Clinical trial results:
A Phase 2, Randomized, Double-Blind, Dose-Ranging Study to Determine the Pharmacokinetics, Safety and Tolerability of Vedolizumab IV in Pediatric Subjects with Ulcerative Colitis or Crohn's Disease

Summary

EudraCT number	2017-002231-41
Trial protocol	GB DE BE HU NL PL FR
Global end of trial date	26 May 2020

Results information

Result version number	v1 (current)
This version publication date	11 December 2020
First version publication date	11 December 2020

Trial information

Trial identification

Sponsor protocol code	MLN0002-2003

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03138655
WHO universal trial number (UTN)	U1111-1174-2041
Other trial identifiers	Israel: MLN0002-2003CTIL, NRES: 17/NE/0257, CRS: MOH_2017-09-18_000675

Notes:

Sponsors

Sponsor organisation name	Takeda Development Centre Europe, Ltd.
Sponsor organisation address	61 Aldwych, London, United Kingdom, WC2B 4AE
Public contact	Medical Director, Clinical Science, Takeda, +1 877-825-3327, clinicaltrialregistry@tpna.com
Scientific contact	Medical Director, Clinical Science, Takeda, +1 877-825-3327, clinicaltrialregistry@tpna.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000645-PIP01-09
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	26 May 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	26 May 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of this trial was to evaluate vedolizumab pharmacokinetics (PK), safety and tolerability in pediatric participants with moderately to severely active ulcerative colitis (UC) or crohn's disease (CD).

Protection of trial subjects:

All study participants were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 November 2017
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 5
Country: Number of subjects enrolled	France: 1
Country: Number of subjects enrolled	Hungary: 17
Country: Number of subjects enrolled	Poland: 15
Country: Number of subjects enrolled	United Kingdom: 6
Country: Number of subjects enrolled	Ukraine: 2
Country: Number of subjects enrolled	Israel: 13
Country: Number of subjects enrolled	Canada: 1
Country: Number of subjects enrolled	United States: 29
Worldwide total number of subjects	89
EEA total number of subjects	44

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0

Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	46
Adolescents (12-17 years)	43
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at 72 investigative sites in United States, Belgium, Canada, France, Germany, Hungary, Israel, Netherlands, Poland, Ukraine, United Kingdom and European Union from 8 November 2017 to 26 March 2020.

Pre-assignment

Screening details:

Pediatric participants who weighed >10 kg with a diagnosis of moderately to severely active ulcerative colitis (UC) or Crohn's disease (CD) were enrolled in 1:1 ratio to receive vedolizumab low or high dose groups per weight (<30 kg and >=30 kg).

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	UC: <30 kg Participants, Vedolizumab 100 mg

Arm description:

Participants with UC having baseline weight of <30 kg were randomized to this low dose group and received vedolizumab 100 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

Arm type	Experimental
Investigational medicinal product name	Vedolizumab
Investigational medicinal product code	
Other name	MLN0002, ENTYVIO, KYNTELES
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab IV infusion.

Arm title	UC: <30 kg Participants, Vedolizumab 200 mg

Arm description:

Participants with UC having baseline weight of <30 kg were randomized to this high dose group and received vedolizumab 200 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

Arm type	Experimental
Investigational medicinal product name	Vedolizumab
Investigational medicinal product code	
Other name	MLN0002, ENTYVIO, KYNTELES
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab IV infusion.

Arm title	CD: <30 kg Participants, Vedolizumab 100 mg

Arm description:

Participants with CD having baseline weight of <30 kg were randomized to this low dose group and received vedolizumab 100 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

Arm type	Experimental

Investigational medicinal product name	Vedolizumab
Investigational medicinal product code	
Other name	MLN0002, ENTYVIO, KYNTELES
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab IV infusion.

Arm title	CD: <30 kg Participants, Vedolizumab 200 mg

Arm description:

Participants with CD having baseline weight of <30 kg were randomized to this high dose group and received vedolizumab 200 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

Arm type	Experimental
Investigational medicinal product name	Vedolizumab
Investigational medicinal product code	
Other name	MLN0002, ENTYVIO, KYNTELES
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab IV infusion.

Arm title	UC: >=30 kg Participants, Vedolizumab 150 mg

Arm description:

Participants with UC having baseline weight of >=30 kg were randomized to this low dose group and received vedolizumab 150 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

Arm type	Experimental
Investigational medicinal product name	Vedolizumab
Investigational medicinal product code	
Other name	MLN0002, ENTYVIO, KYNTELES
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab IV infusion.

Arm title	UC: >=30 kg Participants, Vedolizumab 300 mg

Arm description:

Participants with UC having baseline weight of >=30 kg were randomized to this high dose group and received vedolizumab 300 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

Arm type	Experimental
Investigational medicinal product name	Vedolizumab
Investigational medicinal product code	
Other name	MLN0002, ENTYVIO, KYNTELES
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab IV infusion.

Arm title	CD: >=30 kg Participants, Vedolizumab 150 mg

Arm description:

Participants with CD having baseline weight of >=30 kg were randomized to this low dose group and received vedolizumab 150 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

Arm type	Experimental

Investigational medicinal product name	Vedolizumab
Investigational medicinal product code	
Other name	MLN0002, ENTYVIO, KYNTELES
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab IV infusion.

Arm title	CD: >=30 kg Participants, Vedolizumab 300 mg

Arm description:

Participants with CD having baseline weight of >=30 kg were randomized to this low dose group and received vedolizumab 300 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

Arm type	Experimental
Investigational medicinal product name	Vedolizumab
Investigational medicinal product code	
Other name	MLN0002, ENTYVIO, KYNTELES
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Vedolizumab IV infusion.

Number of subjects in period 1	UC: <30 kg Participants, Vedolizumab 100 mg	UC: <30 kg Participants, Vedolizumab 200 mg	CD: <30 kg Participants, Vedolizumab 100 mg
Started	10	9	11
Completed	7	7	9
Not completed	3	2	2
Consent withdrawn by subject	-	1	-
Adverse event, non-fatal	2	1	2
Reason not Specified	1	-	-

Number of subjects in period 1	CD: <30 kg Participants, Vedolizumab 200 mg	UC: >=30 kg Participants, Vedolizumab 150 mg	UC: >=30 kg Participants, Vedolizumab 300 mg
Started	10	13	12
Completed	7	11	7
Not completed	3	2	5
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	1	1	4
Reason not Specified	2	1	1

Number of subjects in period 1	CD: >=30 kg Participants, Vedolizumab 150 mg	CD: >=30 kg Participants, Vedolizumab 300 mg
Started	12	12
Completed	9	10
Not completed	3	2

Consent withdrawn by subject	1	-
Adverse event, non-fatal	2	2
Reason not Specified	-	-

Baseline characteristics

Reporting groups	
Reporting group title	UC: <30 kg Participants, Vedolizumab 100 mg
Reporting group description:	
Participants with UC having baseline weight of <30 kg were randomized to this low dose group and received vedolizumab 100 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.	
Reporting group title	UC: <30 kg Participants, Vedolizumab 200 mg
Reporting group description:	
Participants with UC having baseline weight of <30 kg were randomized to this high dose group and received vedolizumab 200 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.	
Reporting group title	CD: <30 kg Participants, Vedolizumab 100 mg
Reporting group description:	
Participants with CD having baseline weight of <30 kg were randomized to this low dose group and received vedolizumab 100 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.	
Reporting group title	CD: <30 kg Participants, Vedolizumab 200 mg
Reporting group description:	
Participants with CD having baseline weight of <30 kg were randomized to this high dose group and received vedolizumab 200 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.	
Reporting group title	UC: >=30 kg Participants, Vedolizumab 150 mg
Reporting group description:	
Participants with UC having baseline weight of >=30 kg were randomized to this low dose group and received vedolizumab 150 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.	
Reporting group title	UC: >=30 kg Participants, Vedolizumab 300 mg
Reporting group description:	
Participants with UC having baseline weight of >=30 kg were randomized to this high dose group and received vedolizumab 300 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.	
Reporting group title	CD: >=30 kg Participants, Vedolizumab 150 mg
Reporting group description:	
Participants with CD having baseline weight of >=30 kg were randomized to this low dose group and received vedolizumab 150 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.	
Reporting group title	CD: >=30 kg Participants, Vedolizumab 300 mg
Reporting group description:	
Participants with CD having baseline weight of >=30 kg were randomized to this low dose group and received vedolizumab 300 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.	

Reporting group values	UC: <30 kg Participants, Vedolizumab 100 mg	UC: <30 kg Participants, Vedolizumab 200 mg	CD: <30 kg Participants, Vedolizumab 100 mg
Number of subjects	10	9	11
Age categorical Units: Subjects			
Children (2-11 years)	9	8	9
Adolescents (12-17 years)	1	1	2
Age Continuous Units: years			
arithmetic mean	7.0	8.0	7.4
full range (min-max)	3 to 12	2 to 12	2 to 12
Sex: Female, Male Units: participants			
Female	4	4	4
Male	6	5	7

Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	2	2
Not Hispanic or Latino	10	7	7
Unknown or Not Reported	0	0	2
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	2	1
White	7	7	7
More than one race	0	0	1
Unknown or Not Reported	2	0	2
Region of Enrollment Units: Subjects			
Belgium	1	0	0
France	0	0	1
Hungary	1	0	1
Poland	2	1	4
United Kingdom	0	0	1
Ukraine	1	1	0
Israel	3	2	0
Canada	0	0	0
United States	2	5	4
Height Units: cm			
arithmetic mean	119.59	122.39	120.58
full range (min-max)	82.7 to 146.0	84.9 to 143.0	83.5 to 146.0
Weight Units: kg			
arithmetic mean	22.38	23.23	22.06
full range (min-max)	12.8 to 29.6	10.2 to 29.8	12.0 to 29.9
Body Mass Index (BMI)			
BMI = weight (kg) / height^2 (m^2)			
Units: kg/m^2			
arithmetic mean	15.63	15.29	15.04
full range (min-max)	13.4 to 18.7	12.4 to 20.0	13.5 to 17.2

Reporting group values	CD: <30 kg Participants, Vedolizumab 200 mg	UC: >=30 kg Participants, Vedolizumab 150 mg	UC: >=30 kg Participants, Vedolizumab 300 mg
Number of subjects	10	13	12
Age categorical Units: Subjects			
Children (2-11 years)	9	4	2
Adolescents (12-17 years)	1	9	10
Age Continuous Units: years			
arithmetic mean	8.1	12.4	13.9
full range (min-max)	3 to 12	8 to 17	9 to 17

Sex: Female, Male Units: participants			
Female	5	5	6
Male	5	8	6
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2	1	1
Not Hispanic or Latino	8	12	11
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	2	0
White	9	11	10
More than one race	0	0	2
Unknown or Not Reported	1	0	0
Region of Enrollment Units: Subjects			
Belgium	0	0	1
France	0	0	0
Hungary	1	3	4
Poland	2	1	0
United Kingdom	1	1	0
Ukraine	0	0	0
Israel	2	3	2
Canada	0	0	0
United States	4	5	5
Height Units: cm			
arithmetic mean	124.67	153.11	160.03
full range (min-max)	96.5 to 137.6	128.0 to 176.1	138.3 to 185.4
Weight Units: kg			
arithmetic mean	23.37	46.22	53.98
full range (min-max)	14.3 to 30.0	30.3 to 75.9	32.0 to 78.9
Body Mass Index (BMI)			
BMI = weight (kg) / height^2 (m^2)			
Units: kg/m^2			
arithmetic mean	14.93	19.51	20.76
full range (min-max)	12.4 to 16.9	16.4 to 26.5	16.7 to 27.1

Reporting group values	CD: >=30 kg Participants, Vedolizumab 150 mg	CD: >=30 kg Participants, Vedolizumab 300 mg	Total
Number of subjects	12	12	89
Age categorical Units: Subjects			
Children (2-11 years)	3	2	46
Adolescents (12-17 years)	9	10	43

Age Continuous Units: years			
arithmetic mean	13.4	14.3	
full range (min-max)	10 to 17	11 to 17	-
Sex: Female, Male Units: participants			
Female	8	3	39
Male	4	9	50
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	0	9
Not Hispanic or Latino	11	12	78
Unknown or Not Reported	0	0	2
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	1	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	0	8
White	9	11	71
More than one race	0	0	3
Unknown or Not Reported	0	0	5
Region of Enrollment Units: Subjects			
Belgium	2	1	5
France	0	0	1
Hungary	4	3	17
Poland	2	3	15
United Kingdom	1	2	6
Ukraine	0	0	2
Israel	0	1	13
Canada	1	0	1
United States	2	2	29
Height Units: cm			
arithmetic mean	157.85	157.98	
full range (min-max)	134.3 to 182.5	141.9 to 181.5	-
Weight Units: kg			
arithmetic mean	51.53	45.89	
full range (min-max)	31.4 to 79.0	33.9 to 68.0	-
Body Mass Index (BMI)			
BMI = weight (kg) / height^2 (m^2)			
Units: kg/m^2			
arithmetic mean	20.50	18.26	
full range (min-max)	14.4 to 24.5	15.8 to 25.9	-

End points

End points reporting groups

Reporting group title	UC: <30 kg Participants, Vedolizumab 100 mg
Reporting group description:	
Participants with UC having baseline weight of <30 kg were randomized to this low dose group and received vedolizumab 100 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.	
Reporting group title	UC: <30 kg Participants, Vedolizumab 200 mg
Reporting group description:	
Participants with UC having baseline weight of <30 kg were randomized to this high dose group and received vedolizumab 200 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.	
Reporting group title	CD: <30 kg Participants, Vedolizumab 100 mg
Reporting group description:	
Participants with CD having baseline weight of <30 kg were randomized to this low dose group and received vedolizumab 100 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.	
Reporting group title	CD: <30 kg Participants, Vedolizumab 200 mg
Reporting group description:	
Participants with CD having baseline weight of <30 kg were randomized to this high dose group and received vedolizumab 200 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.	
Reporting group title	UC: >=30 kg Participants, Vedolizumab 150 mg
Reporting group description:	
Participants with UC having baseline weight of >=30 kg were randomized to this low dose group and received vedolizumab 150 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.	
Reporting group title	UC: >=30 kg Participants, Vedolizumab 300 mg
Reporting group description:	
Participants with UC having baseline weight of >=30 kg were randomized to this high dose group and received vedolizumab 300 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.	
Reporting group title	CD: >=30 kg Participants, Vedolizumab 150 mg
Reporting group description:	
Participants with CD having baseline weight of >=30 kg were randomized to this low dose group and received vedolizumab 150 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.	
Reporting group title	CD: >=30 kg Participants, Vedolizumab 300 mg
Reporting group description:	
Participants with CD having baseline weight of >=30 kg were randomized to this low dose group and received vedolizumab 300 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.	

Primary: AUCWeek 14: Area Under the Serum Concentration-time Curve at Week 14

End point title	AUCWeek 14: Area Under the Serum Concentration-time Curve at Week 14[1]
End point description:	
Pharmacokinetic (PK) Analysis Set included all participants who received at least 1 dose of study drug and had at least 1 measurable concentration of vedolizumab. Number of participants analyzed is the number of participants with data available for analyses.	
End point type	Primary
End point timeframe:	
From Day 43 (week 6) post-dose up to pre-dose Day 99 (Week 14)	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analyses data were available for this endpoint.

End point values	UC: <30 kg Participants, Vedolizumab 100 mg	UC: <30 kg Participants, Vedolizumab 200 mg	CD: <30 kg Participants, Vedolizumab 100 mg	CD: <30 kg Participants, Vedolizumab 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	7	7	8
Units: h*ng/mL				
arithmetic mean (standard deviation)	1933.5076 (± 1184.36284)	3231.1001 (± 1152.06628)	2344.4204 (± 1216.58345)	3091.7957 (± 1732.34795)

End point values	UC: >=30 kg Participants, Vedolizumab 150 mg	UC: >=30 kg Participants, Vedolizumab 300 mg	CD: >=30 kg Participants, Vedolizumab 150 mg	CD: >=30 kg Participants, Vedolizumab 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	10	9	10
Units: h*ng/mL				
arithmetic mean (standard deviation)	2449.9433 (± 772.66677)	4182.4869 (± 1751.87940)	1865.0004 (± 509.68268)	3176.6971 (± 928.32630)

Statistical analyses

No statistical analyses for this end point

Primary: Cav,Week 14: Average Serum Concentration During a Dosing Interval at Week 14

End point title	Cav,Week 14: Average Serum Concentration During a Dosing Interval at Week 14[2]

End point description:

PK Analysis Set included all participants who received at least 1 dose of study drug and had at least 1 measurable concentration of vedolizumab. Number of participants analyzed is the number of participants with data available for analyses.

End point type	Primary

End point timeframe:

From Day 43 (week 6) post-dose up to pre-dose Day 99 (Week 14)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analyses data were available for this endpoint.

End point values	UC: <30 kg Participants, Vedolizumab 100 mg	UC: <30 kg Participants, Vedolizumab 200 mg	CD: <30 kg Participants, Vedolizumab 100 mg	CD: <30 kg Participants, Vedolizumab 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	8	7	8
Units: ng/mL				
arithmetic mean (standard deviation)	39.3143 (± 21.34097)	61.2934 (± 18.14446)	46.8716 (± 23.07334)	63.6275 (± 28.29116)

End point values	UC: >=30 kg Participants, Vedolizumab 150 mg	UC: >=30 kg Participants, Vedolizumab 300 mg	CD: >=30 kg Participants, Vedolizumab 150 mg	CD: >=30 kg Participants, Vedolizumab 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	10	9	10
Units: ng/mL				
arithmetic mean (standard deviation)	44.6465 (± 11.48500)	77.2452 (± 28.49511)	37.4752 (± 18.26528)	63.1734 (± 15.08119)

Statistical analyses

No statistical analyses for this end point

Primary: Ctrough,Week 14: Observed Serum Concentration at the end of a Dosing Interval at Week 14

End point title	Ctrough,Week 14: Observed Serum Concentration at the end of a Dosing Interval at Week 14[3]

End point description:

PK Analysis Set included all participants who received at least 1 dose of study drug and had at least 1 measurable concentration of vedolizumab. Number of participants analyzed is the number of participants with data available for analyses.

End point type	Primary

End point timeframe:

At the end of a dosing interval at Week 14

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analyses data were available for this endpoint.

End point values	UC: <30 kg Participants, Vedolizumab 100 mg	UC: <30 kg Participants, Vedolizumab 200 mg	CD: <30 kg Participants, Vedolizumab 100 mg	CD: <30 kg Participants, Vedolizumab 200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	7	8	8
Units: ng/mL				
arithmetic mean (standard deviation)	9.3100 (± 9.48045)	10.7226 (± 10.35423)	8.7395 (± 7.77386)	10.3685 (± 11.30124)

End point values	UC: >=30 kg Participants, Vedolizumab 150 mg	UC: >=30 kg Participants, Vedolizumab 300 mg	CD: >=30 kg Participants, Vedolizumab 150 mg	CD: >=30 kg Participants, Vedolizumab 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	10	10	10
Units: ng/mL				
arithmetic mean (standard deviation)	16.3645 (±	21.4860 (±	3.9006 (±	7.8310 (±

16.93869)	18.01872)	3.62991)	9.44044)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of UC Participants who Achieve Clinical Response Based on Complete Mayo Score

End point title	Percentage of UC Participants who Achieve Clinical Response Based on Complete Mayo Score[4]

End point description:

Clinical response was defined as a reduction in complete Mayo score of >= 3 points and >=30 % from Baseline with an accompanying decrease in rectal bleeding sub-score of >=1 point(s) or absolute rectal bleeding sub-score of <= 1 point. Mayo score was used in to assess UC disease activity. It consisted of 4 subscales: stool frequency, rectal bleeding, findings on endoscopy and physician's global assessment. Each subscale was scored on a scale of 0 to 3, where 0= normal condition and 3 = severe disease condition. The total Mayo score ranged from 0 to 12, with higher scores indicating more severe disease. Full Analysis Set (FAS) included all randomized participants who received at least 1 dose of study drug. Number of participants analyzed is the number of participants with data available for analyses.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 14

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Data is reported by dose in this endpoint.

End point values	UC: <30 kg Participants, Vedolizumab 100 mg	UC: <30 kg Participants, Vedolizumab 200 mg	UC: >=30 kg Participants, Vedolizumab 150 mg	UC: >=30 kg Participants, Vedolizumab 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	9	13	12
Units: percentage of participants				
number (confidence interval 95%)	40.0 (12.2 to 73.8)	66.7 (29.9 to 92.5)	69.2 (38.6 to 90.9)	41.7 (15.2 to 72.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of CD Participants who Achieve Clinical Response Based on Crohn's Disease Activity Index (CDAI)

End point title	Percentage of CD Participants who Achieve Clinical Response Based on Crohn's Disease Activity Index (CDAI)[5]

End point description:

Clinical response was defined as >=70 points decrease from Baseline in CDAI score at Week 14. The CDAI evaluated severity of signs and symptoms of CD. Information was collected on number of liquid stools, intensity of abdominal pain, general well-being, presence of comorbid conditions, use of medications for diarrhea, physical examination, and laboratory, yielding 8 items that were combined

with data from a 7-day diary to obtain total CDAI score. Index values of 150 and below were associated with quiescent disease; values above that indicated active disease, values >=220 indicated moderate to severe disease, and values above 450 were seen with extremely severe disease. FAS included all randomized participants who received at least 1 dose of study drug. Number of participants analyzed is the number of participants with data available for analyses.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 14

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data is reported by dose in this endpoint.

End point values	CD: <30 kg Participants, Vedolizumab 100 mg	CD: <30 kg Participants, Vedolizumab 200 mg	CD: >=30 kg Participants, Vedolizumab 150 mg	CD: >=30 kg Participants, Vedolizumab 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	10	11	12
Units: percentage of participants				
number (confidence interval 95%)	63.6 (30.8 to 89.1)	40.0 (12.2 to 73.8)	45.5 (16.7 to 76.6)	33.3 (9.9 to 65.1)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of study drug up to Week 32

Adverse event reporting additional description:

At each visit investigator had to document any occurrence of AEs and abnormal laboratory findings.Any event spontaneously reported by participant or observed by investigator was recorded, irrespective of relation to study treatment.Safety Analysis Set:all participants who received >=1 dose of study drug.MedDRA v22.0: >30kg group;v23.0:<30kg group).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0 23.0

Reporting groups

Reporting group title	<30 kg Participants, Vedolizumab 200 mg

Reporting group description:

Participants with UC or CD having baseline weight of <30 kg, were randomized to this high dose group and received vedolizumab 200 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

Reporting group title	<30 kg Participants, Vedolizumab 100 mg

Reporting group description:

Participants with UC or CD having baseline weight of <30 kg, were randomized to this low dose group and received vedolizumab 100 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

Reporting group title	>=30 kg Participants, Vedolizumab 300 mg

Reporting group description:

Participants with UC or CD having baseline weight of >=30 kg, were randomized to this low dose group and received vedolizumab 300 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

Reporting group title	<30 kg Participants, Vedolizumab 100 mg to 200 mg

Reporting group description:

Participants from '<30 kg Participants, Vedolizumab 100 mg' low dose group who did not achieve Clinical Response at Week 14 were escalated to receive vedolizumab 200 mg IV infusion at Week 14.

Reporting group title	>=30 kg Participants, Vedolizumab 150 mg

Reporting group description:

Participants with UC or CD having baseline weight of >=30 kg, were randomized to this low dose group and received vedolizumab 150 mg IV infusion on Day 1 and at Weeks 2, 6 and 14.

Reporting group title	>=30 kg Participants, Vedolizumab 150 mg to 300 mg

Reporting group description:

Participants from '>=30 kg Participants, Vedolizumab 150 mg' low dose group who did not achieve Clinical Response at Week 14 were escalated to receive vedolizumab 300 mg IV infusion at Week 14.

Serious adverse events	<30 kg Participants, Vedolizumab 200 mg	<30 kg Participants, Vedolizumab 100 mg	>=30 kg Participants, Vedolizumab 300 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 19 (31.58%)	4 / 17 (23.53%)	8 / 24 (33.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			

Procedural intestinal perforation			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma site inflammation			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	2 / 19 (10.53%)	0 / 17 (0.00%)	3 / 24 (12.50%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	3 / 19 (15.79%)	0 / 17 (0.00%)	2 / 24 (8.33%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal obstruction			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Small intestinal obstruction			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Pleural mass			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Clostridium difficile infection			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter sepsis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic abscess			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Malnutrition			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	<30 kg Participants, Vedolizumab 100 mg to 200 mg	>=30 kg Participants, Vedolizumab 150 mg	>=30 kg Participants, Vedolizumab 150 mg to 300 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	2 / 18 (11.11%)	1 / 6 (16.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Procedural intestinal perforation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma site inflammation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue			

disorders			
Pleural mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Clostridium difficile infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Staphylococcal sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Malnutrition			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	1 / 4 (25.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 4 %

Non-serious adverse events	<30 kg Participants, Vedolizumab 200 mg	<30 kg Participants, Vedolizumab 100 mg	>=30 kg Participants, Vedolizumab 300 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 19 (68.42%)	16 / 17 (94.12%)	20 / 24 (83.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Hot flush			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Pallor			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	1	0

Haematoma			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 19 (10.53%)	1 / 17 (5.88%)	3 / 24 (12.50%)
occurrences (all)	3	1	9
Face oedema			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Infusion site irritation			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Asthenia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Hypersensitivity			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Seasonal allergy			

subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Menstruation delayed			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Vulvovaginal pruritus			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Vulvovaginal swelling			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	3 / 19 (15.79%)	1 / 17 (5.88%)	1 / 24 (4.17%)
occurrences (all)	3	1	1
Cough			
subjects affected / exposed	2 / 19 (10.53%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	2	0	1
Rhinorrhoea			
subjects affected / exposed	1 / 19 (5.26%)	1 / 17 (5.88%)	1 / 24 (4.17%)
occurrences (all)	1	1	1
Nasal congestion			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Tonsillar hypertrophy			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Upper-airway cough syndrome			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Asthma			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			

subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Anxiety			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Fear of injection			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Investigations			
C-reactive protein increased			
subjects affected / exposed	1 / 19 (5.26%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
Blood albumin decreased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	1 / 24 (4.17%)
occurrences (all)	0	1	1
Blood bicarbonate decreased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Blood glucose increased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Body temperature increased			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	3	0	0
Clostridium test positive			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Haematocrit decreased			

subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Haemoglobin decreased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	2 / 24 (8.33%)
occurrences (all)	0	1	3
Weight decreased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Liver function test increased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Red blood cell count decreased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Torus fracture			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Arthropod bite			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Joint injury			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Procedural dizziness			

subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 19 (10.53%)	1 / 17 (5.88%)	3 / 24 (12.50%)
occurrences (all)	2	2	4
Dizziness			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 19 (15.79%)	1 / 17 (5.88%)	1 / 24 (4.17%)
occurrences (all)	3	1	2
Lymphopenia			
subjects affected / exposed	1 / 19 (5.26%)	1 / 17 (5.88%)	2 / 24 (8.33%)
occurrences (all)	1	1	3
Microcytic anaemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Swelling of eyelid			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Eye swelling			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	3 / 19 (15.79%)	5 / 17 (29.41%)	1 / 24 (4.17%)
occurrences (all)	3	8	2
Vomiting			
subjects affected / exposed	1 / 19 (5.26%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	1	4	0
Crohn's disease			
subjects affected / exposed	1 / 19 (5.26%)	2 / 17 (11.76%)	2 / 24 (8.33%)
occurrences (all)	1	2	2
Abdominal distension			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Abdominal rigidity			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Abdominal tenderness			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Abnormal faeces			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Anal fistula			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Chapped lips			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Colitis ulcerative			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	1 / 24 (4.17%)
occurrences (all)	0	1	1

Gastritis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Lip swelling			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Nausea			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Abdominal pain upper			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Gastrointestinal inflammation			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Gastrointestinal obstruction			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Haemorrhoids			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Nail bed inflammation			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Rash pruritic			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Skin lesion			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
Eczema			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Miliaria			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Night sweats			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Psoriasis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Skin exfoliation			

subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Erythema nodosum			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Acute kidney injury			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	4
Proteinuria			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Endocrine disorders			
Cushingoid			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Secondary adrenocortical insufficiency			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 19 (0.00%)	2 / 17 (11.76%)	2 / 24 (8.33%)
occurrences (all)	0	2	2
Back pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Myalgia			

subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 19 (5.26%)	1 / 17 (5.88%)	1 / 24 (4.17%)
occurrences (all)	1	1	1
Fistula discharge			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Joint swelling			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
Respiratory tract infection viral			
subjects affected / exposed	1 / 19 (5.26%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 19 (5.26%)	1 / 17 (5.88%)	1 / 24 (4.17%)
occurrences (all)	1	2	1
Viral infection			
subjects affected / exposed	1 / 19 (5.26%)	1 / 17 (5.88%)	2 / 24 (8.33%)
occurrences (all)	1	1	2
Bronchitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Ear infection			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Hordeolum			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0

Nasopharyngitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	2 / 24 (8.33%)
occurrences (all)	1	0	2
Pharyngitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 17 (0.00%)	3 / 24 (12.50%)
occurrences (all)	1	0	4
Pneumonia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 17 (5.88%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Pharyngitis streptococcal			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Fungal skin infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal candidiasis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Gastrointestinal infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Infected bite			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1

Molluscum contagiosum			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Otitis externa			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Peritonitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Salmonellosis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Weight gain poor			
subjects affected / exposed	0 / 19 (0.00%)	0 / 17 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1

Non-serious adverse events	<30 kg Participants, Vedolizumab 100 mg to 200 mg	>=30 kg Participants, Vedolizumab 150 mg	>=30 kg Participants, Vedolizumab 150 mg to 300 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	15 / 18 (83.33%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			

subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pallor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Face oedema			
subjects affected / exposed	1 / 4 (25.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infusion site irritation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Menstruation delayed			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Rhinorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tonsillar hypertrophy			

subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fear of injection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
C-reactive protein increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood bicarbonate decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Clostridium test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematocrit decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Haemoglobin decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Weight decreased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Amylase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Red blood cell count decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood calcium decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Torus fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			

subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	1 / 4 (25.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Limb injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Procedural dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 4 (0.00%)	2 / 18 (11.11%)	2 / 6 (33.33%)
occurrences (all)	0	2	2
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Microcytic anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Eye disorders			

Swelling of eyelid			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye swelling			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Ocular hyperaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	2 / 4 (50.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	3	1	0
Crohn's disease			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Abdominal distension			
subjects affected / exposed	1 / 4 (25.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Diarrhoea			
subjects affected / exposed	2 / 4 (50.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Abdominal rigidity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abnormal faeces			
subjects affected / exposed	1 / 4 (25.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Anal fissure			

subjects affected / exposed	1 / 4 (25.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Anal fistula			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chapped lips			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Colitis ulcerative			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lip swelling			
subjects affected / exposed	1 / 4 (25.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Melaena			
subjects affected / exposed	1 / 4 (25.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Mouth ulceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Rectal haemorrhage			
subjects affected / exposed	1 / 4 (25.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal inflammation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Glossodynia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Haemorrhoids			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Nail bed inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

Miliaria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Erythema nodosum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cushingoid			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Secondary adrenocortical insufficiency			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Costochondritis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fistula discharge			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Respiratory tract infection viral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Viral infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	2 / 18 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Ear infection			

subjects affected / exposed	0 / 4 (0.00%)	3 / 18 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Influenza			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Pharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pharyngitis streptococcal			
subjects affected / exposed	0 / 4 (0.00%)	2 / 18 (11.11%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Clostridium difficile infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Gastrointestinal candidiasis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Herpes zoster			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infected bite			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Molluscum contagiosum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Peritonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Salmonellosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 4 (25.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Iron deficiency			
subjects affected / exposed	0 / 4 (0.00%)	1 / 18 (5.56%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 18 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1

Weight gain poor subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 18 (0.00%) 0	0 / 6 (0.00%) 0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 April 2017	Amendment 1: The primary purpose of this amendment was to make following changes. • Updated administrative details • Updated exposure information • Updated to allow enrollment of of pediatric participants who weigh <30 kg
17 January 2018	Amendment 3: The primary purpose of this amendment was to make following changes. • Amended references to Study Vedolizumab-2005 to include blinded dosing • Specified that tumor necrotsis factor (TNF)-α antagonists may not be administered after participant consents to participate • Defined chronic nonsteroidal anti-inflammatory drug use • Amended the concomitant oral corticosteroid dosing information. • Added specific details regarding provision of study drug and associated supplies. • Specified that the erythrocyte sedimentation rate may be performed at a local laboratory • Removed urinalysis • Removed electrocardiogram assessments • Amended pharmacokinetic sample collection information • Amended immunogenicity sample information • Deleted pharmacogenomics assessment • Specified that no endoscopy is required if a subject withdraws before Week 6 • Amended the interim analyses information • Updated the protocol deviation information

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported