	5,10 [1,66; 8,54]
			0,054		
Baseline AP average (p-value of the interaction test: 0,508)					
<2	7/72 (9,7)	0/48 (0,0)	10,07 [0,59; >100]	11,11 [0,62; >100]	9,72 [2,88; 16,57]
			0,041		
≥2	11/226 (4,9)	1/97 (1,0)	4,72 [0,62; 36,06]	4,91 [0,63; 38,58]	3,84 [0,39; 7,29]
			0,117		
Baseline SF average (p-value of the interaction test: 0,244)					
<7	14/220 (6,4)	0/100 (0,0)	13,25 [0,80; >100]	14,11 [0,83; >100]	6,36 [3,14; 9,59]
			0,007		
≥7	4/76 (5,3)	1/45 (2,2)	2,37 [0,27; 20,54]	2,44 [0,26; 22,58]	3,04 [-3,57; 9,66]
			0,650		
Baseline CDAI 1 (p-value of the interaction test: 0,350)					
<300	10/109 (9,2)	0/59 (0,0)	11,45 [0,68; >100]	12,56 [0,72; >100]	9,17 [3,76; 14,59]
			0,015		
≥300	8/184 (4,3)	1/84 (1,2)	3,65 [0,46; 28,73]	3,77 [0,46; 30,66]	3,16 [-0,59; 6,91]
			0,281		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Baseline CDAI 2 (p-value of the interaction test: 0,633)					
<220	3/29 (10,3)	0/12 (0,0)	3,03 [0,17; 54,63]	3,30 [0,16; 68,93]	10,34 [-0,74; 21,43]
			0,543		
≥220 and <450	15/244 (6,1)	1/119 (0,8)	7,32 [0,98; 54,73]	7,73 [1,01; 59,23]	5,31 [1,88; 8,74]
			0,026		
≥450	0/20 (0,0)	0/12 (0,0)	NB	NB	NB
			NB		
OECD Country (p-value of the interaction test: 0,316)					
Yes	12/177 (6,8)	0/83 (0,0)	11,80 [0,71; >100]	12,61 [0,74; >100]	6,78 [3,08; 10,48]
			0,011		
No	6/122 (4,9)	1/62 (1,6)	3,05 [0,38; 24,77]	3,16 [0,37; 26,81]	3,31 [-1,65; 8,26]
			0,426		
Datenschnitt: 23. August 2023; Biologic-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn’s Disease; CDAI: Crohn’s Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; TNF: Tumor Necrosis Factor. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_aespt_sub.sas
Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_aeppb012_sub_saftb_a.rtf
Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba
19DEC2024 / 16:53

Subgruppen für TEAE (PT): Skin and subcutaneous tissue disorders/Rash - in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,187)					
<65 years	12/286 (4,2)	0/141 (0,0)	12,37 [0,74; >100]	12,89 [0,76; >100]	4,20 [1,87; 6,52]
			0,011		
≥65 years	0/13 (0,0)	0/4 (0,0)	NB	NB	NB
			NB		
Age 2 (p-value of the interaction test: 0,375)					
<40 years	11/202 (5,4)	0/91 (0,0)	10,42 [0,62; >100]	10,99 [0,64; >100]	5,45 [2,32; 8,57]
			0,020		
≥40 years	1/97 (1,0)	0/54 (0,0)	1,68 [0,07; 40,63]	1,69 [0,07; 42,31]	1,03 [-0,98; 3,04]
			1,000		
Weight (p-value of the interaction test: 0,329)					
<100 kg	11/284 (3,9)	0/140 (0,0)	11,38 [0,68; >100]	11,82 [0,69; >100]	3,87 [1,63; 6,12]
			0,019		
≥100 kg	1/15 (6,7)	0/5 (0,0)	1,13 [0,05; 23,99]	1,14 [0,04; 32,36]	6,67 [-5,96; 19,29]
			1,000		
Tobacco use (p-value of the interaction test: 0,565)					
Current	1/52 (1,9)	0/29 (0,0)	1,70 [0,07; 40,39]	1,72 [0,07; 43,55]	1,92 [-1,81; 5,66]
			1,000		
Former	1/49 (2,0)	0/21 (0,0)	1,32 [0,06; 31,15]	1,33 [0,05; 33,98]	2,04 [-1,92; 6,00]
			1,000		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert ^a					
Never	10/198 (5,1)	0/95 (0,0)	10,13 [0,60; >100]	10,64 [0,62; >100]	5,05 [2,00; 8,10]
0,034					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,120)					
Ever	12/279 (4,3)	0/140 (0,0)	12,59 [0,75; >100]	13,13 [0,77; >100]	4,30 [1,92; 6,68]
0,010					
Never	0/20 (0,0)	0/5 (0,0)	NB	NB	NB
NB					
Prior anti-TNF failure (p-value of the interaction test: 0,164)					
Ever	12/281 (4,3)	0/139 (0,0)	12,41 [0,74; >100]	12,94 [0,76; >100]	4,27 [1,91; 6,63]
0,011					
Never	0/18 (0,0)	0/6 (0,0)	NB	NB	NB
NB					
Baseline immunomodulator use (p-value of the interaction test: 0,552)					
Yes	2/66 (3,0)	0/39 (0,0)	2,99 [0,15; 60,62]	3,06 [0,14; 65,44]	3,03 [-1,11; 7,17]
0,529					
No	10/233 (4,3)	0/106 (0,0)	9,60 [0,57; >100]	10,01 [0,58; >100]	4,29 [1,69; 6,89]
0,034					
Baseline CRP (p-value of the interaction test: 0,600)					
≤10	10/145 (6,9)	0/58 (0,0)	8,49 [0,51; >100]	9,07 [0,52; >100]	6,90 [2,77; 11,02]
0,065					
>10	2/154 (1,3)	0/87 (0,0)	2,84 [0,14; 58,46]	2,87 [0,14; 60,44]	1,30 [-0,49; 3,09]
0,537					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Datenschnitt: 23. August 2023; Biologic-failed Safety Population. Abkürzungen: CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; NB: nicht berechnet; OR: Odds Ratio; PT: Preferred Term; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; RR: relatives Risiko; TNF: Tumor Necrosis Factor. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. Korrektur der Stetigkeit im Falle von keinem oder 100% Ereignissen in einem Behandlungsarm. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_aespt_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_aeppb015_sub_safb_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba

19DEC2024 / 16:53

Subgruppen für TEAE (SOC): Infections and infestations - in RCT VIVID-1 mit dem zu bewertenden Arzneimittel in Teilpopulation B (Safety-Population)

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95 % KI]	OR [95 % KI]	RD [95 % KI]
	p-Wert ^a				
Age 1 (p-value of the interaction test: 0,636)					
<65 years	124/286 (43,4)	76/141 (53,9)	0,80 [0,66; 0,98]	0,65 [0,44; 0,98]	-10,54 [-20,58; -0,51]
			0,050		
≥65 years	6/13 (46,2)	3/4 (75,0)	0,62 [0,27; 1,39]	0,29 [0,02; 3,52]	-28,85 [-79,20; 21,50]
			0,576		
Age 2 (p-value of the interaction test: 0,060)					
<40 years	96/202 (47,5)	47/91 (51,6)	0,92 [0,72; 1,18]	0,85 [0,52; 1,39]	-4,12 [-16,49; 8,24]
			0,530		
≥40 years	34/97 (35,1)	32/54 (59,3)	0,59 [0,42; 0,84]	0,37 [0,19; 0,74]	-24,21 [-40,39; -8,02]
			0,006		
Sex (p-value of the interaction test: 0,301)					
Male	67/178 (37,6)	34/65 (52,3)	0,72 [0,53; 0,97]	0,55 [0,31; 0,98]	-14,67 [-28,74; -0,59]
			0,055		
Female	63/121 (52,1)	45/80 (56,3)	0,93 [0,72; 1,20]	0,84 [0,48; 1,49]	-4,18 [-18,23; 9,87]
			0,567		
Race (p-value of the interaction test: 0,795)					
Asian	43/100 (43,0)	31/56 (55,4)	0,78 [0,56; 1,08]	0,61 [0,31; 1,18]	-12,36 [-28,60; 3,88]
			0,181		
White	79/179 (44,1)	44/82 (53,7)	0,82 [0,63; 1,07]	0,68 [0,40; 1,15]	-9,52 [-22,54; 3,49]
			0,182		

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Other	4/13 (30,8)	4/7 (57,1)	0,54 [0,19; 1,52]	0,33 [0,05; 2,24]	-26,37 [-70,80; 18,05]
0,356					
Geographic region 1 (p-value of the interaction test: 0,639)					
Europe	47/114 (41,2)	29/50 (58,0)	0,71 [0,52; 0,98]	0,51 [0,26; 1,00]	-16,77 [-33,17; -0,38]
0,061					
North America	23/53 (43,4)	12/26 (46,2)	0,94 [0,56; 1,58]	0,89 [0,35; 2,30]	-2,76 [-26,11; 20,59]
1,000					
Other	60/132 (45,5)	38/69 (55,1)	0,83 [0,62; 1,10]	0,68 [0,38; 1,22]	-9,62 [-24,11; 4,87]
0,235					
Geographic region 2 (p-value of the interaction test: 0,846)					
Asia	47/105 (44,8)	31/56 (55,4)	0,81 [0,59; 1,11]	0,65 [0,34; 1,25]	-10,60 [-26,72; 5,53]
0,247					
Central America/South America	11/24 (45,8)	7/13 (53,8)	0,85 [0,44; 1,66]	0,73 [0,19; 2,81]	-8,01 [-41,65; 25,63]
0,737					
Europe and ROW	49/117 (41,9)	29/50 (58,0)	0,72 [0,53; 0,99]	0,52 [0,27; 1,02]	-16,12 [-32,46; 0,22]
0,064					
North America	23/53 (43,4)	12/26 (46,2)	0,94 [0,56; 1,58]	0,89 [0,35; 2,30]	-2,76 [-26,11; 20,59]
1,000					
Weight (p-value of the interaction test: 0,204)					
<100 kg	118/284 (41,5)	76/140 (54,3)	0,77 [0,62; 0,94]	0,60 [0,40; 0,90]	-12,74 [-22,78; -2,69]
0,017					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
≥100 kg	12/15 (80,0)	3/5 (60,0)	1,33 [0,62; 2,85]	2,67 [0,30; 23,86]	20,00 [-27,47; 67,47]
0,560					
BMI (p-value of the interaction test: 0,358)					
Underweight ($<18.5 \text{ kg/m}^2$)	25/54 (46,3)	16/32 (50,0)	0,93 [0,59; 1,45]	0,86 [0,36; 2,07]	-3,70 [-25,54; 18,14]
0,825					
Normal (≥ 18.5 and $<25 \text{ kg/m}^2$)	66/161 (41,0)	31/60 (51,7)	0,79 [0,58; 1,08]	0,65 [0,36; 1,18]	-10,67 [-25,42; 4,08]
0,172					
Overweight (≥ 25 and $<30 \text{ kg/m}^2$)	23/55 (41,8)	25/38 (65,8)	0,64 [0,43; 0,94]	0,37 [0,16; 0,88]	-23,97 [-43,91; -4,03]
0,034					
Obese and Extreme obese ($\geq 30 \text{ kg/m}^2$)	16/29 (55,2)	7/15 (46,7)	1,18 [0,63; 2,23]	1,41 [0,40; 4,91]	8,51 [-22,56; 39,57]
0,752					
Tobacco use (p-value of the interaction test: 0,757)					
Current	22/52 (42,3)	14/29 (48,3)	0,88 [0,54; 1,43]	0,79 [0,32; 1,96]	-5,97 [-28,58; 16,64]
0,646					
Former	23/49 (46,9)	14/21 (66,7)	0,70 [0,46; 1,08]	0,44 [0,15; 1,29]	-19,73 [-44,26; 4,80]
0,192					
Never	85/198 (42,9)	51/95 (53,7)	0,80 [0,63; 1,02]	0,65 [0,40; 1,06]	-10,75 [-22,92; 1,41]
0,104					
Prior biologic inadequate resp./loss of resp. (p-value of the interaction test: 0,437)					
Ever	121/279 (43,4)	75/140 (53,6)	0,81 [0,66; 0,99]	0,66 [0,44; 1,00]	-10,20 [-20,30; -0,10]
0,050					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
			p-Wert ^a		
Never	9/20 (45,0)	4/5 (80,0)	0,56 [0,29; 1,08]	0,20 [0,02; 2,17]	-35,00 [-76,29; 6,29]
0,322					
Prior anti-TNF failure (p-value of the interaction test: 0,821)					
Ever	122/281 (43,4)	76/139 (54,7)	0,79 [0,65; 0,97]	0,64 [0,42; 0,96]	-11,26 [-21,36; -1,16]
0,038					
Never	8/18 (44,4)	3/6 (50,0)	0,89 [0,34; 2,30]	0,80 [0,13; 5,09]	-5,56 [-51,68; 40,57]
1,000					
Prior anti-integrin failure (p-value of the interaction test: 0,556)					
Ever	35/71 (49,3)	17/31 (54,8)	0,90 [0,60; 1,34]	0,80 [0,34; 1,87]	-5,54 [-26,57; 15,48]
0,670					
Never	95/228 (41,7)	62/114 (54,4)	0,77 [0,61; 0,96]	0,60 [0,38; 0,94]	-12,72 [-23,88; -1,56]
0,029					
Baseline corticosteroid use (p-value of the interaction test: 0,114)					
Yes	37/76 (48,7)	18/39 (46,2)	1,05 [0,70; 1,59]	1,11 [0,51; 2,40]	2,53 [-16,73; 21,79]
0,845					
No	93/223 (41,7)	61/106 (57,5)	0,72 [0,58; 0,91]	0,53 [0,33; 0,84]	-15,84 [-27,26; -4,42]
0,009					
Baseline immunomodulator use (p-value of the interaction test: 0,945)					
Yes	33/66 (50,0)	24/39 (61,5)	0,81 [0,57; 1,15]	0,63 [0,28; 1,40]	-11,54 [-31,00; 7,92]
0,312					
No	97/233 (41,6)	55/106 (51,9)	0,80 [0,63; 1,02]	0,66 [0,42; 1,05]	-10,26 [-21,68; 1,17]
0,099					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
p-Wert^a					
Duration of CD (p-value of the interaction test: 0,201)					
<1 year	9/23 (39,1)	8/9 (88,9)	0,44 [0,25; 0,77]	0,08 [0,01; 0,76]	-49,76 [-78,38; -21,13]
				0,018	
≥1 to <5 years	45/104 (43,3)	24/44 (54,5)	0,79 [0,56; 1,12]	0,64 [0,31; 1,29]	-11,28 [-28,80; 6,25]
				0,279	
≥5 years	76/172 (44,2)	47/92 (51,1)	0,86 [0,67; 1,12]	0,76 [0,46; 1,26]	-6,90 [-19,53; 5,73]
				0,302	
Baseline disease location (p-value of the interaction test: 0,563)					
Colonic	47/120 (39,2)	30/59 (50,8)	0,77 [0,55; 1,08]	0,62 [0,33; 1,17]	-11,68 [-27,14; 3,78]
				0,151	
Ileal	15/31 (48,4)	2/6 (33,3)	1,45 [0,44; 4,76]	1,88 [0,30; 11,78]	15,05 [-26,57; 56,67]
				0,667	
Ileal-Colonic	68/148 (45,9)	47/80 (58,8)	0,78 [0,61; 1,01]	0,60 [0,34; 1,03]	-12,80 [-26,25; 0,64]
				0,072	
Baseline fecal calprotectin (p-value of the interaction test: 0,181)					
≤250	18/38 (47,4)	6/15 (40,0)	1,18 [0,59; 2,40]	1,35 [0,40; 4,54]	7,37 [-22,07; 36,81]
				0,762	
>250	90/208 (43,3)	54/93 (58,1)	0,75 [0,59; 0,94]	0,55 [0,34; 0,90]	-14,80 [-26,87; -2,72]
				0,018	
Baseline CRP (p-value of the interaction test: 0,460)					
≤10	63/145 (43,4)	29/58 (50,0)	0,87 [0,63; 1,19]	0,77 [0,42; 1,41]	-6,55 [-21,74; 8,64]
				0,437	

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
>10	67/154 (43,5)	50/87 (57,5)	0,76 [0,59; 0,98]	0,57 [0,34; 0,97]	-13,96 [-26,97; -0,96]
0,044					
Baseline SES-CD total score (p-value of the interaction test: 0,579)					
<12	64/142 (45,1)	35/66 (53,0)	0,85 [0,64; 1,14]	0,73 [0,40; 1,31]	-7,96 [-22,52; 6,60]
0,300					
≥12	66/157 (42,0)	44/79 (55,7)	0,75 [0,58; 0,99]	0,58 [0,33; 1,00]	-13,66 [-27,06; -0,26]
0,054					
Baseline AP average (p-value of the interaction test: 0,170)					
<2	33/72 (45,8)	32/48 (66,7)	0,69 [0,50; 0,95]	0,42 [0,20; 0,90]	-20,83 [-38,45; -3,22]
0,027					
≥2	96/226 (42,5)	47/97 (48,5)	0,88 [0,68; 1,13]	0,79 [0,49; 1,27]	-5,98 [-17,83; 5,88]
0,331					
Baseline SF average (p-value of the interaction test: 0,063)					
<7	96/220 (43,6)	48/100 (48,0)	0,91 [0,71; 1,17]	0,84 [0,52; 1,35]	-4,36 [-16,15; 7,42]
0,470					
≥7	33/76 (43,4)	31/45 (68,9)	0,63 [0,46; 0,87]	0,35 [0,16; 0,75]	-25,47 [-42,99; -7,94]
0,008					
Baseline CDAI 1 (p-value of the interaction test: 0,148)					
<300	41/109 (37,6)	34/59 (57,6)	0,65 [0,47; 0,90]	0,44 [0,23; 0,85]	-20,01 [-35,56; -4,47]
0,015					
≥300	86/184 (46,7)	43/84 (51,2)	0,91 [0,70; 1,18]	0,84 [0,50; 1,40]	-4,45 [-17,34; 8,44]
0,513					

Subgruppe	Mirikizumab	Ustekinumab	Mirikizumab vs. Ustekinumab		
	Pat. mit Ereignis n/N (%)	Pat. mit Ereignis n/N (%)	RR [95% KI]	OR [95% KI]	RD [95% KI]
Baseline CDAI 2 (p-value of the interaction test: 0,199)					
<220	11/29 (37,9)	5/12 (41,7)	0,91 [0,40; 2,06]	0,86 [0,22; 3,37]	-3,74 [-36,75; 29,28]
				1,000	
≥220 and <450	110/244 (45,1)	63/119 (52,9)	0,85 [0,68; 1,06]	0,73 [0,47; 1,13]	-7,86 [-18,79; 3,07]
				0,180	
≥450	6/20 (30,0)	9/12 (75,0)	0,40 [0,19; 0,84]	0,14 [0,03; 0,72]	-45,00 [-76,68; -13,32]
				0,027	
OECD Country (p-value of the interaction test: 0,374)					
Yes	78/177 (44,1)	49/83 (59,0)	0,75 [0,58; 0,95]	0,55 [0,32; 0,93]	-14,97 [-27,83; -2,11]
				0,033	
No	52/122 (42,6)	30/62 (48,4)	0,88 [0,63; 1,22]	0,79 [0,43; 1,46]	-5,76 [-20,99; 9,46]
				0,531	
Datenschnitt: 23. August 2023; Biologic-failed Safety Population. Abkürzungen: AP: Abdominal Pain; BMI: Body-Mass-Index; CD: Crohn's Disease; CDAI: Crohn's Disease Activity Index; CRP: C-Reaktives Protein; kg: Kilogramm; KI: Konfidenzintervall; N: Anzahl der Patienten in der Analyse; OECD: Organisation for Economic Cooperation and Development; OR: Odds Ratio; RCT: randomisierte, kontrollierte Studie; RD: Risikodifferenz; ROW: Rest of the world; RR: relatives Risiko; SES: Simple Endoscopy Score; SF: Stool Frequency; SOC: System Organ Class; TNF: Tumor Necrosis Factor. Patienten mit mehrfachen Ereignissen wurden innerhalb eines Endpunkts nur einmal gezählt. RR, OR, und RD basierend auf einem unstratifizierten Mantel-Haenszel-Ansatz. 95%-KI basierend auf Wald. a: Exakter Test nach Fisher.					

Program Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/programs/tfl/primary/gba/t_effrespf_aespt_sub.sas

Output Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/output/restricted/tfl/gba/t_aespb004_sub_saft_a.rtf

Dataset Location: /lillyce/prd/ly3074828/i6t_mc_amam/intrm1/data/analysis/restricted/gba/adsl_gba, adevtae_gba

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