

**Clinical trial results:****A Phase 2, Multicenter, Randomized, Parallel-Arm, Placebo- Controlled Study of LY3074828 in Subjects with Active Crohn's Disease (SERENITY)****Summary**

EudraCT number	2016-002204-84
Trial protocol	GB CZ HU AT NL PL BE
Global end of trial date	05 February 2021

Results information

Result version number	v2 (current)
This version publication date	15 September 2022
First version publication date	18 February 2022
Version creation reason	<ul style="list-style-type: none">• Correction of full data set resolving 2 advisory ct.gov comments and update EU record for same changes (Adjusting risk numbers for gender specific events in AE section and updating estimation parameter of statistical analysis for outcomes 4, 6, 7 and 8).

Trial information**Trial identification**

Sponsor protocol code	I6T-MC-AMAG
-----------------------	-------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02891226
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 16492

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877CTLilly,
Scientific contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 8772854559,

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	05 February 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	05 February 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate the safety and effectiveness of the study drug Mirikizumab in participants with active Crohn's Disease.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 December 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 4
Country: Number of subjects enrolled	Belgium: 6
Country: Number of subjects enrolled	Czechia: 10
Country: Number of subjects enrolled	Hungary: 7
Country: Number of subjects enrolled	Japan: 18
Country: Number of subjects enrolled	Netherlands: 7
Country: Number of subjects enrolled	Poland: 24
Country: Number of subjects enrolled	Romania: 5
Country: Number of subjects enrolled	Russian Federation: 14
Country: Number of subjects enrolled	Ukraine: 19
Country: Number of subjects enrolled	United Kingdom: 1
Country: Number of subjects enrolled	United States: 76
Worldwide total number of subjects	191
EEA total number of subjects	59

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)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	184
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment additional details: From Study treatment, 5 participants entered into follow-up period at week 52 and 3 participants entered the follow-up period in period 3 and they were followed up for safety and these 3 participants voluntarily discontinued from the follow-up period.

Pre-assignment

Screening details:

Not Applicable.

Period 1

Period 1 title	Period 1 (Weeks 0 to 12)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
------------------------------	-----

Arm title	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W)
------------------	--

Arm description:

Participants received placebo administered intravenously (IV) Q4W.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received placebo administered IV Q4W.

Arm title	Period 1: 200 milligram (mg) Mirikizumab IV Q4W
------------------	---

Arm description:

Participants received 200 mg mirikizumab administered IV Q4W.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	LY3074828
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received 200 mg mirikizumab administered IV Q4W.

Arm title	Period 1: 600 mg Mirikizumab IV Q4W
------------------	-------------------------------------

Arm description:

Participants received 600 mg mirikizumab administered IV Q4W.

Arm type	Experimental
----------	--------------

Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	LY3074828
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received 600 mg mirikizumab administered IV Q4W.

Arm title	Period 1: 1000 mg Mirikizumab IV Q4W
------------------	--------------------------------------

Arm description:

Participants received 1000 mg mirikizumab administered IV Q4W.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	LY3074828
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received 1000 mg mirikizumab administered IV Q4W.

Number of subjects in period 1	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W)	Period 1: 200 milligram (mg) Mirikizumab IV Q4W	Period 1: 600 mg Mirikizumab IV Q4W
Started	64	31	32
Received at least 1 Dose of Study Drug	64	31	32
Completed	59	29	28
Not completed	5	2	4
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	4	1	3
Enrollment Failure	-	-	1
Sponsor Decision	-	-	-
Lost to follow-up	1	1	-
Lack of efficacy	-	-	-

Number of subjects in period 1	Period 1: 1000 mg Mirikizumab IV Q4W
Started	64
Received at least 1 Dose of Study Drug	64
Completed	60
Not completed	4
Consent withdrawn by subject	1
Adverse event, non-fatal	-
Enrollment Failure	-
Sponsor Decision	1
Lost to follow-up	-

Lack of efficacy	2
------------------	---

Period 2	
Period 2 title	Period 2 (Weeks 12 to 52)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator
Arms	
Are arms mutually exclusive?	Yes
Arm title	Period 2: 200 mg Mirikizumab IV Q4W
Arm description: Participants received 200 mg mirikizumab administered IV Q4W. Participants improved on the same mirikizumab dose in Period 1.	
Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	LY3074828
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use
Dosage and administration details: Participants received 200 mg mirikizumab administered IV Q4W.	
Arm title	Period 2: 600 mg Mirikizumab IV Q4W
Arm description: Participants received 600 mg mirikizumab administered IV Q4W. Participants improved on the same mirikizumab dose in Period 1.	
Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	LY3074828
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use
Dosage and administration details: Participants received 600 mg mirikizumab administered IV Q4W.	
Arm title	Period 2: 1000 mg Mirikizumab IV Q4W
Arm description: Participants received 1000 mg mirikizumab administered IV Q4W. Participants improved on the same mirikizumab dose in Period 1.	
Arm type	Experimental

Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	LY3074828
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received 1000 mg mirikizumab administered IV Q4W. Group does not include participants who did not improve on mirikizumab in period 1 or who were on placebo in period 1.

Arm title	Period 2: 300mg Mirikizumab Subcutaneous (SC) Q4W
------------------	---

Arm description:

Participants received 300 mg mirikizumab administered SC Q4W. Participants improved on any mirikizumab dose in Period 1.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	LY3074828
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 300 mg mirikizumab administered SC Q4W.

Arm title	Period 2:1000 mg Mirikizumab IV Q4W(No Improvement in Period1)
------------------	--

Arm description:

Participants who did not improve in period 1 on mirikizumab received 1000 mg mirikizumab administered IV Q4W.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	LY3074828
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants who did not improve in period 1 on mirikizumab received 1000 mg mirikizumab administered IV Q4W.

Arm title	Period 2: 1000 mg Mirikizumab IV Q4W (Placebo in Period 1)
------------------	--

Arm description:

Participants who received placebo in period 1 received 1000 mg mirikizumab administered IV Q4W.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	LY3074828
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants who received placebo in period 1 received 1000 mg mirikizumab administered IV Q4W.

Number of subjects in period 2	Period 2: 200 mg Mirikizumab IV Q4W	Period 2: 600 mg Mirikizumab IV Q4W	Period 2: 1000 mg Mirikizumab IV Q4W
Started	9	9	23
Completed	8	8	20
Not completed	1	1	3
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	-	-	1
Adverse event, non-fatal	-	-	-
Endoscopic Procedure was not Evaluated	-	-	-
PI and Sponsor Decision due to Subject Safety	-	-	1
Lack of Efficacy and Withdrew from Study	-	-	-
Sponsor Decision	-	-	-
Lost to follow-up	-	1	-
PI decision due to Lack of Efficacy	1	-	-
Lack of efficacy	-	-	-

Number of subjects in period 2	Period 2: 300mg Mirikizumab Subcutaneous (SC) Q4W	Period 2:1000 mg Mirikizumab IV Q4W(No Improvement in	Period 2: 1000 mg Mirikizumab IV Q4W (Placebo in Period 1)
Started	46	30	59
Completed	41	24	42
Not completed	5	6	17
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	2	1	6
Adverse event, non-fatal	1	3	7
Endoscopic Procedure was not Evaluated	-	1	-
PI and Sponsor Decision due to Subject Safety	-	-	-
Lack of Efficacy and Withdrew from Study	-	-	1
Sponsor Decision	-	-	1
Lost to follow-up	-	-	1
PI decision due to Lack of Efficacy	-	-	-
Lack of efficacy	2	1	1

Period 3

Period 3 title	Period 3 (Weeks 52 to 208)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Period 3: 300 mg Mirikizumab SC Q4W
Arm description: Participants received 300 mg mirikizumab administered SC Q4W.	
Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	LY3074828
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 300 mg mirikizumab administered SC Q4W.

Number of subjects in period 3^[1]	Period 3: 300 mg Mirikizumab SC Q4W
Started	137
Completed	0
Not completed	137
Consent withdrawn by subject	14
Non-Compliance With Study Visit Schedule	2
Not Participated in Extension Period (Week 104-208)	2
Adverse event, non-fatal	5
PI Decision as Subject Non response to Study Drug	2
Roll over to AMAX	108
Lost to follow-up	1
Lack of efficacy	3

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Participants were assigned to this arm during period 3.

Baseline characteristics

Reporting groups

Reporting group title	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W)
Reporting group description: Participants received placebo administered intravenously (IV) Q4W.	
Reporting group title	Period 1: 200 milligram (mg) Mirikizumab IV Q4W
Reporting group description: Participants received 200 mg mirikizumab administered IV Q4W.	
Reporting group title	Period 1: 600 mg Mirikizumab IV Q4W
Reporting group description: Participants received 600 mg mirikizumab administered IV Q4W.	
Reporting group title	Period 1: 1000 mg Mirikizumab IV Q4W
Reporting group description: Participants received 1000 mg mirikizumab administered IV Q4W.	

Reporting group values	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W)	Period 1: 200 milligram (mg) Mirikizumab IV Q4W	Period 1: 600 mg Mirikizumab IV Q4W
Number of subjects	64	31	32
Age categorical Units: Subjects			

Age continuous			
All randomized participants.			
Units: years arithmetic mean standard deviation	39.00 ± 13.04	38.10 ± 11.80	40.40 ± 13.33
Gender categorical			
All randomized participants.			
Units: Subjects			
Female	36	14	18
Male	28	17	14
Ethnicity (NIH/OMB)			
All randomized participants.			
Units: Subjects			
Hispanic or Latino	4	0	2
Not Hispanic or Latino	53	27	26
Unknown or Not Reported	7	4	4
Race (NIH/OMB)			
All randomized participants.			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	7	1	4
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	2	3
White	55	28	24
More than one race	0	0	1

Unknown or Not Reported	0	0	0
Region of Enrollment			
All randomized participants.			
Units: Subjects			
Australia	3	0	0
Belgium	0	1	1
Czechia	4	1	0
Hungary	3	1	0
Japan	6	1	4
Netherlands	2	3	0
Poland	6	6	3
Romania	0	0	1
Russia	6	3	2
Ukraine	4	5	4
United Kingdom	1	0	0
United States	29	10	17

Reporting group values	Period 1: 1000 mg Mirikizumab IV Q4W	Total	
Number of subjects	64	191	
Age categorical			
Units: Subjects			

Age continuous			
All randomized participants.			
Units: years			
arithmetic mean	37.70		
standard deviation	± 13.11	-	

Gender categorical			
All randomized participants.			
Units: Subjects			
Female	30	98	
Male	34	93	

Ethnicity (NIH/OMB)			
All randomized participants.			
Units: Subjects			
Hispanic or Latino	2	8	
Not Hispanic or Latino	54	160	
Unknown or Not Reported	8	23	

Race (NIH/OMB)			
All randomized participants.			
Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	8	20	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	4	11	
White	52	159	
More than one race	0	1	
Unknown or Not Reported	0	0	

Region of Enrollment			
All randomized participants.			

Units: Subjects			
Australia	1	4	
Belgium	4	6	
Czechia	5	10	
Hungary	3	7	
Japan	7	18	
Netherlands	2	7	
Poland	9	24	
Romania	4	5	
Russia	3	14	
Ukraine	6	19	
United Kingdom	0	1	
United States	20	76	

End points

End points reporting groups

Reporting group title	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W)
Reporting group description: Participants received placebo administered intravenously (IV) Q4W.	
Reporting group title	Period 1: 200 milligram (mg) Mirikizumab IV Q4W
Reporting group description: Participants received 200 mg mirikizumab administered IV Q4W.	
Reporting group title	Period 1: 600 mg Mirikizumab IV Q4W
Reporting group description: Participants received 600 mg mirikizumab administered IV Q4W.	
Reporting group title	Period 1: 1000 mg Mirikizumab IV Q4W
Reporting group description: Participants received 1000 mg mirikizumab administered IV Q4W.	
Reporting group title	Period 2: 200 mg Mirikizumab IV Q4W
Reporting group description: Participants received 200 mg mirikizumab administered IV Q4W. Participants improved on the same mirikizumab dose in Period 1.	
Reporting group title	Period 2: 600 mg Mirikizumab IV Q4W
Reporting group description: Participants received 600 mg mirikizumab administered IV Q4W. Participants improved on the same mirikizumab dose in Period 1.	
Reporting group title	Period 2: 1000 mg Mirikizumab IV Q4W
Reporting group description: Participants received 1000 mg mirikizumab administered IV Q4W. Participants improved on the same mirikizumab dose in Period 1.	
Reporting group title	Period 2: 300mg Mirikizumab Subcutaneous (SC) Q4W
Reporting group description: Participants received 300 mg mirikizumab administered SC Q4W. Participants improved on any mirikizumab dose in Period 1.	
Reporting group title	Period 2:1000 mg Mirikizumab IV Q4W(No Improvement in Period1)
Reporting group description: Participants who did not improve in period 1 on mirikizumab received 1000 mg mirikizumab administered IV Q4W.	
Reporting group title	Period 2: 1000 mg Mirkizumab IV Q4W (Placebo in Period 1)
Reporting group description: Participants who received placebo in period 1 received 1000 mg mirikizumab administered IV Q4W.	
Reporting group title	Period 3: 300 mg Mirikizumab SC Q4W
Reporting group description: Participants received 300 mg mirikizumab administered SC Q4W.	
Subject analysis set title	Mirikizumab IV Q4W
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants received 200 mg, 600 mg, 1000 mg mirikizumab administered IV Q4W.	

Primary: Percentage of Participants Achieving Endoscopic Response at Week 12

End point title	Percentage of Participants Achieving Endoscopic Response at Week 12
End point description: Endoscopic response defined as $\geq 50\%$ reduction from baseline in Simple Endoscopic Score for Crohn's Disease (SES-CD) at Week 12. The SES-CD evaluates 4 endoscopic variables: presence and size of	

ulcers, proportion of surface covered by ulcers, proportion of surface affected by disease, and presence and severity of stenosis. The total SES-CD calculated as sum of 4 variables for 5 bowel segments: (ileum;right,transverse,and left colon;and rectum): presence and size of ulcers (none = score 0; diameter 0.1-0.5 cm = score 1; 0.5-2 cm = score 2; >2 cm = score 3); extent of ulcerated surface (none = 0; <10% = 1;10-30% = 2;>30% = 3);extent of affected surface (none = 0; <50% = 1;50-75% = 2;>75% =3); and presence and type of narrowings (none=0; single, can be passed=1; multiple,can be passed=2; cannot be passed=3). Total SES-CD scores range from 0 to 56, with higher scores indicating more severe disease.

End point type	Primary
End point timeframe:	
Week 12	

End point values	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W)	Period 1: 200 milligram (mg) Mirikizumab IV Q4W	Period 1: 600 mg Mirikizumab IV Q4W	Period 1: 1000 mg Mirikizumab IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64 ^[1]	31 ^[2]	32 ^[3]	64 ^[4]
Units: percentage of participants				
number (confidence interval 90%)	10.9 (4.5 to 17.4)	25.8 (12.9 to 38.7)	37.5 (23.4 to 51.6)	43.8 (33.6 to 53.9)

Notes:

- [1] - All randomized participants.
- [2] - All randomized participants.
- [3] - All randomized participants.
- [4] - All randomized participants.

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 200 milligram (mg) Mirikizumab IV Q4W
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.079
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.75
Confidence interval	
level	90 %
sides	2-sided
lower limit	1.07
upper limit	7.08

Statistical analysis title	Statistical analysis 2
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 600 mg Mirikizumab IV Q4W

Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.92
Confidence interval	
level	90 %
sides	2-sided
lower limit	2.01
upper limit	12.07

Statistical analysis title	Statistical analysis 3
Comparison groups	Period 1: 1000 mg Mirikizumab IV Q4W v Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W)
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	6.14
Confidence interval	
level	90 %
sides	2-sided
lower limit	2.81
upper limit	13.42

Secondary: Percentage of Participants Achieving Endoscopic Remission at Week 12

End point title	Percentage of Participants Achieving Endoscopic Remission at Week 12
End point description:	
<p>Endoscopic remission defined as SES-CD of <4 ileal-colonic or <2 for isolated ileal disease, and no subscore >1 at week 12. The SES-CD evaluates 4 endoscopic variables: presence and size of ulcers, proportion of surface covered by ulcers, proportion of surface affected by disease, and presence and severity of stenosis. The total SES-CD is calculated as the sum of the 4 variables for the 5 bowel segments: (ileum; right, transverse, and left colon; and rectum): presence and size of ulcers (none = score 0; diameter 0.1-0.5 cm = score 1; 0.5-2 cm = score 2; greater than (>) 2 cm = score 3); extent of ulcerated surface (none = 0; less than (<) 10% = 1; 10-30% = 2; >30% = 3); extent of affected surface (none = 0; <50% = 1; 50-75% = 2; >75% = 3); and presence and type of narrowings (none=0; single, can be passed=1; multiple, can be passed=2; cannot be passed=3). Total SES-CD scores range from 0 to 56, with higher scores indicating more severe disease.</p>	
End point type	Secondary
End point timeframe:	
Week 12	

End point values	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W)	Period 1: 200 milligram (mg) Mirikizumab IV Q4W	Period 1: 600 mg Mirikizumab IV Q4W	Period 1: 1000 mg Mirikizumab IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64 ^[5]	31 ^[6]	32 ^[7]	64 ^[8]
Units: percentage of participants				
number (confidence interval 90%)	1.6 (0.0 to 4.1)	6.5 (0.0 to 13.7)	15.6 (5.1 to 26.2)	20.3 (12.0 to 28.6)

Notes:

[5] - All randomized participants.

[6] - All randomized participants.

[7] - All randomized participants.

[8] - All randomized participants.

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 200 milligram (mg) Mirikizumab IV Q4W
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.241
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.31
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.55
upper limit	33.58

Statistical analysis title	Statistical analysis 2
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 600 mg Mirikizumab IV Q4W
Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.032
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	11.16
Confidence interval	
level	90 %
sides	2-sided
lower limit	1.76
upper limit	70.64

Statistical analysis title	Statistical analysis 3
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 1000 mg Mirikizumab IV Q4W
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.009
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	16.04
Confidence interval	
level	90 %
sides	2-sided
lower limit	2.82
upper limit	91.32

Secondary: Percentage of Participants Achieving Patient Reported Outcome Remission at Week 12

End point title	Percentage of Participants Achieving Patient Reported Outcome Remission at Week 12
End point description:	PRO remission is defined as stool frequency (SF) ≤ 2.5 and abdominal pain (AP) ≤ 1 and no worse than baseline at week 12. SF captures the number of liquid or very soft stools. AP score is classified as 0=none, 1=mild, 2=moderate, 3=severe.
End point type	Secondary
End point timeframe:	Week 12

End point values	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W)	Period 1: 200 milligram (mg) Mirikizumab IV Q4W	Period 1: 600 mg Mirikizumab IV Q4W	Period 1: 1000 mg Mirikizumab IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	64 ^[9]	31 ^[10]	32 ^[11]	64 ^[12]
Units: percentage of participants				
number (confidence interval 90%)	6.3 (1.3 to 11.2)	12.9 (3.0 to 22.8)	28.1 (15.1 to 41.2)	21.9 (13.4 to 30.4)

Notes:

- [9] - All randomized participants.
- [10] - All randomized participants.
- [11] - All randomized participants.
- [12] - All randomized participants.

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 200 milligram (mg) Mirikizumab IV Q4W
Number of subjects included in analysis	95
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.33
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.62
upper limit	6.45

Statistical analysis title	Statistical analysis 2
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 600 mg Mirikizumab IV Q4W
Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	5.72
Confidence interval	
level	90 %
sides	2-sided
lower limit	2.02
upper limit	16.21

Statistical analysis title	Statistical analysis 3
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 1000 mg Mirikizumab IV Q4W
Number of subjects included in analysis	128
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.029
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.52
Confidence interval	
level	90 %
sides	2-sided
lower limit	1.37
upper limit	9.07

Secondary: Mean Change From Baseline on the Patient Global Rating – Severity (PGRS) Crohn’s Disease Score at Week 12

End point title	Mean Change From Baseline on the Patient Global Rating – Severity (PGRS) Crohn’s Disease Score at Week 12
End point description:	The PGRS is a 1-item patient-rated questionnaire designed to assess the participant's rating of their disease symptom severity over the past 24 hours. Responses are graded on a 6-point scale in which a score of 1 indicates the subject has no symptoms (that is, "none") and a score of 6 indicates that the participant's symptom are "very severe." Least Squares Mean (LS Mean) was calculated using Mixed Model for Repeated Measures (MMRM) model with treatment, geographic region, geographic region, prior biologic CD therapy use (prior biologic experience versus prior biologic naive), baseline score, visit, and the interaction of treatment-by-visit and baseline-by-visit as fixed factors.
End point type	Secondary
End point timeframe:	Baseline, Week 12

End point values	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W)	Period 1: 200 milligram (mg) Mirikizumab IV Q4W	Period 1: 600 mg Mirikizumab IV Q4W	Period 1: 1000 mg Mirikizumab IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58 ^[13]	26 ^[14]	29 ^[15]	56 ^[16]
Units: score on a scale				
least squares mean (standard error)	-0.44 (± 0.132)	-1.08 (± 0.194)	-1.27 (± 0.189)	-0.98 (± 0.134)

Notes:

[13] - All randomized participants who had a baseline and at least one post-baseline PGRS value.

[14] - All randomized participants who had a baseline and at least one post-baseline PGRS value.

[15] - All randomized participants who had a baseline and at least one post-baseline PGRS value.

[16] - All randomized participants who had a baseline and at least one post-baseline PGRS value.

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 200 milligram (mg) Mirikizumab IV Q4W
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	-0.64
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.03
upper limit	-0.25

Variability estimate	Standard error of the mean
Dispersion value	0.234

Statistical analysis title	Statistical analysis 2
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 600 mg Mirikizumab IV Q4W
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	-0.83
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.21
upper limit	-0.45
Variability estimate	Standard error of the mean
Dispersion value	0.23

Statistical analysis title	Statistical analysis 3
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 1000 mg Mirikizumab IV Q4W
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.005
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	-0.53
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.84
upper limit	-0.22
Variability estimate	Standard error of the mean
Dispersion value	0.188

Secondary: Mean of Patient Global Rating – Change (PGRC) Crohn’s Disease Score at Week 12

End point title	Mean of Patient Global Rating – Change (PGRC) Crohn’s Disease Score at Week 12
-----------------	--

End point description:

The PGRC scale is a patient-rated instrument designed to assess the participant's rating of change in

their symptom(s). Responses are graded on a 7-point Likert scale in which a score of 1 indicates that the participant's symptom is "very much better," a score of 4 indicates that the participant's symptom has experienced "no change," and a score of 7 indicates that the participant's symptom is "very much worse."

End point type	Secondary
End point timeframe:	
Baseline, Week 12	

End point values	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W)	Period 1: 200 milligram (mg) Mirikizumab IV Q4W	Period 1: 600 mg Mirikizumab IV Q4W	Period 1: 1000 mg Mirikizumab IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[17]	29 ^[18]	27 ^[19]	57 ^[20]
Units: score on a scale				
arithmetic mean (standard deviation)	3.6 (± 1.11)	2.8 (± 1.26)	2.6 (± 0.97)	2.5 (± 0.89)

Notes:

[17] - All randomized participants who had a baseline and at least one post-baseline PGRC value.

[18] - All randomized participants who had a baseline and at least one post-baseline PGRC value.

[19] - All randomized participants who had a baseline and at least one post-baseline PGRC value.

[20] - All randomized participants who had a baseline and at least one post-baseline PGRC value.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline on the Inflammatory Bowel Disease Questionnaire (IBDQ) Score at Week 12

End point title	Mean Change From Baseline on the Inflammatory Bowel Disease Questionnaire (IBDQ) Score at Week 12
-----------------	---

End point description:

The IBDQ is a 32-item self-administered questionnaire. The IBDQ has 4 dimensions: bowel symptoms (10 items), systemic symptoms (5 items), emotional function (12 items), and social function (5 items). Responses are graded on a 7-point Likert scale in which 7 denotes "not a problem at all" and 1 denotes "a very severe problem." Scores range from 32 to 224; a higher score indicates a better quality of life. LS Mean was calculated using Mixed Model for Repeated Measures (MMRM) model with treatment, geographic region, geographic region, prior biologic CD therapy use (prior biologic experience versus prior biologic naive), baseline score, visit, and the interaction of treatment-by-visit and baseline-by-visit as fixed factors.

End point type	Secondary
End point timeframe:	
Baseline, Week 12	

End point values	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W)	Period 1: 200 milligram (mg) Mirikizumab IV Q4W	Period 1: 600 mg Mirikizumab IV Q4W	Period 1: 1000 mg Mirikizumab IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[21]	29 ^[22]	28 ^[23]	57 ^[24]
Units: score on a scale				

least squares mean (standard error)	17.11 (± 3.725)	41.16 (± 5.311)	46.57 (± 5.244)	42.35 (± 3.770)
-------------------------------------	-----------------	-----------------	-----------------	-----------------

Notes:

[21] - All randomized participants who had a baseline and at least one post-baseline IBDQ value.

[22] - All randomized participants who had a baseline and at least one post-baseline IBDQ value.

[23] - All randomized participants who had a baseline and at least one post-baseline IBDQ value.

[24] - All randomized participants who had a baseline and at least one post-baseline IBDQ value.

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 200 milligram (mg) Mirikizumab IV Q4W
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	24.05
Confidence interval	
level	90 %
sides	2-sided
lower limit	13.53
upper limit	34.56
Variability estimate	Standard error of the mean
Dispersion value	6.358

Statistical analysis title	Statistical analysis 2
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 600 mg Mirikizumab IV Q4W
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	29.46
Confidence interval	
level	90 %
sides	2-sided
lower limit	18.84
upper limit	40.08
Variability estimate	Standard error of the mean
Dispersion value	6.421

Statistical analysis title	Statistical analysis 3
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v

	Period 1: 1000 mg Mirikizumab IV Q4W
Number of subjects included in analysis	113
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	25.24
Confidence interval	
level	90 %
sides	2-sided
lower limit	16.67
upper limit	33.82
Variability estimate	Standard error of the mean
Dispersion value	5.185

Secondary: Mean Change From Baseline on the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) Score at Week 12

End point title	Mean Change From Baseline on the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) Score at Week 12
End point description:	The Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) Scale is a 13-item, symptom-specific questionnaire that specifically assesses the participant's self-reported severity of fatigue and its impact upon daily activities and functioning. The FACIT-F uses a numeric rating scale of 0-4 associated with a range over "Not at all" to "Very much" for each item to assess fatigue and its impact in the past 7 days. Total scores range from 0 to 52, with higher scores indicating less fatigue. LS Mean was calculated using Mixed Model for Repeated Measures (MMRM) model with treatment, geographic region, geographic region, prior biologic CD therapy use (prior biologic experience versus prior biologic naive), baseline score, visit, and the interaction of treatment-by-visit and baseline-by-visit as fixed factors.
End point type	Secondary
End point timeframe:	Baseline, Week 12

End point values	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W)	Period 1: 200 milligram (mg) Mirikizumab IV Q4W	Period 1: 600 mg Mirikizumab IV Q4W	Period 1: 1000 mg Mirikizumab IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[25]	29 ^[26]	28 ^[27]	57 ^[28]
Units: score on a scale				
least squares mean (standard error)	2.90 (± 1.209)	10.81 (± 1.728)	9.09 (± 1.721)	9.62 (± 1.223)

Notes:

[25] - All randomized participants who had a baseline and at least one post-baseline FACIT-F value.

[26] - All randomized participants who had a baseline and at least one post-baseline FACIT-F value.

[27] - All randomized participants who had a baseline and at least one post-baseline FACIT-F value.

[28] - All randomized participants who had a baseline and at least one post-baseline FACIT-F value.

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 200 milligram (mg) Mirikizumab IV Q4W
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	7.91
Confidence interval	
level	90 %
sides	2-sided
lower limit	4.48
upper limit	11.34
Variability estimate	Standard error of the mean
Dispersion value	2.072

Statistical analysis title	Statistical analysis 2
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 600 mg Mirikizumab IV Q4W
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	6.2
Confidence interval	
level	90 %
sides	2-sided
lower limit	2.72
upper limit	9.67
Variability estimate	Standard error of the mean
Dispersion value	2.102

Statistical analysis title	Statistical analysis 3
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 1000 mg Mirikizumab IV Q4W
Number of subjects included in analysis	113
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	6.73

Confidence interval	
level	90 %
sides	2-sided
lower limit	3.94
upper limit	9.51
Variability estimate	Standard error of the mean
Dispersion value	1.686

Secondary: Mean Change From Baseline on the 36-Item Short Form Health Survey (SF-36) Physical Component Summary (PCS) and Mental Component Summary (MCS) Scores at Week 12

End point title	Mean Change From Baseline on the 36-Item Short Form Health Survey (SF-36) Physical Component Summary (PCS) and Mental Component Summary (MCS) Scores at Week 12
-----------------	---

End point description:

The SF-36 is a health-related survey that assesses participant's quality of life and consists of 36 questions covering 8 health domains: physical functioning, bodily pain, role limitations due to physical problems and emotional problems, general health, mental health, social functioning, vitality, 2 component scores (MCS and PCS). MCS consisted of social functioning, vitality, mental health, and role-emotional scales. PCS consisted of physical functioning, bodily pain, role-physical, and general health scales. Each domain is scored by summing individual items and transforming scores into a 0 to 100 scale with higher scores indicating better health status or functioning. LS Mean was calculated using Mixed Model for Repeated Measures (MMRM) model with treatment, geographic region, geographic region, prior biologic CD therapy use (prior biologic experience versus prior biologic naive), baseline score, visit, and the interaction of treatment-by-visit and baseline-by-visit as fixed factors.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline, Week 12

End point values	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W)	Period 1: 200 milligram (mg) Mirikizumab IV Q4W	Period 1: 600 mg Mirikizumab IV Q4W	Period 1: 1000 mg Mirikizumab IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56 ^[29]	29 ^[30]	28 ^[31]	57 ^[32]
Units: Baseline, Week 12				
least squares mean (standard error)				
MCS	2.34 (± 1.133)	7.47 (± 1.602)	6.52 (± 1.592)	6.05 (± 1.152)
PCS	3.11 (± 0.774)	4.70 (± 1.096)	8.01 (± 1.108)	6.70 (± 0.787)

Notes:

[29] - All randomized participants who had a baseline and at least one post-baseline PCS and MCS value.

[30] - All randomized participants who had a baseline and at least one post-baseline PCS and MCS value.

[31] - All randomized participants who had a baseline and at least one post-baseline PCS and MCS value.

[32] - All randomized participants who had a baseline and at least one post-baseline PCS and MCS value.

Statistical analyses

Statistical analysis title	Statistical analysis 1: MCS
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 200 milligram (mg) Mirikizumab IV Q4W
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.008
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	5.14
Confidence interval	
level	90 %
sides	2-sided
lower limit	1.95
upper limit	8.32
Variability estimate	Standard error of the mean
Dispersion value	1.927

Statistical analysis title	Statistical analysis 2: MCS
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 600 mg Mirikizumab IV Q4W
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.033
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	4.18
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.96
upper limit	7.41
Variability estimate	Standard error of the mean
Dispersion value	1.951

Statistical analysis title	Statistical analysis 3: MCS
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 1000 mg Mirikizumab IV Q4W
Number of subjects included in analysis	113
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.021
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	3.71

Confidence interval	
level	90 %
sides	2-sided
lower limit	1.08
upper limit	6.34
Variability estimate	Standard error of the mean
Dispersion value	1.589

Statistical analysis title	Statistical analysis 4: PCS
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 200 milligram (mg) Mirikizumab IV Q4W
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.229
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	1.59
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.59
upper limit	3.77
Variability estimate	Standard error of the mean
Dispersion value	1.319

Statistical analysis title	Statistical analysis 5: PCS
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 600 mg Mirikizumab IV Q4W
Number of subjects included in analysis	84
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	4.91
Confidence interval	
level	90 %
sides	2-sided
lower limit	2.67
upper limit	7.14
Variability estimate	Standard error of the mean
Dispersion value	1.349

Statistical analysis title	Statistical analysis 6: PCS
Comparison groups	Period 1: Placebo Intravenous (IV) every 4 weeks (Q4W) v Period 1: 1000 mg Mirikizumab IV Q4W
Number of subjects included in analysis	113
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Mixed models analysis
Parameter estimate	LS Mean difference (Final Values)
Point estimate	3.6
Confidence interval	
level	90 %
sides	2-sided
lower limit	1.81
upper limit	5.38
Variability estimate	Standard error of the mean
Dispersion value	1.078

Secondary: Population Pharmacokinetics (PopPK): Mean Population Clearance of Mirikizumab

End point title	Population Pharmacokinetics (PopPK): Mean Population Clearance of Mirikizumab
End point description: Population mean (between-subject coefficient variance [CV %]) apparent clearance. Clearance is estimated based on concentration data collected in the time frame of 0-208 weeks.	
End point type	Secondary
End point timeframe: Week 0, 4, 8: Predose, end of infusion; Week 2; 4; 6; 8, 11-12; 12-13; 16; 20; 24; 28; 36; 44; 52; 60; 68; 76; 84; 92; 104; 108; 112; 120; 128; 136; 144; 156; 164; 172; 180; 188; 196 and 208 weeks post infusion	

End point values	Mirikizumab IV Q4W			
Subject group type	Subject analysis set			
Number of subjects analysed	186 ^[33]			
Units: Liters per Hour (L/h)				
geometric mean (geometric coefficient of variation)	0.0225 (± 30)			

Notes:

[33] - All randomized participants who received at least one dose of study drug and had evaluable PK data.

Statistical analyses

No statistical analyses for this end point

Secondary: Population Pharmacokinetics (PopPK): Mean Population Volume of Distribution of Mirikizumab

End point title	Population Pharmacokinetics (PopPK): Mean Population Volume
-----------------	---

End point description:

Population mean (between-subject coefficient variance [CV %]) apparent volume of distribution. Volume of distribution is estimated based on concentration data collected in the time frame of 0-208 weeks.

End point type Secondary

End point timeframe:

Week 0, 4, 8: Predose, end of infusion; Week 2; 4; 6; 8, 11-12; 12-13; 16; 20; 24; 28; 36; 44; 52; 60; 68; 76; 84; 92; 104; 108; 112; 120; 128; 136; 144; 156; 164; 172; 180; 188; 196 and 208 weeks post infusion

End point values	Mirikizumab IV Q4W			
Subject group type	Subject analysis set			
Number of subjects analysed	186 ^[34]			
Units: Liters (L)				
geometric mean (geometric coefficient of variation)	5.05 (± 18)			

Notes:

[34] - All randomized participants who received at least one dose of study drug and had evaluable PK data.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline Up To 208 Weeks

Adverse event reporting additional description:

All randomized participants who received at least 1 dose of study drug.

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	23.0
--------------------	------

Reporting groups

Reporting group title	Period 1: Placebo Intravenous (IV) Every 4 Weeks (Q4W)
-----------------------	--

Reporting group description:

Participants received placebo administered intravenously (IV) Q4W.

Reporting group title	Period 1: 200 Milligram (mg) Mirikizumab IV Q4W
-----------------------	---

Reporting group description:

Participants received 200 mg mirikizumab administered IV Q4W.

Reporting group title	Period 1: 600 mg Mirikizumab IV Q4W
-----------------------	-------------------------------------

Reporting group description:

Participants received 600 mg mirikizumab administered IV Q4W.

Reporting group title	Period 1: 1000 mg Mirikizumab IV Q4W
-----------------------	--------------------------------------

Reporting group description:

Participants received 1000 mg mirikizumab administered IV Q4W.

Reporting group title	Period 2: 200 mg Mirikizumab IV Q4W
-----------------------	-------------------------------------

Reporting group description:

Participants received 200 mg mirikizumab administered IV Q4W. Participants improved on the same mirikizumab dose in Period 1.

Reporting group title	Period 2: 1000 mg Mirikizumab IV Q4W
-----------------------	--------------------------------------

Reporting group description:

Participants received 1000 mg mirikizumab administered IV Q4W. Participants improved on the same mirikizumab dose in Period 1.

Reporting group title	Period 2: 600 mg Mirikizumab IV Q4W
-----------------------	-------------------------------------

Reporting group description:

Participants received 600 mg mirikizumab administered IV Q4W. Participants improved on the same mirikizumab dose in Period 1.

Reporting group title	Period 2: 300mg Mirikizumab Subcutaneous (SC) Q4W
-----------------------	---

Reporting group description:

Participants received 300 mg mirikizumab administered SC Q4W. Participants improved on any mirikizumab dose in Period 1.

Reporting group title	Period 2: 1000 mg Mirikizumab IV Q4W (NI)
-----------------------	---

Reporting group description:

Participants who did not improve in Period 1 on mirikizumab (any dose) received 1000 mg mirikizumab administered IV Q4W.

Reporting group title	Period 2: 1000 mg Mirikizumab IV Q4W (PBO)
-----------------------	--

Reporting group description:

Participants who received placebo in period 1 received 1000 mg mirikizumab administered IV Q4W.

Reporting group title	Period 3: 300 mg Mirikizumab SC Q4W
-----------------------	-------------------------------------

Reporting group description:

Participants received 300 mg mirikizumab administered SC Q4W.

Reporting group title	Follow-up Period: 200 mg Mirikizumab IV Q4W in Period 2
-----------------------	---

Reporting group description:

Participants did not receive drug during the follow-up period. Group includes participants who received 200 mg mirikizumab IV Q4W during period 2.

Reporting group title	Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv)
-----------------------	--

Reporting group description:

Participants did not receive drug during the follow-up period. Group includes participants who received 1000 mg mirikizumab IV Q4W during period 2 after improving on the same dose in Period 1. Impv = Improvers.

Reporting group title	Follow-up Period: 1000 mg Mirikizumab IV Q4W in Period 2 (NI)
-----------------------	---

Reporting group description:

Participants did not receive drug during the follow-up period. Group includes participants who did not improve in period 1, and received 1000 mg mirikizumab IV Q4W during period 2.

Reporting group title	Follow-up Period: 1000 mg Mirkizumab IV Q4W in Period 2 (PBO)
-----------------------	---

Reporting group description:

Participants did not receive drug during the follow-up period. Group includes participants who received placebo (PBO) in period 1 and 1000 mg mirikizumab administered IV Q4W.

Reporting group title	Follow-up Period: 300 mg Mirikizumab SC Q4W in Period 3
-----------------------	---

Reporting group description:

Participants did not receive drug during the follow-up period. Group includes participants who received 300 mg mirikizumab administered SC Q4W during period 3.

Serious adverse events	Period 1: Placebo Intravenous (IV) Every 4 Weeks (Q4W)	Period 1: 200 Milligram (mg) Mirikizumab IV Q4W	Period 1: 600 mg Mirikizumab IV Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 64 (10.94%)	0 / 31 (0.00%)	3 / 32 (9.38%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) gastrointestinal tract adenoma alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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
Vascular disorders deep vein thrombosis alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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
Pregnancy, puerperium and perinatal conditions			

abortion spontaneous	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[1]	0 / 36 (0.00%)	0 / 14 (0.00%)	0 / 18 (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
General disorders and administration site conditions			
malaise			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 64 (1.56%)	0 / 31 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 64 (1.56%)	0 / 31 (0.00%)	0 / 32 (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
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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
infusion related hypersensitivity reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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

Respiratory, thoracic and mediastinal disorders pulmonary embolism alternative dictionary used: MedDRA 23.0 subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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
Investigations blood potassium decreased alternative dictionary used: MedDRA 23.0 subjects affected / exposed	1 / 64 (1.56%)	0 / 31 (0.00%)	0 / 32 (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
Injury, poisoning and procedural complications concussion alternative dictionary used: MedDRA 23.0 subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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
intestinal anastomosis complication alternative dictionary used: MedDRA 23.0 subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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
maternal exposure during pregnancy	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
alternative dictionary used: MedDRA 23.0 subjects affected / exposed ^[2]	0 / 36 (0.00%)	0 / 14 (0.00%)	0 / 18 (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
paternal exposure during pregnancy	Additional description: Follow-up Period:200 mg Mirikizumab IV Q4W in Period 2;1000 mg Mirikizumab IV Q4W in Period 2 (NI);1000 mg Mirkizumab IV Q4W in Period 2 (PBO)=Subjects exposed number=0.However,due to EudraCT database constraint we have included all the participants		
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed ^[3]	0 / 28 (0.00%)	0 / 17 (0.00%)	0 / 14 (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
Cardiac disorders			
cardiac failure			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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 disorders			
abdominal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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
crohn's disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 64 (4.69%)	0 / 31 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ileal perforation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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
ileal stenosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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
ileus			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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
intestinal obstruction alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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
intestinal perforation alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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
large intestinal stenosis alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestine perforation alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	1 / 32 (3.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower gastrointestinal haemorrhage alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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
pneumatosis intestinalis alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 64 (1.56%)	0 / 31 (0.00%)	0 / 32 (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

<p>small intestinal stenosis</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>0 / 64 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	<p>0 / 31 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	<p>0 / 32 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>
<p>Renal and urinary disorders</p> <p>renal colic</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>0 / 64 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	<p>0 / 31 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	<p>0 / 32 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>
<p>Musculoskeletal and connective tissue disorders</p> <p>back pain</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>0 / 64 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	<p>0 / 31 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	<p>0 / 32 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>
<p>osteoarthritis</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>0 / 64 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	<p>0 / 31 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	<p>0 / 32 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>
<p>rotator cuff syndrome</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>0 / 64 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	<p>0 / 31 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	<p>0 / 32 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>
<p>Infections and infestations</p> <p>clostridium difficile infection</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>0 / 64 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	<p>0 / 31 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>	<p>0 / 32 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>
<p>peritonitis</p>			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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
pyelonephritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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			
dehydration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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
hypokalaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (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	Period 1: 1000 mg Mirikizumab IV Q4W	Period 2: 200 mg Mirikizumab IV Q4W	Period 2: 1000 mg Mirikizumab IV Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 64 (3.13%)	0 / 9 (0.00%)	0 / 23 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
gastrointestinal tract adenoma			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[1]	0 / 30 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
General disorders and administration site conditions			
malaise			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
non-cardiac chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
pyrexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
Immune system disorders			

anaphylactic reaction alternative dictionary used: MedDRA 23.0 subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
infusion related hypersensitivity reaction alternative dictionary used: MedDRA 23.0 subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
Respiratory, thoracic and mediastinal disorders pulmonary embolism alternative dictionary used: MedDRA 23.0 subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
Investigations blood potassium decreased alternative dictionary used: MedDRA 23.0 subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
Injury, poisoning and procedural complications concussion alternative dictionary used: MedDRA 23.0 subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
intestinal anastomosis complication alternative dictionary used: MedDRA 23.0 subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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

maternal exposure during pregnancy	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[2]	0 / 30 (0.00%)	0 / 4 (0.00%)	0 / 12 (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
paternal exposure during pregnancy	Additional description: Follow-up Period:200 mg Mirikizumab IV Q4W in Period 2;1000 mg Mirikizumab IV Q4W in Period 2 (NI);1000 mg Mirikizumab IV Q4W in Period 2 (PBO)=Subjects exposed number=0.However,due to EudraCT database constraint we have included all the participants		
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[3]	0 / 34 (0.00%)	0 / 5 (0.00%)	0 / 11 (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
Cardiac disorders			
cardiac failure			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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 disorders			
abdominal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 64 (1.56%)	0 / 9 (0.00%)	0 / 23 (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
crohn's disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
ileal perforation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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

ileal stenosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
ileus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
intestinal obstruction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
intestinal perforation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
large intestinal stenosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
large intestine perforation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
lower gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
pneumatosis intestinalis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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 stenosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
Renal and urinary disorders			
renal colic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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			
back pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 64 (1.56%)	0 / 9 (0.00%)	0 / 23 (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
osteoarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
rotator cuff syndrome			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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 alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
peritonitis alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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 alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
pyelonephritis alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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			
dehydration alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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
hypokalaemia alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (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	Period 2: 600 mg Mirikizumab IV Q4W	Period 2: 300mg Mirikizumab Subcutaneous (SC) Q4W	Period 2: 1000 mg Mirikizumab IV Q4W (NI)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 9 (0.00%)	2 / 46 (4.35%)	3 / 30 (10.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) gastrointestinal tract adenoma alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
Vascular disorders deep vein thrombosis alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
Pregnancy, puerperium and perinatal conditions abortion spontaneous			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[1]	0 / 4 (0.00%)	0 / 23 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions malaise alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
non-cardiac chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
pyrexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
infusion related hypersensitivity reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
Respiratory, thoracic and mediastinal disorders			
pulmonary embolism			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
Investigations			
blood potassium decreased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
Injury, poisoning and procedural complications			
concussion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
intestinal anastomosis complication			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
maternal exposure during pregnancy	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[2]	0 / 4 (0.00%)	0 / 23 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
paternal exposure during pregnancy	Additional description: Follow-up Period:200 mg Mirikizumab IV Q4W in Period 2;1000 mg Mirikizumab IV Q4W in Period 2 (NI);1000 mg Mirkizumab IV Q4W in Period 2 (PBO)=Subjects exposed number=0.However,due to EudraCT database constraint we have included all the participants		
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[3]	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 17 (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
Cardiac disorders			
cardiac failure			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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 disorders			

abdominal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
crohn's disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ileal perforation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 30 (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
ileal stenosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
ileus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
intestinal obstruction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
intestinal perforation			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
large intestinal stenosis alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
large intestine perforation alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
lower gastrointestinal haemorrhage alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
pneumatosis intestinalis alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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 stenosis alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
Renal and urinary disorders renal colic alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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			
back pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
osteoarthritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
rotator cuff syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (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
peritonitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 30 (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
pneumonia			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 30 (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
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 30 (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
hypokalaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 30 (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

Serious adverse events	Period 2: 1000 mg Mirkizumab IV Q4W (PBO)	Period 3: 300 mg Mirkizumab SC Q4W	Follow-up Period: 200 mg Mirkizumab IV Q4W in Period 2
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 59 (15.25%)	15 / 136 (11.03%)	0 / 1 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
gastrointestinal tract adenoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	1 / 136 (0.74%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 59 (0.00%)	1 / 136 (0.74%)	0 / 1 (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
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[1]	0 / 33 (0.00%)	0 / 61 (0.00%)	0 / 1 (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
General disorders and administration site conditions			
malaise			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	0 / 136 (0.00%)	0 / 1 (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
non-cardiac chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 59 (1.69%)	0 / 136 (0.00%)	0 / 1 (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
pyrexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	1 / 136 (0.74%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 59 (3.39%)	0 / 136 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infusion related hypersensitivity reaction			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 59 (1.69%)	0 / 136 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
pulmonary embolism			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	1 / 136 (0.74%)	0 / 1 (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
Investigations			
blood potassium decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	0 / 136 (0.00%)	0 / 1 (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
Injury, poisoning and procedural complications			
concussion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	1 / 136 (0.74%)	0 / 1 (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
intestinal anastomosis complication			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 59 (1.69%)	0 / 136 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
maternal exposure during pregnancy	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[2]	0 / 33 (0.00%)	0 / 61 (0.00%)	0 / 1 (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

paternal exposure during pregnancy	Additional description: Follow-up Period:200 mg Mirikizumab IV Q4W in Period 2;1000 mg Mirikizumab IV Q4W in Period 2 (NI);1000 mg Mirkizumab IV Q4W in Period 2 (PBO)=Subjects exposed number=0.However,due to EudraCT database constraint we have included all the participants		
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[3]	0 / 26 (0.00%)	2 / 75 (2.67%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
cardiac failure			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	1 / 136 (0.74%)	0 / 1 (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
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	0 / 136 (0.00%)	0 / 1 (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
crohn's disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 59 (1.69%)	2 / 136 (1.47%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ileal perforation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	0 / 136 (0.00%)	0 / 1 (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
ileal stenosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	1 / 136 (0.74%)	0 / 1 (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
ileus			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	1 / 136 (0.74%)	0 / 1 (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
intestinal obstruction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 59 (1.69%)	0 / 136 (0.00%)	0 / 1 (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
intestinal perforation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	1 / 136 (0.74%)	0 / 1 (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
large intestinal stenosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	0 / 136 (0.00%)	0 / 1 (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
large intestine perforation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	0 / 136 (0.00%)	0 / 1 (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
lower gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	1 / 136 (0.74%)	0 / 1 (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
pneumatosis intestinalis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 59 (0.00%)	0 / 136 (0.00%)	0 / 1 (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 stenosis alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	1 / 136 (0.74%)	0 / 1 (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
Renal and urinary disorders			
renal colic alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	1 / 136 (0.74%)	0 / 1 (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
Musculoskeletal and connective tissue disorders			
back pain alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	0 / 136 (0.00%)	0 / 1 (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
osteoarthritis alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 59 (1.69%)	0 / 136 (0.00%)	0 / 1 (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
rotator cuff syndrome alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	1 / 136 (0.74%)	0 / 1 (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
Infections and infestations			
clostridium difficile infection alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 59 (1.69%)	0 / 136 (0.00%)	0 / 1 (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
peritonitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	0 / 136 (0.00%)	0 / 1 (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			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	0 / 136 (0.00%)	0 / 1 (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
pyelonephritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	0 / 136 (0.00%)	0 / 1 (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			
dehydration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	0 / 136 (0.00%)	0 / 1 (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
hypokalaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	0 / 136 (0.00%)	0 / 1 (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	Follow-up Period: 1000 mg Mirikizumab IV Q4W in Period 2 (Impv)	Follow-up Period: 1000 mg Mirikizumab IV Q4W in Period 2 (NI)	Follow-up Period: 1000 mg Mirikizumab IV Q4W in Period 2 (PBO)
Total subjects affected by serious adverse events			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
gastrointestinal tract adenoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[1]	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
General disorders and administration site conditions			
malaise			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
non-cardiac chest pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
pyrexia			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
Immune system disorders			
anaphylactic reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
infusion related hypersensitivity reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
Respiratory, thoracic and mediastinal disorders			
pulmonary embolism			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
Investigations			
blood potassium decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
Injury, poisoning and procedural complications			
concussion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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

intestinal anastomosis complication alternative dictionary used: MedDRA 23.0 subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
maternal exposure during pregnancy	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
alternative dictionary used: MedDRA 23.0 subjects affected / exposed ^[2]	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
paternal exposure during pregnancy	Additional description: Follow-up Period:200 mg Mirikizumab IV Q4W in Period 2;1000 mg Mirikizumab IV Q4W in Period 2 (NI);1000 mg Mirkizumab IV Q4W in Period 2 (PBO)=Subjects exposed number=0.However,due to EudraCT database constraint we have included all the participants		
alternative dictionary used: MedDRA 23.0 subjects affected / exposed ^[3]	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
Cardiac disorders cardiac failure alternative dictionary used: MedDRA 23.0 subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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 disorders abdominal pain alternative dictionary used: MedDRA 23.0 subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
crohn's disease alternative dictionary used: MedDRA 23.0 subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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

ileal perforation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
ileal stenosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
ileus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
intestinal obstruction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
intestinal perforation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
large intestinal stenosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
large intestine perforation			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
lower gastrointestinal haemorrhage alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
pneumatosis intestinalis alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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 stenosis alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
Renal and urinary disorders			
renal colic alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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			
back pain alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
osteoarthritis alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
rotator cuff syndrome alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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 alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
peritonitis alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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 alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
pyelonephritis alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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			
dehydration alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
hypokalaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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	Follow-up Period: 300 mg Mirikizumab SC Q4W in Period 3		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
gastrointestinal tract adenoma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
deep vein thrombosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
abortion spontaneous	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[1]	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration			

<p>site conditions</p> <p>malaise</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>0 / 3 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>		
<p>non-cardiac chest pain</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>0 / 3 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>		
<p>pyrexia</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>0 / 3 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>		
<p>Immune system disorders</p> <p>anaphylactic reaction</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>0 / 3 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>		
<p>infusion related hypersensitivity reaction</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>0 / 3 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>		
<p>Respiratory, thoracic and mediastinal disorders</p> <p>pulmonary embolism</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences causally related to treatment / all</p> <p>deaths causally related to treatment / all</p>	<p>0 / 3 (0.00%)</p> <p>0 / 0</p> <p>0 / 0</p>		

Investigations blood potassium decreased alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 3 (0.00%) 0 / 0 0 / 0		
Injury, poisoning and procedural complications concussion alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 3 (0.00%) 0 / 0 0 / 0		
intestinal anastomosis complication alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 3 (0.00%) 0 / 0 0 / 0		
maternal exposure during pregnancy	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
alternative dictionary used: MedDRA 23.0 subjects affected / exposed ^[2] occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 1 (0.00%) 0 / 0 0 / 0		
paternal exposure during pregnancy	Additional description: Follow-up Period:200 mg Mirikizumab IV Q4W in Period 2;1000 mg Mirikizumab IV Q4W in Period 2 (NI);1000 mg Mirkizumab IV Q4W in Period 2 (PBO)=Subjects exposed number=0.However,due to EudraCT database constraint we have included all the participants		
alternative dictionary used: MedDRA 23.0 subjects affected / exposed ^[3] occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 2 (0.00%) 0 / 0 0 / 0		
Cardiac disorders cardiac failure alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
crohn's disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
ileal perforation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
ileal stenosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
ileus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
intestinal obstruction			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
intestinal perforation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
large intestinal stenosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
large intestine perforation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
lower gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pneumatosis intestinalis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
small intestinal stenosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Renal and urinary disorders renal colic alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 3 (0.00%) 0 / 0 0 / 0		
Musculoskeletal and connective tissue disorders back pain alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 3 (0.00%) 0 / 0 0 / 0		
osteoarthritis alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 3 (0.00%) 0 / 0 0 / 0		
rotator cuff syndrome alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 3 (0.00%) 0 / 0 0 / 0		
Infections and infestations clostridium difficile infection alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 3 (0.00%) 0 / 0 0 / 0		
peritonitis alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 3 (0.00%) 0 / 0 0 / 0		
pneumonia			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pyelonephritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
hypokalaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: Gender specific events occurring only in male or female participants have had the number of participants at risk adjusted accordingly.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: Gender specific events occurring only in male or female participants have had the number of participants at risk adjusted accordingly.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: Gender specific events occurring only in male or female participants have had the number of participants at risk adjusted accordingly.

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Period 1: Placebo Intravenous (IV) Every 4 Weeks (Q4W)	Period 1: 200 Milligram (mg) Mirikizumab IV Q4W	Period 1: 600 mg Mirikizumab IV Q4W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 64 (37.50%)	11 / 31 (35.48%)	12 / 32 (37.50%)
Vascular disorders			

hypertension alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	1 / 31 (3.23%) 1	0 / 32 (0.00%) 0
General disorders and administration site conditions fatigue alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	3 / 64 (4.69%) 3	0 / 31 (0.00%) 0	0 / 32 (0.00%) 0
infusion site reaction alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 31 (0.00%) 0	0 / 32 (0.00%) 0
injection site pain alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 31 (0.00%) 0	0 / 32 (0.00%) 0
injection site reaction alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 31 (0.00%) 0	0 / 32 (0.00%) 0
pyrexia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	1 / 64 (1.56%) 1	0 / 31 (0.00%) 0	3 / 32 (9.38%) 3
Reproductive system and breast disorders endometrial hyperplasia alternative dictionary used: MedDRA 23.0 subjects affected / exposed ^[4] occurrences (all)	0 / 36 (0.00%) 0	0 / 14 (0.00%) 0	0 / 18 (0.00%) 0
endometriosis alternative dictionary used: MedDRA 23.0	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		

subjects affected / exposed ^[5] occurrences (all)	0 / 36 (0.00%) 0	0 / 14 (0.00%) 0	0 / 18 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
rhinorrhoea alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 31 (0.00%) 0	0 / 32 (0.00%) 0
sinus congestion alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 31 (0.00%) 0	2 / 32 (6.25%) 2
Psychiatric disorders			
anxiety alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	1 / 64 (1.56%) 1	1 / 31 (3.23%) 1	0 / 32 (0.00%) 0
depression alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 31 (0.00%) 0	0 / 32 (0.00%) 0
insomnia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	1 / 31 (3.23%) 1	0 / 32 (0.00%) 0
irritability alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 31 (0.00%) 0	0 / 32 (0.00%) 0
panic attack alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 31 (0.00%) 0	0 / 32 (0.00%) 0
Investigations			

alanine aminotransferase increased alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	2 / 31 (6.45%) 2	0 / 32 (0.00%) 0
aspartate aminotransferase increased alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	2 / 31 (6.45%) 2	0 / 32 (0.00%) 0
blood creatine phosphokinase increased alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 31 (0.00%) 0	0 / 32 (0.00%) 0
weight increased alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	1 / 31 (3.23%) 1	3 / 32 (9.38%) 3
Injury, poisoning and procedural complications skin laceration alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 31 (0.00%) 0	0 / 32 (0.00%) 0
Nervous system disorders headache alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	2 / 64 (3.13%) 2	2 / 31 (6.45%) 2	2 / 32 (6.25%) 3
hypoaesthesia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 31 (0.00%) 0	0 / 32 (0.00%) 0
Blood and lymphatic system disorders anaemia alternative dictionary used: MedDRA 23.0			

subjects affected / exposed occurrences (all)	1 / 64 (1.56%) 1	2 / 31 (6.45%) 2	1 / 32 (3.13%) 1
Eye disorders lacrimation increased alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 31 (0.00%) 0	0 / 32 (0.00%) 0
Gastrointestinal disorders abdominal distension alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 31 (0.00%) 0	2 / 32 (6.25%) 2
abdominal pain alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	1 / 64 (1.56%) 1	0 / 31 (0.00%) 0	1 / 32 (3.13%) 1
anal incontinence alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 31 (0.00%) 0	0 / 32 (0.00%) 0
crohn's disease alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	6 / 64 (9.38%) 7	0 / 31 (0.00%) 0	0 / 32 (0.00%) 0
diarrhoea alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	1 / 64 (1.56%) 1	1 / 31 (3.23%) 1	0 / 32 (0.00%) 0
flatulence alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 31 (0.00%) 0	0 / 32 (0.00%) 0
haemorrhoids alternative dictionary used: MedDRA 23.0			

subjects affected / exposed occurrences (all)	1 / 64 (1.56%) 1	1 / 31 (3.23%) 1	0 / 32 (0.00%) 0
intestinal obstruction alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 31 (0.00%) 0	0 / 32 (0.00%) 0
nausea alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	2 / 64 (3.13%) 2	0 / 31 (0.00%) 0	2 / 32 (6.25%) 2
rectal polyp alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 31 (0.00%) 0	0 / 32 (0.00%) 0
Endocrine disorders hypothyroidism alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 31 (0.00%) 0	0 / 32 (0.00%) 0
Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	3 / 64 (4.69%) 3	1 / 31 (3.23%) 1	1 / 32 (3.13%) 1
joint stiffness alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 31 (0.00%) 0	0 / 32 (0.00%) 0
myalgia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	1 / 31 (3.23%) 1	0 / 32 (0.00%) 0
Infections and infestations			

cystitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	2 / 31 (6.45%)	0 / 32 (0.00%)
occurrences (all)	0	2	0
epididymitis	Additional description: Follow-up Period:200 mg Mirikizumab IV Q4W in Period 2;1000 mg Mirikizumab IV Q4W in Period 2 (NI);1000 mg Mirkizumab IV Q4W in Period 2 (PBO)=Subjects exposed number=0.However,due to EudraCT database constraint we have included all the participants		
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[6]	0 / 28 (0.00%)	0 / 17 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
erysipelas			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
gastroenteritis viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
human anaplasmosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
nasopharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 64 (1.56%)	0 / 31 (0.00%)	2 / 32 (6.25%)
occurrences (all)	1	0	2
respiratory tract infection viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 64 (1.56%)	1 / 31 (3.23%)	0 / 32 (0.00%)
occurrences (all)	1	1	0
sinusitis			
alternative dictionary used:			

MedDRA 23.0			
subjects affected / exposed	1 / 64 (1.56%)	0 / 31 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 64 (3.13%)	1 / 31 (3.23%)	0 / 32 (0.00%)
occurrences (all)	2	1	0
urinary tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 64 (1.56%)	1 / 31 (3.23%)	0 / 32 (0.00%)
occurrences (all)	1	1	0
vulvovaginal mycotic infection	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[7]	1 / 36 (2.78%)	0 / 14 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
vitamin d deficiency			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 31 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Period 1: 1000 mg Mirikizumab IV Q4W	Period 2: 200 mg Mirikizumab IV Q4W	Period 2: 1000 mg Mirikizumab IV Q4W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	27 / 64 (42.19%)	7 / 9 (77.78%)	14 / 23 (60.87%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 64 (3.13%)	0 / 9 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 64 (1.56%)	0 / 9 (0.00%)	1 / 23 (4.35%)
occurrences (all)	1	0	1
infusion site reaction			

<p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 64 (0.00%)</p> <p>0</p>	<p>1 / 9 (11.11%)</p> <p>2</p>	<p>0 / 23 (0.00%)</p> <p>0</p>
<p>injection site pain</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 64 (0.00%)</p> <p>0</p>	<p>0 / 9 (0.00%)</p> <p>0</p>	<p>1 / 23 (4.35%)</p> <p>1</p>
<p>injection site reaction</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 64 (0.00%)</p> <p>0</p>	<p>0 / 9 (0.00%)</p> <p>0</p>	<p>0 / 23 (0.00%)</p> <p>0</p>
<p>pyrexia</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 64 (1.56%)</p> <p>1</p>	<p>1 / 9 (11.11%)</p> <p>1</p>	<p>0 / 23 (0.00%)</p> <p>0</p>
<p>Reproductive system and breast disorders</p> <p>endometrial hyperplasia</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed^[4]</p> <p>occurrences (all)</p>	<p>0 / 30 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>1 / 12 (8.33%)</p> <p>1</p>
<p>endometriosis</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed^[5]</p> <p>occurrences (all)</p>	<p>0 / 30 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>1 / 12 (8.33%)</p> <p>1</p>
<p>Respiratory, thoracic and mediastinal disorders</p> <p>rhinorrhoea</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 64 (1.56%)</p> <p>1</p>	<p>0 / 9 (0.00%)</p> <p>0</p>	<p>2 / 23 (8.70%)</p> <p>2</p>
<p>sinus congestion</p> <p>alternative dictionary used: MedDRA 23.0</p>			

Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.

Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.

subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 9 (0.00%) 0	0 / 23 (0.00%) 0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 9 (0.00%) 0	0 / 23 (0.00%) 0
depression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 9 (0.00%) 0	0 / 23 (0.00%) 0
insomnia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 9 (0.00%) 0	0 / 23 (0.00%) 0
irritability			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 9 (0.00%) 0	0 / 23 (0.00%) 0
panic attack			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 9 (0.00%) 0	0 / 23 (0.00%) 0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed occurrences (all)	1 / 64 (1.56%) 1	0 / 9 (0.00%) 0	0 / 23 (0.00%) 0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed occurrences (all)	1 / 64 (1.56%) 1	0 / 9 (0.00%) 0	0 / 23 (0.00%) 0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 23.0			

<p>subjects affected / exposed occurrences (all)</p> <p>weight increased alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p>	<p>0 / 64 (0.00%) 0</p> <p>3 / 64 (4.69%) 3</p>	<p>0 / 9 (0.00%) 0</p> <p>1 / 9 (11.11%) 1</p>	<p>0 / 23 (0.00%) 0</p> <p>1 / 23 (4.35%) 1</p>
<p>Injury, poisoning and procedural complications skin laceration alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p>	<p>0 / 64 (0.00%) 0</p>	<p>0 / 9 (0.00%) 0</p>	<p>0 / 23 (0.00%) 0</p>
<p>Nervous system disorders headache alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p> <p>hypoaesthesia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p>	<p>7 / 64 (10.94%) 7</p> <p>1 / 64 (1.56%) 1</p>	<p>0 / 9 (0.00%) 0</p> <p>0 / 9 (0.00%) 0</p>	<p>3 / 23 (13.04%) 4</p> <p>0 / 23 (0.00%) 0</p>
<p>Blood and lymphatic system disorders anaemia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p>	<p>2 / 64 (3.13%) 2</p>	<p>1 / 9 (11.11%) 1</p>	<p>1 / 23 (4.35%) 2</p>
<p>Eye disorders lacrimation increased alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p>	<p>0 / 64 (0.00%) 0</p>	<p>0 / 9 (0.00%) 0</p>	<p>1 / 23 (4.35%) 1</p>
<p>Gastrointestinal disorders abdominal distension alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p> <p>abdominal pain</p>	<p>1 / 64 (1.56%) 1</p>	<p>0 / 9 (0.00%) 0</p>	<p>1 / 23 (4.35%) 1</p>

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	1 / 9 (11.11%)	2 / 23 (8.70%)
occurrences (all)	0	1	2
anal incontinence			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
crohn's disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
diarrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 64 (3.13%)	0 / 9 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
flatulence			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 64 (1.56%)	0 / 9 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
haemorrhoids			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
intestinal obstruction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 64 (3.13%)	0 / 9 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
rectal polyp			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	1 / 9 (11.11%) 1	0 / 23 (0.00%) 0
Endocrine disorders hypothyroidism alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 9 (0.00%) 0	0 / 23 (0.00%) 0
Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all) joint stiffness alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all) myalgia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	3 / 64 (4.69%) 3 0 / 64 (0.00%) 0 0 / 64 (0.00%) 0	1 / 9 (11.11%) 1 0 / 9 (0.00%) 0 1 / 9 (11.11%) 1	1 / 23 (4.35%) 1 0 / 23 (0.00%) 0 0 / 23 (0.00%) 0
Infections and infestations cystitis alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 9 (0.00%) 0	0 / 23 (0.00%) 0
epididymitis alternative dictionary used: MedDRA 23.0 subjects affected / exposed ^[6] occurrences (all)	0 / 34 (0.00%) 0	0 / 5 (0.00%) 0	1 / 11 (9.09%) 2
erysipelas alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	1 / 9 (11.11%) 1	0 / 23 (0.00%) 0
gastroenteritis viral			

Additional description: Follow-up Period:200 mg Mirikizumab IV Q4W in Period 2;1000 mg Mirikizumab IV Q4W in Period 2 (NI);1000 mg Mirkizumab IV Q4W in Period 2 (PBO)=Subjects exposed number=0.However,due to EudraCT database constraint we have included all the participants

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	1 / 9 (11.11%)	1 / 23 (4.35%)
occurrences (all)	0	1	1
human anaplasmosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 64 (6.25%)	0 / 9 (0.00%)	2 / 23 (8.70%)
occurrences (all)	4	0	2
respiratory tract infection viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 64 (3.13%)	1 / 9 (11.11%)	1 / 23 (4.35%)
occurrences (all)	2	1	1
urinary tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 9 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
vulvovaginal mycotic infection	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed ^[7] occurrences (all)	0 / 30 (0.00%) 0	0 / 4 (0.00%) 0	0 / 12 (0.00%) 0
Metabolism and nutrition disorders vitamin d deficiency alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 64 (0.00%) 0	0 / 9 (0.00%) 0	0 / 23 (0.00%) 0

Non-serious adverse events	Period 2: 600 mg Mirikizumab IV Q4W	Period 2: 300mg Mirikizumab Subcutaneous (SC) Q4W	Period 2: 1000 mg Mirikizumab IV Q4W (NI)
Total subjects affected by non-serious adverse events subjects affected / exposed	5 / 9 (55.56%)	30 / 46 (65.22%)	16 / 30 (53.33%)
Vascular disorders hypertension alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	3 / 46 (6.52%) 3	0 / 30 (0.00%) 0
General disorders and administration site conditions fatigue alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 46 (2.17%) 1	0 / 30 (0.00%) 0
infusion site reaction alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 46 (0.00%) 0	0 / 30 (0.00%) 0
injection site pain alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 15	4 / 46 (8.70%) 64	1 / 30 (3.33%) 7
injection site reaction alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 4	3 / 46 (6.52%) 4	0 / 30 (0.00%) 0
pyrexia alternative dictionary used:			

MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	2 / 46 (4.35%)	2 / 30 (6.67%)
occurrences (all)	0	2	2
Reproductive system and breast disorders			
endometrial hyperplasia	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[4]	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
endometriosis	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[5]	0 / 4 (0.00%)	0 / 23 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
rhinorrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	1 / 46 (2.17%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
sinus congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
depression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 9 (11.11%)	1 / 46 (2.17%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
insomnia			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	2 / 46 (4.35%) 2	1 / 30 (3.33%) 1
irritability alternative dictionary used: MedDRA 23.0			
subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 46 (0.00%) 0	0 / 30 (0.00%) 0
panic attack alternative dictionary used: MedDRA 23.0			
subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 46 (0.00%) 0	0 / 30 (0.00%) 0
Investigations			
alanine aminotransferase increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	3 / 46 (6.52%) 3	0 / 30 (0.00%) 0
aspartate aminotransferase increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	2 / 46 (4.35%) 2	0 / 30 (0.00%) 0
blood creatine phosphokinase increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 46 (2.17%) 1	1 / 30 (3.33%) 1
weight increased alternative dictionary used: MedDRA 23.0			
subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	2 / 46 (4.35%) 3	1 / 30 (3.33%) 1
Injury, poisoning and procedural complications			
skin laceration alternative dictionary used: MedDRA 23.0			
subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 46 (0.00%) 0	1 / 30 (3.33%) 1
Nervous system disorders			

<p>headache</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 9 (0.00%)</p> <p>0</p>	<p>4 / 46 (8.70%)</p> <p>4</p>	<p>3 / 30 (10.00%)</p> <p>4</p>
<p>hypoesthesia</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 9 (0.00%)</p> <p>0</p>	<p>1 / 46 (2.17%)</p> <p>1</p>	<p>0 / 30 (0.00%)</p> <p>0</p>
<p>Blood and lymphatic system disorders</p> <p>anaemia</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 9 (0.00%)</p> <p>0</p>	<p>2 / 46 (4.35%)</p> <p>2</p>	<p>2 / 30 (6.67%)</p> <p>2</p>
<p>Eye disorders</p> <p>lacrimation increased</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 9 (11.11%)</p> <p>1</p>	<p>0 / 46 (0.00%)</p> <p>0</p>	<p>0 / 30 (0.00%)</p> <p>0</p>
<p>Gastrointestinal disorders</p> <p>abdominal distension</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>abdominal pain</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>anal incontinence</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>crohn's disease</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>diarrhoea</p>	<p>0 / 9 (0.00%)</p> <p>0</p> <p>0 / 9 (0.00%)</p> <p>0</p> <p>1 / 9 (11.11%)</p> <p>1</p> <p>0 / 9 (0.00%)</p> <p>0</p>	<p>3 / 46 (6.52%)</p> <p>3</p> <p>3 / 46 (6.52%)</p> <p>3</p> <p>0 / 46 (0.00%)</p> <p>0</p> <p>3 / 46 (6.52%)</p> <p>3</p>	<p>0 / 30 (0.00%)</p> <p>0</p>

<p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 9 (11.11%)</p> <p>1</p>	<p>3 / 46 (6.52%)</p> <p>3</p>	<p>1 / 30 (3.33%)</p> <p>1</p>
<p>flatulence</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 9 (11.11%)</p> <p>1</p>	<p>0 / 46 (0.00%)</p> <p>0</p>	<p>0 / 30 (0.00%)</p> <p>0</p>
<p>haemorrhoids</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 9 (11.11%)</p> <p>1</p>	<p>1 / 46 (2.17%)</p> <p>1</p>	<p>1 / 30 (3.33%)</p> <p>1</p>
<p>intestinal obstruction</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 9 (11.11%)</p> <p>1</p>	<p>0 / 46 (0.00%)</p> <p>0</p>	<p>0 / 30 (0.00%)</p> <p>0</p>
<p>nausea</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 9 (0.00%)</p> <p>0</p>	<p>0 / 46 (0.00%)</p> <p>0</p>	<p>1 / 30 (3.33%)</p> <p>2</p>
<p>rectal polyp</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 9 (0.00%)</p> <p>0</p>	<p>0 / 46 (0.00%)</p> <p>0</p>	<p>0 / 30 (0.00%)</p> <p>0</p>
<p>Endocrine disorders</p> <p>hypothyroidism</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 9 (11.11%)</p> <p>1</p>	<p>0 / 46 (0.00%)</p> <p>0</p>	<p>0 / 30 (0.00%)</p> <p>0</p>
<p>Musculoskeletal and connective tissue disorders</p> <p>arthralgia</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>joint stiffness</p> <p>alternative dictionary used:</p>	<p>1 / 9 (11.11%)</p> <p>1</p>	<p>6 / 46 (13.04%)</p> <p>6</p>	<p>1 / 30 (3.33%)</p> <p>1</p>

MedDRA 23.0			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
myalgia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
cystitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
epididymitis	Additional description: Follow-up Period:200 mg Mirikizumab IV Q4W in Period 2;1000 mg Mirikizumab IV Q4W in Period 2 (NI);1000 mg Mirkizumab IV Q4W in Period 2 (PBO)=Subjects exposed number=0.However,due to EudraCT database constraint we have included all the participants		
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[6]	0 / 5 (0.00%)	0 / 23 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
erysipelas			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 9 (0.00%)	0 / 46 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
gastroenteritis viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	1 / 30 (3.33%)
occurrences (all)	1	0	1
human anaplasmosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 9 (11.11%)	0 / 46 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
influenza			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 9 (11.11%)	1 / 46 (2.17%)	1 / 30 (3.33%)
occurrences (all)	1	1	1
nasopharyngitis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	6 / 46 (13.04%) 7	3 / 30 (10.00%) 3
respiratory tract infection viral alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 46 (2.17%) 1	0 / 30 (0.00%) 0
sinusitis alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 46 (2.17%) 1	1 / 30 (3.33%) 1
upper respiratory tract infection alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	3 / 46 (6.52%) 4	2 / 30 (6.67%) 2
urinary tract infection alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 46 (2.17%) 1	1 / 30 (3.33%) 1
vulvovaginal mycotic infection alternative dictionary used: MedDRA 23.0 subjects affected / exposed ^[7] occurrences (all)	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
	1 / 4 (25.00%) 1	0 / 23 (0.00%) 0	0 / 13 (0.00%) 0
Metabolism and nutrition disorders vitamin d deficiency alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 46 (0.00%) 0	2 / 30 (6.67%) 2

Non-serious adverse events	Period 2: 1000 mg Mirikizumab IV Q4W (PBO)	Period 3: 300 mg Mirikizumab SC Q4W	Follow-up Period: 200 mg Mirikizumab IV Q4W in Period 2
Total subjects affected by non-serious adverse events subjects affected / exposed	30 / 59 (50.85%)	89 / 136 (65.44%)	0 / 1 (0.00%)
Vascular disorders hypertension alternative dictionary used: MedDRA 23.0			

subjects affected / exposed occurrences (all)	2 / 59 (3.39%) 2	11 / 136 (8.09%) 12	0 / 1 (0.00%) 0
General disorders and administration site conditions			
fatigue alternative dictionary used: MedDRA 23.0			
subjects affected / exposed occurrences (all)	4 / 59 (6.78%) 4	7 / 136 (5.15%) 7	0 / 1 (0.00%) 0
infusion site reaction alternative dictionary used: MedDRA 23.0			
subjects affected / exposed occurrences (all)	0 / 59 (0.00%) 0	0 / 136 (0.00%) 0	0 / 1 (0.00%) 0
injection site pain alternative dictionary used: MedDRA 23.0			
subjects affected / exposed occurrences (all)	3 / 59 (5.08%) 16	8 / 136 (5.88%) 162	0 / 1 (0.00%) 0
injection site reaction alternative dictionary used: MedDRA 23.0			
subjects affected / exposed occurrences (all)	1 / 59 (1.69%) 2	18 / 136 (13.24%) 114	0 / 1 (0.00%) 0
pyrexia alternative dictionary used: MedDRA 23.0			
subjects affected / exposed occurrences (all)	1 / 59 (1.69%) 1	6 / 136 (4.41%) 6	0 / 1 (0.00%) 0
Reproductive system and breast disorders			
endometrial hyperplasia alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[4] occurrences (all)	0 / 33 (0.00%) 0	0 / 61 (0.00%) 0	0 / 1 (0.00%) 0
endometriosis alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[5] occurrences (all)	0 / 33 (0.00%) 0	0 / 61 (0.00%) 0	0 / 1 (0.00%) 0
Respiratory, thoracic and mediastinal			

disorders			
rhinorrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	3 / 136 (2.21%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
sinus congestion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	0 / 136 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 59 (3.39%)	2 / 136 (1.47%)	0 / 1 (0.00%)
occurrences (all)	3	2	0
depression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 59 (1.69%)	1 / 136 (0.74%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
insomnia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	2 / 136 (1.47%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
irritability			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	0 / 136 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
panic attack			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	0 / 136 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 59 (3.39%)	8 / 136 (5.88%)	0 / 1 (0.00%)
occurrences (all)	2	10	0
aspartate aminotransferase			

<p>increased</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 59 (1.69%)</p> <p>1</p>	<p>3 / 136 (2.21%)</p> <p>3</p>	<p>0 / 1 (0.00%)</p> <p>0</p>
<p>blood creatine phosphokinase increased</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>2 / 59 (3.39%)</p> <p>2</p>	<p>7 / 136 (5.15%)</p> <p>7</p>	<p>0 / 1 (0.00%)</p> <p>0</p>
<p>weight increased</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>2 / 59 (3.39%)</p> <p>4</p>	<p>5 / 136 (3.68%)</p> <p>5</p>	<p>0 / 1 (0.00%)</p> <p>0</p>
<p>Injury, poisoning and procedural complications</p> <p>skin laceration</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 59 (0.00%)</p> <p>0</p>	<p>1 / 136 (0.74%)</p> <p>1</p>	<p>0 / 1 (0.00%)</p> <p>0</p>
<p>Nervous system disorders</p> <p>headache</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>hypoaesthesia</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>4 / 59 (6.78%)</p> <p>4</p> <p>3 / 59 (5.08%)</p> <p>3</p>	<p>16 / 136 (11.76%)</p> <p>30</p> <p>1 / 136 (0.74%)</p> <p>1</p>	<p>0 / 1 (0.00%)</p> <p>0</p> <p>0 / 1 (0.00%)</p> <p>0</p>
<p>Blood and lymphatic system disorders</p> <p>anaemia</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>5 / 59 (8.47%)</p> <p>6</p>	<p>7 / 136 (5.15%)</p> <p>8</p>	<p>0 / 1 (0.00%)</p> <p>0</p>
<p>Eye disorders</p> <p>lacrimation increased</p> <p>alternative dictionary used: MedDRA 23.0</p>			

subjects affected / exposed occurrences (all)	0 / 59 (0.00%) 0	0 / 136 (0.00%) 0	0 / 1 (0.00%) 0
Gastrointestinal disorders			
abdominal distension alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 59 (0.00%) 0	1 / 136 (0.74%) 1	0 / 1 (0.00%) 0
abdominal pain alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	3 / 59 (5.08%) 3	8 / 136 (5.88%) 10	0 / 1 (0.00%) 0
anal incontinence alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 59 (0.00%) 0	2 / 136 (1.47%) 2	0 / 1 (0.00%) 0
crohn's disease alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	1 / 59 (1.69%) 1	8 / 136 (5.88%) 10	0 / 1 (0.00%) 0
diarrhoea alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 59 (0.00%) 0	6 / 136 (4.41%) 7	0 / 1 (0.00%) 0
flatulence alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 59 (0.00%) 0	0 / 136 (0.00%) 0	0 / 1 (0.00%) 0
haemorrhoids alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	1 / 59 (1.69%) 1	1 / 136 (0.74%) 1	0 / 1 (0.00%) 0
intestinal obstruction alternative dictionary used: MedDRA 23.0			

<p>subjects affected / exposed occurrences (all)</p> <p>nausea alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p> <p>rectal polyp alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p>	<p>0 / 59 (0.00%) 0</p> <p>3 / 59 (5.08%) 3</p> <p>1 / 59 (1.69%) 1</p>	<p>0 / 136 (0.00%) 0</p> <p>6 / 136 (4.41%) 8</p> <p>0 / 136 (0.00%) 0</p>	<p>0 / 1 (0.00%) 0</p> <p>0 / 1 (0.00%) 0</p> <p>0 / 1 (0.00%) 0</p>
<p>Endocrine disorders hypothyroidism alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p>	<p>0 / 59 (0.00%) 0</p>	<p>1 / 136 (0.74%) 1</p>	<p>0 / 1 (0.00%) 0</p>
<p>Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p> <p>joint stiffness alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p> <p>myalgia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p>	<p>3 / 59 (5.08%) 4</p> <p>0 / 59 (0.00%) 0</p> <p>0 / 59 (0.00%) 0</p>	<p>8 / 136 (5.88%) 9</p> <p>0 / 136 (0.00%) 0</p> <p>0 / 136 (0.00%) 0</p>	<p>0 / 1 (0.00%) 0</p> <p>0 / 1 (0.00%) 0</p> <p>0 / 1 (0.00%) 0</p>
<p>Infections and infestations cystitis alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p> <p>epididymitis</p>	<p>0 / 59 (0.00%) 0</p>	<p>2 / 136 (1.47%) 2</p>	<p>0 / 1 (0.00%) 0</p>
<p>Additional description: Follow-up Period:200 mg Mirikizumab IV Q4W in Period 2;1000 mg Mirikizumab IV Q4W in Period 2 (NI);1000 mg Mirkizumab IV Q4W in Period 2 (PBO)=Subjects exposed number=0.However,due to EudraCT database constraint we have included all the participants</p>			

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[6]	0 / 26 (0.00%)	0 / 75 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
erysipelas			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 59 (1.69%)	1 / 136 (0.74%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
gastroenteritis viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 59 (1.69%)	1 / 136 (0.74%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
human anaplasmosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 59 (0.00%)	0 / 136 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 59 (1.69%)	5 / 136 (3.68%)	0 / 1 (0.00%)
occurrences (all)	1	5	0
nasopharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 59 (6.78%)	25 / 136 (18.38%)	0 / 1 (0.00%)
occurrences (all)	6	33	0
respiratory tract infection viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 59 (1.69%)	2 / 136 (1.47%)	0 / 1 (0.00%)
occurrences (all)	1	2	0
sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 59 (5.08%)	5 / 136 (3.68%)	0 / 1 (0.00%)
occurrences (all)	3	8	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed occurrences (all)	3 / 59 (5.08%) 3	14 / 136 (10.29%) 18	0 / 1 (0.00%) 0
urinary tract infection alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	3 / 59 (5.08%) 3	1 / 136 (0.74%) 1	0 / 1 (0.00%) 0
vulvovaginal mycotic infection alternative dictionary used: MedDRA 23.0 subjects affected / exposed ^[7] occurrences (all)	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
	2 / 33 (6.06%) 2	2 / 61 (3.28%) 2	0 / 1 (0.00%) 0
Metabolism and nutrition disorders vitamin d deficiency alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 59 (0.00%) 0	0 / 136 (0.00%) 0	0 / 1 (0.00%) 0

Non-serious adverse events	Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv)	Follow-up Period: 1000 mg Mirikizumab IV Q4W in Period 2 (NI)	Follow-up Period: 1000 mg Mirikizumab IV Q4W in Period 2 (PBO)
Total subjects affected by non-serious adverse events subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	0 / 1 (0.00%)
Vascular disorders hypertension alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
General disorders and administration site conditions fatigue alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
infusion site reaction alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
injection site pain			

alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
injection site reaction alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
pyrexia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Reproductive system and breast disorders			
endometrial hyperplasia alternative dictionary used: MedDRA 23.0 subjects affected / exposed ^[4] occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
endometriosis alternative dictionary used: MedDRA 23.0 subjects affected / exposed ^[5] occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
rhinorrhoea alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
sinus congestion alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Psychiatric disorders			
anxiety alternative dictionary used: MedDRA 23.0			

Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.

Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
depression			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
irritability			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
panic attack			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Injury, poisoning and procedural complications skin laceration alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Nervous system disorders headache alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all) hypoesthesia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0 0 / 2 (0.00%) 0	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0
Blood and lymphatic system disorders anaemia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Eye disorders lacrimation increased alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Gastrointestinal disorders abdominal distension alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all) abdominal pain alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all) anal incontinence	0 / 2 (0.00%) 0 0 / 2 (0.00%) 0	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
crohn's disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
diarrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
flatulence			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
haemorrhoids			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
intestinal obstruction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
rectal polyp			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
hypothyroidism			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Musculoskeletal and connective tissue disorders			
arthralgia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
joint stiffness alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
myalgia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Infections and infestations			
cystitis alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
epididymitis	Additional description: Follow-up Period:200 mg Mirikizumab IV Q4W in Period 2;1000 mg Mirikizumab IV Q4W in Period 2 (NI);1000 mg Mirkizumab IV Q4W in Period 2 (PBO)=Subjects exposed number=0.However,due to EudraCT database constraint we have included all the participants		
alternative dictionary used: MedDRA 23.0 subjects affected / exposed ^[6] occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
erysipelas alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
gastroenteritis viral alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
human anaplasmosis alternative dictionary used:			

MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
respiratory tract infection viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
sinusitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
vulvovaginal mycotic infection	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[7]	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
vitamin d deficiency			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Follow-up Period: 300 mg Mirikizumab SC Q4W in Period 3		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)		
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
infusion site reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
injection site pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
injection site reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
pyrexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			

endometrial hyperplasia	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
alternative dictionary used: MedDRA 23.0 subjects affected / exposed ^[4] occurrences (all)	0 / 1 (0.00%) 0		
endometriosis	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.		
alternative dictionary used: MedDRA 23.0 subjects affected / exposed ^[5] occurrences (all)	0 / 1 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders			
rhinorrhoea alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
sinus congestion alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Psychiatric disorders			
anxiety alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
depression alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
insomnia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
irritability alternative dictionary used: MedDRA 23.0			

<p>subjects affected / exposed occurrences (all)</p> <p>panic attack alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p>	<p>0 / 3 (0.00%) 0</p> <p>0 / 3 (0.00%) 0</p>		
<p>Investigations</p> <p>alanine aminotransferase increased alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p> <p>aspartate aminotransferase increased alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p> <p>blood creatine phosphokinase increased alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p> <p>weight increased alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p>	<p>0 / 3 (0.00%) 0</p> <p>0 / 3 (0.00%) 0</p> <p>0 / 3 (0.00%) 0</p> <p>0 / 3 (0.00%) 0</p>		
<p>Injury, poisoning and procedural complications</p> <p>skin laceration alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p>	<p>0 / 3 (0.00%) 0</p>		
<p>Nervous system disorders</p> <p>headache alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)</p> <p>hypoesthesia</p>	<p>0 / 3 (0.00%) 0</p>		

<p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>		
<p>Blood and lymphatic system disorders</p> <p>anaemia</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>		
<p>Eye disorders</p> <p>lacrimation increased</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>		
<p>Gastrointestinal disorders</p> <p>abdominal distension</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>abdominal pain</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>anal incontinence</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>crohn's disease</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>diarrhoea</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>flatulence</p>	<p>0 / 3 (0.00%)</p> <p>0</p>		

<p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed occurrences (all)</p> <p>0 / 3 (0.00%) 0</p> <p>haemorrhoids</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed occurrences (all)</p> <p>0 / 3 (0.00%) 0</p> <p>intestinal obstruction</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed occurrences (all)</p> <p>0 / 3 (0.00%) 0</p> <p>nausea</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed occurrences (all)</p> <p>0 / 3 (0.00%) 0</p> <p>rectal polyp</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed occurrences (all)</p> <p>0 / 3 (0.00%) 0</p>			
<p>Endocrine disorders</p> <p>hypothyroidism</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed occurrences (all)</p> <p>0 / 3 (0.00%) 0</p>			
<p>Musculoskeletal and connective tissue disorders</p> <p>arthralgia</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed occurrences (all)</p> <p>0 / 3 (0.00%) 0</p> <p>joint stiffness</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed occurrences (all)</p> <p>0 / 3 (0.00%) 0</p> <p>myalgia</p> <p>alternative dictionary used:</p>			

MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Infections and infestations			
cystitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
epididymitis	Additional description: Follow-up Period:200 mg Mirikizumab IV Q4W in Period 2;1000 mg Mirikizumab IV Q4W in Period 2 (NI);1000 mg Mirkizumab IV Q4W in Period 2 (PBO)=Subjects exposed number=0.However,due to EudraCT database constraint we have included all the participants		
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed ^[6]	0 / 2 (0.00%)		
occurrences (all)	0		
erysipelas			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
gastroenteritis viral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
human anaplasmosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
influenza			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
nasopharyngitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
respiratory tract infection viral			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
sinusitis alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
upper respiratory tract infection alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
urinary tract infection alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
vulvovaginal mycotic infection alternative dictionary used: MedDRA 23.0 subjects affected / exposed ^[7] occurrences (all)	0 / 1 (0.00%) 0	Additional description: Follow-up Period:1000 mg Mirikizumab IV Q4W in Period 2 (Impv) = Subjects exposed number = 0. However, due to EudraCT database constraint we have included all the participants for this arm.	
Metabolism and nutrition disorders vitamin d deficiency alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		

Notes:

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender specific events occurring only in male or female participants have had the number of participants at risk adjusted accordingly.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender specific events occurring only in male or female participants have had the number of participants at risk adjusted accordingly.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender specific events occurring only in male or female participants have had the number of participants at risk adjusted accordingly.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender specific events occurring only in male or female participants have had the number of participants at risk adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 July 2016	- Added, modified or deleted major secondary and other secondary objectives and endpoints; - Updated power calculations and window for schedule of activities; - Clarification of the participant for whom follicle-stimulating hormone (FSH) should be performed; - Clarification to be consistent with management of hypersensitivity and infusion-related event section; - Clarification of definition of normal stool frequency for the modified Mayo score to participants entering the study; -Clarification of inclusion and exclusion criteria; - Clarification of safety criteria for drug discontinuation.
21 November 2017	-Increased duration of all IV study drug administration to 2 hours; - Addition of a 1-hour post infusion observation period to allow adequate evaluation of potential hypersensitivity or infusion related reactions; Clarification added that patients who experience serious adverse reactions and clarification comment and correction on schedule of activities; - Clarification added that the intent of the treatment regimens is to keep the dosing within the visit windows and as close to every 4 weeks as possible.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported