Clinical trial results:
A randomized, parallel-group, double-blind, placebo-controlled, multicenter phase 2 trial to investigate the safety and efficacy of secukinumab (AIN457) in patients with giant cell arteritis

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use https://www.novctrd.com/CtrdWeb/home.nov for complete trial results.

Summary

EudraCT number	2018-002610-12
Trial protocol	DE
Global end of trial date	08 June 2021

Results information

Result version number	v2 (current)
This version publication date	15 June 2023
First version publication date	19 June 2022
Version creation reason	• Correction of full data set Updates: change in endpoint title (endpoint #6), change in Week 4 Physical Functioning data and endpoint description (endpoint #10), change in number of subjects analyzed: Endpoints # 7 - 11).

Trial information

Trial identification

Sponsor protocol code	CAIN457ADE11C

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03765788
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma, AG
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma, AG, +41 613241111, novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma, AG, +41 613241111, novartis.email@novartis.com

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	08 June 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	08 June 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of secukinumab compared to placebo, in combination with a 26-week prednisolone taper regimen, based on the proportion of patients with giant cell arteritis (GCA) who had sustained remission.
- Definition of remission: Absence of flare.
- Definition of sustained remission: Patients without flare until Week 28 and in adherence to the protocol prednisolone taper regimen.
- Definition of flare: Determined by the investigator and defined as the recurrence after remission of signs or symptoms of GCA and/or erythrocyte sedimentation rate (ESR) ≥ 30 mm/hr and/or C-reactive protein (CRP) ≥ 10 mg/L attributable to GCA.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 January 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 52
Worldwide total number of subjects	52
EEA total number of subjects	52

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)	9
From 65 to 84 years	42
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Participants took part in 11 investigative sites in 1 country.

Pre-assignment

Screening details:

The screening period began once patients had signed the study informed consent. Screening evaluations were performed up to 6 weeks before the beginning of the Treatment period.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Secukinumab

Arm description:

Participants received secukinumab at a dose of 300 milligrams (mg) as subcutaneous (s.c.) injection at Baseline, Week 1,2,3,4 and then every 4 weeks thereafter through to week 48 along with a 26-week prednisolone tapering regimen.

Arm type	Experimental
Investigational medicinal product name	prednisolone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Provided as tablets (1 mg, 5 mg, 10 mg, 20 mg tablets) for daily administration as tapered regimen from a dose of 25 mg to 60 mg at Baseline to 1 mg at Week 26 (last dose)

Investigational medicinal product name	Secukinumab
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

secukinumab 300 mg (2 injections of 150 mg) provided in 2 x 1.0 mL Prefilled syringe (PFS) weekly from Week 0 to 4 then every 4 weeks from Week 4 to Week 48

Arm title	Placebo

Arm description:

Participants received placebo as subcutaneous (s.c.) injection at Baseline, Week 1,2,3,4 and then every 4 weeks thereafter through to week 48 along with a 26-week prednisolone tapering regimen.

Arm type	Placebo
Investigational medicinal product name	Secukinumab Placebo
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Secukinumab placebo 300 mg (2 injections of 150 mg) provided in 2 x 1.0 mL Prefilled syringe (PFS) weekly from Week 0 to 4 then every 4 weeks from Week 4 to Week 48

Investigational medicinal product name	prednisolone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Provided as tablets (1 mg, 5 mg, 10 mg, 20 mg tablets) for daily administration as tapered regimen from a dose of 25 mg to 60 mg at Baseline to 1 mg at Week 26 (last dose)

Number of subjects in period 1	Secukinumab	Placebo
Started	27	25
Completed	22	17
Not completed	5	8
Adverse event, serious fatal	-	1
Physician decision	2	4
Subject decision	2	3
Lost to follow-up	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Secukinumab
Reporting group description:	
Participants received secukinumab at a dose of 300 milligrams (mg) as subcutaneous (s.c.) injection at Baseline, Week 1,2,3,4 and then every 4 weeks thereafter through to week 48 along with a 26-week prednisolone tapering regimen.	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo as subcutaneous (s.c.) injection at Baseline, Week 1,2,3,4 and then every 4 weeks thereafter through to week 48 along with a 26-week prednisolone tapering regimen.	

Reporting group values	Secukinumab	Placebo	Total
Number of subjects	27	25	52
Age categorical Units: Subjects			
Adults (18-64 years)	0	9	9
From 65-84 years	26	16	42
85 years and over	1	0	1
Age Continuous Units: years			
arithmetic mean	76.4	69.6	
standard deviation	± 5.31	± 8.02	-
Sex: Female, Male Units: participants			
Female	17	18	35
Male	10	7	17
Race/Ethnicity, Customized Units: Subjects			
White	27	25	52

End points

End points reporting groups

Reporting group title	Secukinumab
Reporting group description:	
Participants received secukinumab at a dose of 300 milligrams (mg) as subcutaneous (s.c.) injection at Baseline, Week 1,2,3,4 and then every 4 weeks thereafter through to week 48 along with a 26-week prednisolone tapering regimen.	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo as subcutaneous (s.c.) injection at Baseline, Week 1,2,3,4 and then every 4 weeks thereafter through to week 48 along with a 26-week prednisolone tapering regimen.	

Primary: Percentage of participants in sustained remission until Week 28

End point title	Percentage of participants in sustained remission until Week 28
End point description:	
Remission was defined as the absence of flare. Sustained remission was defined as the absence of flare until Week 28 and in adherence to the protocol prednisolone taper regimen. Flare was determined by the investigator and was defined as the recurrence after remission of signs or symptoms of Giant Cell Arteritis (GCA) and/or erythrocyte sedimentation rate (ESR) greater than or equal to (>/=) 30 millimeters per hour (mm/hr) and/or C-reactive Protein (CRP) (>/=10.0 mg/L) attributable to GCA. Patients were classified as non-responders if they did not achieve remission within 12 weeks of Baseline (remission referred to the absence of flare), were in the "escape arm" (this referred to patients entering escape between Baseline and Week 28), prematurely discontinued study treatment prior to Week 28 (absence of flare was checked prior to study treatment administration), did not have information to evaluate sustained remission response until Week 28.	
End point type	Primary
End point timeframe:	
Until week 28	

End point values	Secukinumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	25		
Units: Participants	19	6		

Statistical analyses

Statistical analysis title	Sustained Remission until week 28
Statistical analysis description:	
Odds Ratio	
Comparison groups	Secukinumab v Placebo

Number of subjects included in analysis	52
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Odds ratio (OR)
Point estimate	9.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.54
upper limit	26.29

Secondary: Percentage of participants in remission at Week 12

End point title	Percentage of participants in remission at Week 12

End point description:

Remission was defined as the absence of flare.
Sustained remission was defined as the absence of flare until Week 28 and in adherence to the protocol prednisolone taper Regimen.
Flare was determined by the investigator and was defined as the recurrence after remission of signs or symptoms of GCA and/or erythrocyte sedimentation rate (ESR) greater than or equal to (>/=) 30 millimeters per hour (mm/hr) and/or CRP (>/=10.0 mg/L) attributable to GCA.
Patients were classified as non-responders if they did not achieve remission within 12 weeks of Baseline (remission referred to the absence of flare), were in the "escape arm" (this referred to patients entering escape between Baseline and Week 28), prematurely discontinued study treatment prior to Week 28 (absence of flare was checked prior to study treatment administration), did not have information to evaluate sustained remission response until Week 28.

End point type	Secondary

End point timeframe:

Week 12

End point values	Secukinumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	25		
Units: Participants	22	12		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to first GCA flare after clinical remission

End point title	Time to first GCA flare after clinical remission

End point description:

Flare was determined by the investigator and was defined as the recurrence after remission of signs or symptoms of GCA and/or erythrocyte sedimentation rate (ESR) greater than or equal to (>/=) 30 millimeters per hour (mm/hr) and/or CRP (>/=10.0 mg/L) attributable to GCA. Time to first flare after remission referred to time from first day of study treatment until first post-Baseline flare.
For time to first GCA flare after remission (up to and including Week 52), patients who prematurely discontinued study treatment prior to Week 52 were censored at the time of premature discontinuation and patients who completed treatment and did not have a flare were censored at their last visit in the

treatment phase.
Time to first GCA flare after remission was calculated using Kaplan-Meier plot of time.

End point type	Secondary

End point timeframe:

Up to Week 52 (included)

End point values	Secukinumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	25		
Units: days				
median (confidence interval 95%)	999 (999 to 999)	197.0 (101.0 to 280.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Total cumulative prednisolone dose over 28 weeks and 52 weeks

End point title	Total cumulative prednisolone dose over 28 weeks and 52 weeks

End point description:

Total cumulative co-administered prednisolone treatment was summarized over time by treatment arm. Patients received a daily dose of prednisolone, which was decreased (i.e. tapered down) from Baseline to Week 26. No additional prednisolone or equivalent was permitted.

End point type	Secondary

End point timeframe:

from Baseline to week 28, from baseline to week 52 weeks

End point values	Secukinumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	25		
Units: milligrams				
arithmetic mean (standard deviation)				
Baseline to Week 28	2689.70 (± 935.860)	2693.74 (± 1241.907)		
Baseline to Week 52	2841.26 (± 1116.192)	3375.58 (± 1720.978)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with GCA who had sustained remission until Week 52

End point title	Percentage of participants with GCA who had sustained remission until Week 52

End point description:

Remission was defined as the absence of flare. Sustained remission was defined as patients without flare until Week 52 and in adherence to the protocol prednisolone taper regimen plus prednisolone-free phase from Week 27 onwards. Flare was determined by the investigator and was defined as the recurrence after remission of signs or symptoms of GCA and/or erythrocyte sedimentation rate (ESR) greater than or equal to (>/=) 30 millimeters per hour (mm/hr) and/or CRP (>/=10.0 mg/L) attributable to GCA. Patients were classified as non-responders if they did not achieve remission within 12 weeks of Baseline (remission referred to the absence of flare), were in the "escape arm" (this referred to patients entering escape between Baseline and Week 28), prematurely discontinued study treatment prior to Week 28 (absence of flare was checked prior to study treatment administration), did not have information to evaluate sustained remission response until Week 28.

End point type	Secondary

End point timeframe:

Until Week 52

End point values	Secukinumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	25		
Units: Participants	16	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants on prednisolone dose ≤ 5mg/day

End point title	Number of participants on prednisolone dose ≤ 5mg/day

End point description:

Percentage of participants on co-administered prednisolone treatment ≤ 5mg/day who responded at Week 19, Week 26 and Week 52.
Remission was defined as the absence of flare.
Sustained remission was defined as the absence of flare until Week 28 and in adherence to the protocol prednisolone taper Regimen. There were 2 taper regimens: for patients on 40 to 60 mg/day prednisolone at Baseline and for patients on 25 to 40 mg/day prednisolone at Baseline depending on patients' prednisolone levels at Baseline. Prednisolone was tapered from a dose of 25 mg to 60 mg at Baseline to 1 mg at Week 26 [last dose].

End point type	Secondary

End point timeframe:

Week 19, Week 28, Week 52

End point values	Secukinumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	25		
Units: Participants				
Week 19 (n = 25, 20)	22	10		
Week 28 (n = 23, 20)	19	9		
Week 52 (n = 21, 17)	19	13		

Statistical analyses

No statistical analyses for this end point

Secondary: Physicians global assessment (PhGA) of disease activity: Change from Baseline Score via visual analogue scale (VAS)

End point title	Physicians global assessment (PhGA) of disease activity: Change from Baseline Score via visual analogue scale (VAS)

End point description:

Clinician Reported Outcome: Physicians global assessment (PhGA) using a visual analogue scale (VAS) scale. VAS is a range of scores from 0-100, with lower change from baseline scores indicating a more favorable outcome and higher change from baseline scores indicating a greater disease activity.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20, 24, 28, 36, 44 & 52

End point values	Secukinumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	23		
Units: scores on a scale				
arithmetic mean (standard error)				
Week 4 (n = 27, 23)	-4.8 (± 14.43)	-3.2 (± 18.45)		
Week 8 (n = 26, 21)	-5.8 (± 12.77)	2.1 (± 18.94)		
Week 12 (n = 25, 20)	-3.4 (± 21.93)	-3.1 (± 10.81)		
Week 16 (n = 25, 20)	-4.1 (± 15.62)	0.7 (± 13.97)		
Week 20 (n = 24, 20)	-6.9 (± 14.78)	-1.5 (± 14.32)		
Week 24 (n = 23, 20)	-4.3 (± 15.92)	2.2 (± 17.22)		
Week 28 (23, 19)	-5.4 (± 15.61)	3.9 (± 21.47)		
Week 36 (21, 19)	-8.7 (± 18.45)	0.7 (± 17.45)		
Week 44 (n = 21, 16)	-5.5 (± 16.87)	1.1 (± 15.20)		
Week 52 (n = 21, 16)	-9.5 (± 16.72)	4.0 (± 21.24)		

Statistical analyses

No statistical analyses for this end point

Secondary: Patients global assessment (PGA) of disease activity: Change from Baseline via visual analogue scale (VAS)

End point title	Patients global assessment (PGA) of disease activity: Change from Baseline via visual analogue scale (VAS)

End point description:

Patient Reported Outcome: Patients global assessment (PGA) score using a VAS scale. VAS is a range of scores from 0-100, with lower change from baseline scores indicating a more favorable outcome and higher change from baseline scores indicating a greater disease activity.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20, 24, 28, 36, 44 & 52

End point values	Secukinumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	23		
Units: scores on a scale				
arithmetic mean (standard deviation)				
Week 4 (n = 27, 23)	-15.8 (± 28.17)	-0.5 (± 23.58)		
Week 8 (n = 26, 21)	-15.8 (± 27.61)	-10.8 (± 27.64)		
Week 12 (n = 25, 20)	-8.0 (± 29.43)	-11.9 (± 31.46)		
Week 16 (n = 25, 20)	-18.6 (± 19.39)	-8.8 (± 31.43)		
Week 20 (n = 24, 20)	-19.18 (± 30.68)	-6.9 (± 31.94)		
Week 24 (n = 23, 20)	-14.9 (± 28.84)	-7.0 (± 30.61)		
Week 28 (n = 23, 19)	-14.4 (± 25.46)	-8.0 (± 31.31)		
Week 36 (n = 21, 19)	-20.9 (± 22.31)	-8.6 (± 29.90)		
Week 44 (n = 21, 16)	-21.7 (± 27.35)	-9.4 (± 30.58)		
Week 52 (n = 21, 16)	-19.2 (± 27.35)	-15.9 (± 24.04)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in FACIT-Fatigue scale

End point title	Change from Baseline in FACIT-Fatigue scale

End point description:

Patient Reported Outcome: Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue is a 13-item questionnaire with a full scale of 0 -52 that assesses self-reported fatigue and its impact upon daily activities and function. The higher the score the better functioning (less fatigue).

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20, 24, 28, 36, 44 & 52

End point values	Secukinumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	23		
Units: scores on a scale				
arithmetic mean (standard deviation)				
Week 4 (n = 27, 23)	2.11 (± 9.613)	-0.96 (± 7.358)		
Week 8 (n = 26, 21)	2.19 (± 10.190)	0.81 (± 7.498)		
Week 12 (n = 25, 20)	0.96 (± 11.175)	-0.25 (± 10.047)		
Week 16 (n = 25, 20)	2.12 (± 8.876)	-0.36 (± 8.884)		
Week 20 (n =24, 20)	3.42 (± 8.617)	0.05 (± 10.318)		
Week 24 (n = 23, 20)	2.91 (± 10.409)	-3.10 (± 11.281)		
Week 28 (n = 23, 19)	3.61 (± 11.044)	0.42 (± 9.203)		
Week 36 (n = 21, 19)	3.90 (± 7.245)	1.84 (± 8.719)		
Week 44 (n = 21, 16)	2.67 (± 5.986)	0.31 (± 10.928)		
Week 52 (n = 21, 16)	3.19 (± 7.033)	0.19 (± 8.848)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Short-Form (SF)-36 questionnaire

End point title	Change from Baseline in Short-Form (SF)-36 questionnaire

End point description:

Patient Reported Outcome: The SF-36 is a standardized questionnaire used to measure health-related quality of life among healthy patients and patients with acute and chronic conditions. It consists of 8 subscales that can be scored individually: Physical Functioning, Role-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional and Mental Health. 2 overall summary scores, the Physical Component Summary (PCS) and the Mental Component Summary (MCS) also can be computed. The higher the score (change from baseline) the more favorable the outcome. The values were evaluated as follows: -SF-36 domain scores: SF-36 domain score responders: Type I responders (improvement of ≥ 5 points in ≥ 6 domains); Type II responders (improvement of ≥ 10 points in ≥ 3 domains) -SF-36 PCS and MCS scores SF-36 PCS and MCS score responders: Type I responders (improvement of ≥ 2.5 points) Type II responders (improvement of ≥ 5 points

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20, 24, 28, 36, 44 & 52

End point values	Secukinumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	23		
Units: scores on a scale				
arithmetic mean (standard deviation)				
Week 4: Physical Functioning (PF) (n = 27, 23)	0.14 (± 7.562)	-1.25 (± 4.417)		
Week 8: PF (n = 26 ,21)	-0.44 (± 8.849)	0.18 (± 4.987)		
Week 12: PF (n = 25, 20)	0.38 (± 6.322)	-0.38 (± 8.750)		
Week 16: PF (n = 25, 20)	-0.00 (± 8.646)	-0.86 (± 6.814)		
Week 20: PF (n = 24, 20)	0.80 (± 8.098)	-0.10 (± 6.495)		
Week 24: PF (n = 22, 20)	0.52 (± 5.702)	-2.11 (± 8.667)		
Week 28: PF (n = 23, 19)	1.25 (± 5.276)	-0.40 (± 6.460)		
Week 36: PF (n = 21, 19)	1.37 (± 5.778)	-1.31 (± 6.631)		
Week 44: PF (n = 21, 16)	1.00 (± 6.674)	-0.36 (± 8.065)		
Week 52: PF (n = 21, 16)	2.46 (± 4.770)	0.12 (± 5.696)		
Week 4: Role-Physical (R-P) (n =27, 23)	3.49 (± 7.886)	0.49 (± 10.616)		
Week 8: R-P (n =26, 21)	3.80 (± 9.628)	-0.75 (± 10.515)		
Week 12: R-P (n = 25, 20)	3.32 (± 9.3301)	1.01 (± 9.539)		
Week 16: R-P (n = 25, 20)	4.58 (± 8.947)	-1.12 (± 8.847)		
Week 20: R-P (n = 24, 20)	4.40 (± 9.538)	-0.45 (± 8.163)		
Week 24: R-P (n = 22, 20)	3.37 (± 7.458)	-0.00 (± 10.094)		
Week 28: R-P (n = 23, 19)	5.96 (± 10.034)	1.77 (± 8.553)		
Week 36: R-P (n = 21, 19)	5.99 (± 6.444)	0.24 (± 10.121)		
Week 44: R-P (n = 21, 16)	5.13 (± 6.515)	0.70 (± 11.262)		
Week 52: R-P (n = 21, 16)	6.20 (± 6.659)	1.40 (± 9.126)		
Week 4: Bodily Pain (BP) (n = 27, 23)	8.03 (± 13.272)	7.68 (± 11.235)		
Week 8: BP (n = 26, 21	5.80 (± 14.475)	9.68 (± 10.485)		
Week 12: BP (n = 25, 20)	6.92 (± 13.426)	6.84 (± 11.674)		
Week 16: BP (n = 25, 20)	7.69 (± 14.841)	4.50 (± 13.560)		
Week 20: BP (n = 24, 20)	6.10 (± 14.072)	8.63 (± 12.457)		
Week 24: BP (n = 22, 20)	5.97 (± 12.689)	3.93 (± 11.952)		
Week 28: BP (n = 23, 19)	6.47 (± 12.643)	6.32 (± 13.149)		
Week 36: BP (n = 21, 19)	7.20 (± 13.724)	7.81 (± 10.794)		

Week 44: BP (n = 21, 16)	8.01 (± 15.378)	9.00 (± 7.910)		
Week 52: BP (n = 21, 16)	5.49 (± 12.328)	8.39 (± 11.866)		
Week 4: General Health (GH) (n = 27, 23)	3.49 (± 9.207)	0.23 (± 6.761)		
Week 8: GH (n = 26, 21)	2.74 (± 8.119)	0.18 (± 6.758)		
Week 12: GH (n = 25, 20	2.22 (± 7.383)	0.62 (± 8.158)		
Week 16: GH (n = 25, 20)	2.28 (± 8.235)	-0.74 (± 7.858)		
Week 20: GH (n = 24, 20)	4.50 (± 6.774)	-0.38 (± 7.933)		
Week 24: GH (n = 22, 20)	2.85 (± 7.149)	-0.19 (± 9.031)		
Week 28: GH (n = 23, 19)	3.53 (± 7.285)	1.18 (± 7.837)		
Week 36:GH (n = 21, 19)	3.42 (± 6.680)	-0.47 (± 7.833)		
Week 44: GH (n = 21, 16)	1.02 (± 8.127)	-0.30 (± 9.597)		
Week 52: GH (n = 21, 16)	3.03 (± 6.733)	0.15 (± 10.277)		
Week 4: Vitality (n = 27, 23)	4.07 (± 8.607)	-1.42 (± 7.699)		
Week 8: Vitality (n = 26, 21)	2.17 (± 7.952)	0.71 (± 8.185)		
Week 12: Vitality (n = 25, 20)	3.57 (± 7.477)	-0.30 (± 9.241)		
Week 16: Vitality (n = 25, 20)	4.28 (± 7.431)	-0.45 (± 7.847)		
Week 20: Vitality (n = 24, 20)	4.70 (± 8.445)	0.45 (± 9.652)		
Week 24: Vitality (n = 22, 20)	3.78 (± 7.112)	-1.93 (± 11.697)		
Week 28: Vitality (n = 23, 19)	6.20 (± 7.489)	0.16 (± 6.679)		
Week 36: Vitality (n = 21, 19)	7.07 (± 7.060)	1.41 (± 5.635)		
Week 44: Vitality (n = 21, 16)	6.08 (± 8.375)	-0.93 (± 12.497)		
Week 52: Vitality (n = 21, 16)	7.21 (± 8.690)	0.37 (± 11.474)		
Week 4: Social Functioning (SF) (n = 27, 23)	3.71 (± 7.939)	1.74 (± 7.499)		
Week 8: SF (n = 26, 21)	4.82 (± 8.327)	2.63 (± 9.979)		
Week 12: SF (n = 25, 20)	4.01 (± 9.154)	1.76 (± 7.325)		
Week 16: SF (n = 25, 20)	5.21 (± 11.069)	0.75 (± 7.325)		
Week 20: SF (n = 24, 20)	4.81 (± 10.080)	3.51 (± 8.150)		
Week 24: SF (n = 22, 20)	4.56 (± 8.602)	0.00 (± 10.912)		
Week 28: SF (n = 23, 19)	3.49 (± 8.476)	3.17 (± 9.631)		
Week 36: SF (n = 21, 19)	7.16 (± 10.703)	5.01 (± 7.285)		
Week 44: SF (n = 21, 16)	6.45 (± 8.988)	0.63 (± 11.561)		
Week 52: SF (n = 21, 16)	7.16 (± 8.621)	2.82 (± 9.681)		
Week 4: Role-Emotional (RE) (n = 27, 23)	-0.77 (± 12.454)	3.48 (± 12.985)		
Week 8: RE (n = 26, 21)	3.08 (± 11.457)	1.99 (± 13.239)		
Week 12: RE (n = 25, 20)	-0.42 (± 12.076)	0.52 (± 13.188)		

Week 16: RE (n = 25, 20)	3.76 (± 10.586)	-0.00 (± 11.465)		
Week 20: RE (n = 24, 20)	3.48 (± 11.058)	0.35 (± 11.569)		
Week 24: RE (n = 22, 20)	2.85 (± 11.753)	-1.22 (± 16.025)		
Week 28: RE (n = 23, 19)	3.63 (± 11.853)	1.10 (± 11.725)		
Week 36: RE (n = 21, 19)	5.47 (± 10.066)	0.73 (± 16.518)		
Week 44: RE (n = 21, 16)	4.15 (± 12.293)	3.26 (± 16.354)		
Week 52: RE (n = 21, 16)	6.14 (± 11.385)	0.43 (± 19.234)		
Week 4: Mental Health (MH) (n = 27, 23)	3.0 (± 8.514)	0.57 (± 8.420)		
Week 8: MH (n = 26, 21)	2.82 (± 10.643)	1.49 (± 6.950)		
Week 12: MH (n = 25, 20)	3.14 (± 10.786)	4.45 (± 7.690)		
Week 16: MH (n = 25, 20)	4.29 (± 8.337)	5.36 (± 6.379)		
Week 20: MH (n = 24, 20)	3.49 (± 10.926)	6.41 (± 7.984)		
Week 24: MH (n = 22, 20)	2.62 (± 8.730)	2.61 (± 13.149)		
Week 28: MH (n = 23, 19)	2.84 (± 9.816)	6.06 (± 7.350)		
Week 36: MH (n = 21, 19)	5.98 (± 8.111)	5.64 (± 8.988)		
Week 44: MH (n = 21, 16)	4.11 (± 8.969)	1.14 (± 11.891)		
Week 52: MH (n = 21, 16)	5.73 (± 7.473)	4.25 (± 11.257)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in EQ-5D-5L (EuroQol 5D) questionnaire

End point title	Change from Baseline in EQ-5D-5L (EuroQol 5D) questionnaire

End point description:

EQ-5D-5L, a self-administered questionnaire assessing health status in adults, is divided into 2 sections. The 1st section addresses 5 dimensions (mobility, self-care, usual activity, pain/discomfort, & anxiety/depression). Items are rated either "no problem", "slight problems", "moderate problems", "severe problems", or "extreme problems/unable." A composite health index is defined by combining the levels for each dimension. The 2nd section measures self-rated (global) health status via vertically oriented VAS where 100 represents the "best possible health state" & 0 represents the "worst possible health state." The EQ-5D-5L contains 6 items assessing health status via a single index value or health utility score and allows "weighting" by the patient of health states & generation of patient utilities. Published weights are available allowing for creation of a single summary health utility score. Scores range from 0 to 1, with lower scores representing a higher level of dysfunction.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20, 24, 28, 36, 44 & 52

End point values	Secukinumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	23		
Units: scores on a scale				
arithmetic mean (standard deviation)				
Week 4 (n = 27, 23)	11.26 (± 16.819)	1.87 (± 21.467)		
Week 8 (n = 26, 21)	5.58 (± 16.650)	5.52 (± 29.646)		
Week 12 (n = 25, 20)	4.64 (± 19.598)	3.30 (± 22.850)		
Week 16 (n = 25, 20)	7.000 (± 19.530)	4.40 (± 27.354)		
Week 20 (n = 24, 20)	7.88 (± 19.077)	6.30 (± 25.041)		
Week 24 (n = 23, 20)	6.39 (± 17.598)	-1.00 (± 29.902)		
Week 28 (n = 23, 19)	4.43 (± 17.840)	10.37 (± 21.670)		
Week 36 (n = 21, 19)	6.90 (± 17.972)	5.32 (± 28.825)		
Week 44 (n = 21, 16)	6.38 (± 19.505)	12.69 (± 21.941)		
Week 52 (n = 21, 16)	11.62 (± 16.877)	10.81 (± 24.109)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Erythrocyte Sedimentation Rate (ESR)

End point title	Change from Baseline in Erythrocyte Sedimentation Rate (ESR)

End point description:

ESR is a laboratory test that provides a non-specific measure of inflammation. This was assessed in order to identify the presence of inflammation, to determine its severity, and to monitor response to treatment. The test assesses the rate at which red blood cells fall in a test tube. Normal range is 0-30 mm/hr. A higher rate is consistent with inflammation.

End point type	Secondary

End point timeframe:

Baseline, Week 28, Week 52

End point values	Secukinumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	25		
Units: mm/hr				
arithmetic mean (standard deviation)				
Week 28 (n = 23, 18)	4.043 (± 16.1934)	14.667 (± 23.9141)		
Week 52 (n = 21, 16)	-3.286 (± 10.6167)	10.000 (± 14.8728)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in C-Reactive Protein (CRP) Level

End point title	Change from Baseline in C-Reactive Protein (CRP) Level

End point description:

The test for CRP is a laboratory measurement for evaluation of an acute phase reactant of inflammation through the use of an ultrasensitive assay. This was assessed in order to identify the presence of inflammation, to determine its severity, and to monitor response to treatment. A decrease in the level of CRP indicates reduction in inflammation and therefore improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 28, Week 52

End point values	Secukinumab	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	25		
Units: mg/L				
arithmetic mean (standard deviation)				
Week 28 (n = 23, 19)	4.426 (± 9.6836)	5.216 (± 8.9820)		
Week 52 (n = 21, 16)	-1.433 (± 8.7909)	4.650 (± 14.3691)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Adverse Events were reported from first dose of study treatment and co-administered Prednisolone treatment until end of treatment (48 weeks) plus 4 weeks (52 weeks).	
Adverse event reporting additional description:	
Consistent with EudraCT disclosure specifications, Novartis has reported under the Serious adverse events field "number of deaths resulting from adverse events" all those deaths, resulting from serious adverse events that are deemed to be causally related to treatment by the investigator.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups	
Reporting group title	Secukinumab
Reporting group description:	
Secukinumab	
Reporting group title	All subjects
Reporting group description:	
All subjects	
Reporting group title	Placebo
Reporting group description:	
Placebo	

Serious adverse events	Secukinumab	All subjects	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 27 (22.22%)	17 / 52 (32.69%)	11 / 25 (44.00%)
number of deaths (all causes)	1	2	1
number of deaths resulting from adverse events	1	2	1
Investigations			
Inflammatory marker increased			
subjects affected / exposed	1 / 27 (3.70%)	1 / 52 (1.92%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Face injury			
subjects affected / exposed	1 / 27 (3.70%)	1 / 52 (1.92%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	1 / 27 (3.70%)	2 / 52 (3.85%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	1 / 1	1 / 1	0 / 0
Femur fracture			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula fracture			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	1 / 27 (3.70%)	2 / 52 (3.85%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 27 (3.70%)	1 / 52 (1.92%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	1 / 27 (3.70%)	1 / 52 (1.92%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Atrial fibrillation			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial tachycardia			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	1 / 27 (3.70%)	2 / 52 (3.85%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 2
deaths causally related to treatment / all	1 / 1	1 / 1	0 / 0
Tachyarrhythmia			
subjects affected / exposed	1 / 27 (3.70%)	1 / 52 (1.92%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	1 / 27 (3.70%)	1 / 52 (1.92%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	1 / 27 (3.70%)	1 / 52 (1.92%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial aneurysm			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological symptom			

subjects affected / exposed	1 / 27 (3.70%)	1 / 52 (1.92%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 27 (3.70%)	1 / 52 (1.92%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
General physical health deterioration			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 27 (3.70%)	1 / 52 (1.92%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Faecaloma			
subjects affected / exposed	1 / 27 (3.70%)	1 / 52 (1.92%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal pain			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Noninfective sialoadenitis			
subjects affected / exposed	1 / 27 (3.70%)	1 / 52 (1.92%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Asphyxia			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	1 / 1
Aspiration			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	1 / 1
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 27 (3.70%)	1 / 52 (1.92%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Spinal stenosis			
subjects affected / exposed	1 / 27 (3.70%)	2 / 52 (3.85%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	1 / 1
Infections and infestations			
Arthritis bacterial			
subjects affected / exposed	1 / 27 (3.70%)	1 / 52 (1.92%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	1 / 27 (3.70%)	1 / 52 (1.92%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Fluid retention			
subjects affected / exposed	1 / 27 (3.70%)	1 / 52 (1.92%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Secukinumab	All subjects	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 27 (92.59%)	48 / 52 (92.31%)	23 / 25 (92.00%)
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 27 (0.00%)	2 / 52 (3.85%)	2 / 25 (8.00%)
occurrences (all)	0	2	2
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 27 (3.70%)	3 / 52 (5.77%)	2 / 25 (8.00%)
occurrences (all)	1	3	2
C-reactive protein increased			
subjects affected / exposed	1 / 27 (3.70%)	3 / 52 (5.77%)	2 / 25 (8.00%)
occurrences (all)	1	3	2
Injury, poisoning and procedural complications			
Rib fracture			
subjects affected / exposed	2 / 27 (7.41%)	2 / 52 (3.85%)	0 / 25 (0.00%)
occurrences (all)	2	2	0
Fall			
subjects affected / exposed	2 / 27 (7.41%)	2 / 52 (3.85%)	0 / 25 (0.00%)
occurrences (all)	3	3	0
Bone contusion			
subjects affected / exposed	2 / 27 (7.41%)	2 / 52 (3.85%)	0 / 25 (0.00%)
occurrences (all)	2	2	0
Thoracic vertebral fracture			

subjects affected / exposed	0 / 27 (0.00%)	2 / 52 (3.85%)	2 / 25 (8.00%)
occurrences (all)	0	2	2
Skin laceration			
subjects affected / exposed	1 / 27 (3.70%)	3 / 52 (5.77%)	2 / 25 (8.00%)
occurrences (all)	1	4	3
Tooth fracture			
subjects affected / exposed	1 / 27 (3.70%)	3 / 52 (5.77%)	2 / 25 (8.00%)
occurrences (all)	1	3	2
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 27 (3.70%)	4 / 52 (7.69%)	3 / 25 (12.00%)
occurrences (all)	1	4	3
Giant cell arteritis			
subjects affected / exposed	1 / 27 (3.70%)	3 / 52 (5.77%)	2 / 25 (8.00%)
occurrences (all)	1	3	2
Hypertension			
subjects affected / exposed	6 / 27 (22.22%)	14 / 52 (26.92%)	8 / 25 (32.00%)
occurrences (all)	6	15	9
Nervous system disorders			
Dizziness			
subjects affected / exposed	3 / 27 (11.11%)	3 / 52 (5.77%)	0 / 25 (0.00%)
occurrences (all)	7	7	0
Polyneuropathy			
subjects affected / exposed	2 / 27 (7.41%)	2 / 52 (3.85%)	0 / 25 (0.00%)
occurrences (all)	3	3	0
Headache			
subjects affected / exposed	4 / 27 (14.81%)	7 / 52 (13.46%)	3 / 25 (12.00%)
occurrences (all)	10	13	3
Tension headache			
subjects affected / exposed	1 / 27 (3.70%)	3 / 52 (5.77%)	2 / 25 (8.00%)
occurrences (all)	1	3	2
Sciatica			
subjects affected / exposed	1 / 27 (3.70%)	3 / 52 (5.77%)	2 / 25 (8.00%)
occurrences (all)	1	3	2
General disorders and administration site conditions			

Oedema peripheral			
subjects affected / exposed	2 / 27 (7.41%)	6 / 52 (11.54%)	4 / 25 (16.00%)
occurrences (all)	2	6	4
Fatigue			
subjects affected / exposed	2 / 27 (7.41%)	3 / 52 (5.77%)	1 / 25 (4.00%)
occurrences (all)	2	3	1
Eye disorders			
Glaucoma			
subjects affected / exposed	2 / 27 (7.41%)	4 / 52 (7.69%)	2 / 25 (8.00%)
occurrences (all)	2	4	2
Vision blurred			
subjects affected / exposed	1 / 27 (3.70%)	3 / 52 (5.77%)	2 / 25 (8.00%)
occurrences (all)	1	3	2
Gastrointestinal disorders			
Dental caries			
subjects affected / exposed	2 / 27 (7.41%)	2 / 52 (3.85%)	0 / 25 (0.00%)
occurrences (all)	2	2	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 27 (0.00%)	2 / 52 (3.85%)	2 / 25 (8.00%)
occurrences (all)	0	2	2
Diarrhoea			
subjects affected / exposed	2 / 27 (7.41%)	4 / 52 (7.69%)	2 / 25 (8.00%)
occurrences (all)	2	4	2
Nausea			
subjects affected / exposed	0 / 27 (0.00%)	2 / 52 (3.85%)	2 / 25 (8.00%)
occurrences (all)	0	2	2
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	2 / 27 (7.41%)	3 / 52 (5.77%)	1 / 25 (4.00%)
occurrences (all)	2	3	1
Rash			
subjects affected / exposed	2 / 27 (7.41%)	4 / 52 (7.69%)	2 / 25 (8.00%)
occurrences (all)	3	5	2
Skin ulcer			
subjects affected / exposed	2 / 27 (7.41%)	2 / 52 (3.85%)	0 / 25 (0.00%)
occurrences (all)	2	2	0
Endocrine disorders			

Cushingoid			
subjects affected / exposed	1 / 27 (3.70%)	3 / 52 (5.77%)	2 / 25 (8.00%)
occurrences (all)	1	3	2
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 27 (0.00%)	5 / 52 (9.62%)	5 / 25 (20.00%)
occurrences (all)	0	5	5
Arthralgia			
subjects affected / exposed	3 / 27 (11.11%)	6 / 52 (11.54%)	3 / 25 (12.00%)
occurrences (all)	4	7	3
Muscle spasms			
subjects affected / exposed	4 / 27 (14.81%)	5 / 52 (9.62%)	1 / 25 (4.00%)
occurrences (all)	4	5	1
Bursitis			
subjects affected / exposed	3 / 27 (11.11%)	4 / 52 (7.69%)	1 / 25 (4.00%)
occurrences (all)	3	4	1
Osteoporosis			
subjects affected / exposed	2 / 27 (7.41%)	3 / 52 (5.77%)	1 / 25 (4.00%)
occurrences (all)	2	3	1
Osteoarthritis			
subjects affected / exposed	3 / 27 (11.11%)	5 / 52 (9.62%)	2 / 25 (8.00%)
occurrences (all)	3	6	3
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	1 / 27 (3.70%)	3 / 52 (5.77%)	2 / 25 (8.00%)
occurrences (all)	1	3	2
Nasopharyngitis			
subjects affected / exposed	5 / 27 (18.52%)	10 / 52 (19.23%)	5 / 25 (20.00%)
occurrences (all)	5	10	5
Rhinitis			
subjects affected / exposed	2 / 27 (7.41%)	2 / 52 (3.85%)	0 / 25 (0.00%)
occurrences (all)	2	2	0
Respiratory tract infection			
subjects affected / exposed	2 / 27 (7.41%)	3 / 52 (5.77%)	1 / 25 (4.00%)
occurrences (all)	2	3	1
Oral candidiasis			

subjects affected / exposed	4 / 27 (14.81%)	5 / 52 (9.62%)	1 / 25 (4.00%)
occurrences (all)	4	5	1
Urinary tract infection			
subjects affected / exposed	4 / 27 (14.81%)	6 / 52 (11.54%)	2 / 25 (8.00%)
occurrences (all)	6	8	2
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	1 / 27 (3.70%)	3 / 52 (5.77%)	2 / 25 (8.00%)
occurrences (all)	1	3	2

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 March 2019	Accepted patient ultrasound/MR/images for the corresponding sub-studies taken up to 6 weeks prior to Randomization. Added measurement of HbA1c to assess all relevant domains of the GTI. questionnaire.
13 May 2019	Added extension phase to assess the effect of secukinumab after completed steroid tapering. Added an additional secondary endpoint to assess the proportion of patients receiving prednisolone ≤ 5 mg/day at Week 19, Week 28 and Week 52.
29 November 2019	Added an additional imaging assessment in Week 50 (ultrasound and/or MRA). Shifted the GTI endpoint to the exploratory endpoint section.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use https://www.novctrd.com/CtrdWeb/home.nov for complete trial results.

Notes: