Clinical trial results:
An extension study of subcutaneous secukinumab to evaluate the long-term efficacy, safety and tolerability up to 4 years in patients with Juvenile Idiopathic Arthritis subtypes of Juvenile Psoriatic Arthritis and Enthesitis Related Arthritis

Summary

EudraCT number	2018-002521-30
Trial protocol	DE ES PL BE IT
Global end of trial date	07 November 2024

Results information

Result version number	v1 (current)
This version publication date	18 May 2025
First version publication date	18 May 2025

Trial information

Trial identification

Sponsor protocol code	CAIN457F2304E1

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03769168
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	Novartis Campus, 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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	07 November 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 November 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of this extension study was to provide continuous treatment with secukinumab in pre-filled syringe (PFS) for patients who completed the core study F2304 Week 104 and opted to enter the extension study to obtain further long-term efficacy, safety, and tolerability information

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	07 June 2019
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	Belgium: 3
Country: Number of subjects enrolled	Germany: 11
Country: Number of subjects enrolled	Italy: 2
Country: Number of subjects enrolled	Poland: 4
Country: Number of subjects enrolled	Russian Federation: 15
Country: Number of subjects enrolled	South Africa: 3
Country: Number of subjects enrolled	Spain: 5
Country: Number of subjects enrolled	Türkiye: 8
Country: Number of subjects enrolled	United States: 3
Worldwide total number of subjects	54
EEA total number of subjects	25

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)	20
Adolescents (12-17 years)	34
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited in 24 centers across 9 countries

Pre-assignment

Screening details:

One participant enrolled with planned treatment secukinumab 150 mgdiscontinued the study before receiving study treatment due to physician decision. This participant is not included in the analyses.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1- Secukinumab 75 mg

Arm description:

Participants were planned to initially receive secukinumab 75mg subcutaneously once every four weeks. If the signs and symptoms of the participants were not adequately controlled with the 75mg dose, as determined by the investigator, the dose could be escalated to 150mg subcutaneously. For patients weighing 50kg and over, the dose could further be escalated to 300mg subcutaneously every four weeks. The dose escalation from secukinumab 75mg subcutaneously to 300mg subcutaneously was to be implemented in two steps, with the first step being an increase to 150mg subcutaneously, followed by another escalation to 300mg subcutaneously, based on the judgement of the investigator.

Arm type	Experimental
Investigational medicinal product name	Secukinumab
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Secukinumab solution for subcutaneous injections was provided in PFS.Initially, participants continued to receive secukinumab at either 75 mg (in0.5mL) every 4 weeks, consistent with their dosage at the Week 100 visitof the core study. The dose could be escalated from 75 mg to 150 mg forpatients whose signs and symptoms were not fully controlled, as judged bythe investigator, with the current 75 mg dose. Furthermore, the dose couldalso be escalated to 300 mg every 4 weeks for patients weighing 50kg andover who were currently on the 150 mg dose and whose signs andsymptoms were not well-controlled, as judged by the investigator. The doseescalation from secukinumab 75 mg to 300 mg was to be implemented intwo steps (first 150 mg and then 300 mg based on the investigator'sjudgment). At each study treatment time point, one or two subcutaneousinjections in the form of PFS were administered.

Arm title	Group 2 - Secukinumab 150 mg

Arm description:

Participants were planned to initially receive secukinumab 150mg subcutaneously once every four weeks. If the signs and symptoms of the participants were not adequately controlled with the 150mg dose, as determined by the investigator, the dose could be escalated to 300mg subcutaneously.

Arm type	Experimental
Investigational medicinal product name	Secukinumab
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Secukinumab solution for subcutaneous injections was provided in PFS.Initially, participants continued to receive secukinumab at 150 mg (in 1mL)every 4 weeks, consistent with their dosage at the Week 100 visit of thecore study. The dose could be escalated to 300 mg every 4 weeks forpatients weighing 50kg and over who were currently on the 150 mg doseand whose signs and symptoms were not well-controlled, as judged by theinvestigator. At each study treatment time point, one or two subcutaneousinjections in the form of PFS were administered.

Number of subjects in period 1	Group 1-Secukinumab 75 mg	Group 2 - Secukinumab 150 mg
Started	19	35
Completed	10	12
Not completed	9	23
Post study access to treatment	3	11
Physician decision	1	3
Subject Decision	2	4
Adverse event, non-fatal	-	1
Lack of efficacy	2	4
Guardian decision	1	-

Baseline characteristics

Reporting groups

Reporting group title	Group 1- Secukinumab 75 mg

Reporting group description:

Participants were planned to initially receive secukinumab 75mg subcutaneously once every four weeks. If the signs and symptoms of the participants were not adequately controlled with the 75mg dose, as determined by the investigator, the dose could be escalated to 150mg subcutaneously. For patients weighing 50kg and over, the dose could further be escalated to 300mg subcutaneously every four weeks. The dose escalation from secukinumab 75mg subcutaneously to 300mg subcutaneously was to be implemented in two steps, with the first step being an increase to 150mg subcutaneously, followed by another escalation to 300mg subcutaneously, based on the judgement of the investigator.

Reporting group title	Group 2 - Secukinumab 150 mg

Reporting group description:

Participants were planned to initially receive secukinumab 150mg subcutaneously once every four weeks. If the signs and symptoms of the participants were not adequately controlled with the 150mg dose, as determined by the investigator, the dose could be escalated to 300mg subcutaneously.

Reporting group values	Group 1- Secukinumab 75 mg	Group 2 - Secukinumab 150 mg	Total
Number of subjects	19	35	54
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	15	5	20
Adolescents (12-17 years)	4	30	34
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	9.5	14.1	
standard deviation	± 3.49	± 2.02	-
Sex: Female, Male Units: Participants			
Female	8	10	18
Male	11	25	36
Race/Ethnicity, Customized Units: Subjects			
White	19	33	52
Other	0	2	2

Subject analysis sets

Subject analysis set title	Total Secukinumab Dose
Subject analysis set type	Full analysis

Subject analysis set description:
Total participants from Group 1 and Group 2

Reporting group values	Total Secukinumab Dose		
Number of subjects	54		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	20		
Adolescents (12-17 years)	34		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Age Continuous Units: Years			
arithmetic mean	12.5		
standard deviation	± 3.40		
Sex: Female, Male Units: Participants			
Female	18		
Male	36		
Race/Ethnicity, Customized Units: Subjects			
White	52		
Other	2		

End points

End points reporting groups

Reporting group title	Group 1- Secukinumab 75 mg

Reporting group description:

Participants were planned to initially receive secukinumab 75mg subcutaneously once every four weeks. If the signs and symptoms of the participants were not adequately controlled with the 75mg dose, as determined by the investigator, the dose could be escalated to 150mg subcutaneously. For patients weighing 50kg and over, the dose could further be escalated to 300mg subcutaneously every four weeks. The dose escalation from secukinumab 75mg subcutaneously to 300mg subcutaneously was to be implemented in two steps, with the first step being an increase to 150mg subcutaneously, followed by another escalation to 300mg subcutaneously, based on the judgement of the investigator.

Reporting group title	Group 2 - Secukinumab 150 mg

Reporting group description:

Participants were planned to initially receive secukinumab 150mg subcutaneously once every four weeks. If the signs and symptoms of the participants were not adequately controlled with the 150mg dose, as determined by the investigator, the dose could be escalated to 300mg subcutaneously.

Subject analysis set title	Total Secukinumab Dose
Subject analysis set type	Full analysis

Subject analysis set description:

Total participants from Group 1 and Group 2

Primary: Percentage of participants with Juvenile Idiopathic Arthritis American College of Rheumatology (JIA ACR) 30 response

End point title	Percentage of participants with Juvenile Idiopathic Arthritis American College of Rheumatology (JIA ACR) 30 response[1]

End point description:

The JIA ACR response criteria consisted of 6 core criteria:
- Physician global assessment of disease activity on a 0-100 mm VAS (0=very good and 100=very poor).
- Parent's or patients' global assessment of overall well-being on a 0-100 mm VAS (0=very well and 100=very poor).
- Functional ability (CHAQ: Childhood Health Assessment Questionnaire): 30 questions across 8 domains assessing the child's functional abilities. The total score was calculated as the average of the scores for each domain. It ranged from 0 (no disability) to 3 (very severe disability).
- Number of joints with active arthritis (as per ACR definition), ranging from 0 to 73.
- Number of joints with limited range of motion, ranging from 0 to 69.
- Index of inflammation: C-reactive Protein (CRP) levels

The JIA ACR 30 response was achieved if 3 of any 6 core set variables improved by at least 30% from baseline of the core study, and no more than 1 variable worsening more than 30%

End point type	Primary

End point timeframe:

Baseline of the core study, Week 104 (start of extension study), 116, 128, 140, 156, 180, 208, 232, 260, 284 , 308 and 312. Study week is defined with respect to the core study.

Notes:

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

End point values	Group 1- Secukinumab 75 mg	Group 2 - Secukinumab 150 mg	Total Secukinumab Dose	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	35	54	
Units: Percentage of Participants				
number (confidence interval 95%)				
Week 104	100 (79.1 to 100)	100 (87.7 to 100)	100 (91.7 to 100)	

Week 116	100 (79.1 to 100)	96.9 (82.0 to 99.8)	98.9 (88.2 to 99.9)	
Week 128	100 (78.1 to 100)	100 (86.3 to 100)	100 (90.9 to 100)	
Week 140	100 (78.1 to 100)	100 (87.0 to 100)	100 (91.3 to 100)	
Week 156	94.7 (71.9 to 99.7)	100 (87.0 to 100)	98.1 (88.4 to 99.9)	
Week 180	94.7 (71.9 to 99.7)	97.0 (82.5 to 99.8)	96.2 (85.7 to 99.3)	
Week 208	100 (78.1 to 100)	100 (86.3 to 100)	100 (90.9 to 100)	
Week 232	94.1 (69.2 to 99.7)	100 (84.5 to 100)	97.7 (86.5 to 99.9)	
Week 260	92.9 (64.2 to 99.6)	96.2 (78.4 to 99.8)	95.0 (81.8 to 99.1)	
Week 284	100 (73.2 to 100)	95.7 (76.0 to 99.8)	97.3 (84.2 to 99.9)	
Week 308	100 (69.9 to 100)	100 (77.1 to 100)	100 (85.4 to 100)	
Week 312	90.0 (54.1 to 99.5)	100 (69.9 to 100)	95.5 (75.1 to 99.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with JIA ACR 50 response

End point title	Percentage of participants with JIA ACR 50 response

End point description:

The JIA ACR response criteria consisted of 6 core criteria:
- Physician global assessment of disease activity on a 0-100 mm VAS (0=very good and 100=very poor).
- Parent's or patients' global assessment of overall well-being on a 0-100 mm VAS (0=very well and 100=very poor).
- Functional ability (CHAQ): 30 questions across 8 domains assessing the child’s functional abilities. The total score was calculated as the average of the scores for each domain (0 [no disability] to 3 [very severe disability]).
- Number of joints with active arthritis (as per ACR definition), ranging from 0 to 73.
- Number of joints with limited range of motion, ranging from 0 to 69.
- Index of inflammation: CRP levels

The JIA ACR 50 responses were achieved if 3 of any 6 core set variables improved by at least 50% from baseline of the core study, and no more than 1 variable worsening > 30%

End point type	Secondary

End point timeframe:

Baseline of the core study, Week 104 (start of extension study), 116, 128, 140, 156, 180, 208, 232, 260, 284 , 308 and 312. Study week is defined with respect to the core study.

End point values	Group 1- Secukinumab 75 mg	Group 2 - Secukinumab 150 mg	Total Secukinumab Dose	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	35	54	
Units: Percentage of participants				
number (confidence interval 95%)				
Week 104	94.7 (71.9 to 99.7)	94.3 (79.5 to 99.0)	94.4 (83.7 to 98.6)	
Week 116	100 (79.1 to 100)	93.8 (77.8 to 98.9)	96.1 (85.4 to 99.3)	
Week 128	94.4 (74.2 to 98.7)	93.5 (77.2 to 98.9)	93.9 (82.1 to 98.4)	
Week 140	100 (78.1 to 100)	90.9 (74.5 to 97.6)	94.1 (82.8 to 98.5)	
Week 156	94.7 (71.9 to 99.7)	87.9 (70.9 to 96.0)	90.4 (78.2 to 96.4)	
Week 180	94.7 (71.9 to 99.7)	93.9 (78.4 to 98.9)	94.2 (83.1 to 98.5)	
Week 208	100 (78.1 to 100)	90.3 (73.1 to 97.5)	93.9 (82.1 to 98.4)	
Week 232	94.1 (69.2 to 99.7)	96.3 (79.1 to 99.8)	95.5 (83.3 to 99.2)	
Week 260	92.9 (64.2 to 99.6)	96.2 (78.4 to 99.8)	95.0 (81.8 to 99.1)	
Week 284	100 (73.2 to 100)	95.7 (76.0 to 99.8)	97.3 (84.2 to 99.9)	
Week 308	100 (69.9 to 100)	100 (77.1 to 100)	100 (85.4 to 100)	
Week 312	90.0 (54.1 to 99.5)	100 (69.9 to 100)	95.5 (75.1 to 99.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with JIA ACR 70 response

End point title	Percentage of participants with JIA ACR 70 response

End point description:

The JIA ACR response criteria consisted of 6 core criteria:
- Physician global assessment of disease activity on a 0-100 mm VAS (0=very good and 100=very poor).
- Parent's or patients' global assessment of overall well-being on a 0-100 mm VAS (0=very well and 100=very poor).
- Functional ability (CHAQ): 30 questions across 8 domains assessing the child’s functional abilities. The total score was calculated as the average of the scores for each domain (0 [no disability] to 3 [very severe disability]).
- Number of joints with active arthritis (as per ACR definition), ranging from 0 to 73.
- Number of joints with limited range of motion, ranging from 0 to 69.
- Index of inflammation: CRP levels

The JIA ACR 70 responses were achieved if 3 of any 6 core set variables improved by at least 70%, from baseline of the core study, and no more than 1 variable worsening > 30%

End point type	Secondary

End point timeframe:

Baseline of the core study, Week 104 (start of extension study), 116, 128, 140, 156, 180, 208, 232, 260, 284 , 308 and 312. Study week is defined with respect to the core study.

End point values	Group 1- Secukinumab 75 mg	Group 2 - Secukinumab 150 mg	Total Secukinumab Dose	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	35	54	
Units: Percentage of participants				
number (confidence interval 95%)				
Week 104	94.7 (71.9 to 99.7)	82.9 (65.7 to 92.8)	87.0 (74.5 to 94.2)	
Week 116	94.7 (71.9 to 99.7)	90.6 (73.8 to 97.5)	92.2 (80.3 to 97.5)	
Week 128	94.4 (70.6 to 99.7)	90.3 (73.1 to 97.5)	91.8 (79.5 to 97.4)	
Week 140	88.9 (63.9 to 98.1)	84.8 (67.3 to 94.3)	86.3 (73.1 to 93.8)	
Week 156	94.7 (71.9 to 99.7)	84.8 (67.3 to 94.3)	88.5 (75.9 to 95.2)	
Week 180	89.5 (65.5 to 98.2)	81.8 (63.9 to 92.4)	84.6 (71.4 to 92.7)	
Week 208	94.4 (70.6 to 99.7)	90.3 (73.1 to 97.5)	91.8 (79.5 to 97.4)	
Week 232	88.2 (62.3 to 97.9)	85.2 (65.4 to 95.1)	86.4 (72.0 to 94.3)	
Week 260	92.9 (64.2 to 99.6)	96.2 (78.4 to 99.8)	95.0 (81.8 to 99.1)	
Week 284	100 (73.2 to 100)	95.7 (76.0 to 99.8)	97.3 (84.2 to 99.9)	
Week 308	100 (69.9 to 100)	100 (77.1 to 100)	100 (85.4 to 100)	
Week 312	90.0 (54.1 to 99.5)	83.3 (50.9 to 97.1)	86.4 (64.0 to 96.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with JIA ACR 90 response

End point title	Percentage of participants with JIA ACR 90 response

End point description:

The JIA ACR response criteria consisted of 6 core criteria:
- Physician global assessment of disease activity on a 0-100 mm VAS (0=very good and 100=very poor).
- Parent's or patients' global assessment of overall well-being on a 0-100 mm VAS (0=very well and 100=very poor).
- Functional ability (CHAQ): 30 questions across 8 domains assessing the child’s functional abilities. The total score was calculated as the average of the scores for each domain (0 [no disability] to 3 [very severe disability]).
- Number of joints with active arthritis (as per ACR definition), ranging from 0 to 73.
- Number of joints with limited range of motion, ranging from 0 to 69.
- Index of inflammation: CRP levels

The JIA ACR 90 responses were achieved if 3 of any 6 core set variables improved by at least 90% from baseline of the core study, and no more than 1 variable worsening > 30%

End point type	Secondary

End point timeframe:

Baseline of the core study, Week 104 (start of extension study), 116, 128, 140, 156, 180, 208, 232, 260, 284 , 308 and 312. Study week is defined with respect to the core study.

End point values	Group 1- Secukinumab 75 mg	Group 2 - Secukinumab 150 mg	Total Secukinumab Dose	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	35	54	
Units: Percentage of participants				
number (confidence interval 95%)				
Week 104	84.2 (59.5 to 95.8)	74.3 (56.4 to 86.9)	77.8 (64.1 to 87.5)	
Week 116	73.7 (48.6 to 89.9)	75.0 (56.2 to 87.9)	74.5 (60.1 to 85.2)	
Week 128	83.3 (57.7 to 95.6)	77.4 (58.5 to 89.7)	79.6 (65.2 to 89.3)	
Week 140	83.3 (57.7 to 95.6)	72.7 (54.2 to 86.1)	76.5 (62.2 to 86.8)	
Week 156	73.7 (48.6 to 89.9)	75.8 (57.4 to 88.3)	75.0 (60.8 to 85.5)	
Week 180	84.2 (59.5 to 95.8)	69.7 (51.1 to 83.8)	75.0 (60.8 to 85.5)	
Week 208	77.8 (51.9 to 92.6)	71.0 (51.8 to 85.1)	73.5 (58.7 to 84.6)	
Week 232	76.5 (49.8 to 92.2)	81.5 (61.3 to 93.0)	79.5 (64.2 to 89.7)	
Week 260	71.4 (42.0 to 90.4)	84.6 (64.3 to 95.0)	80.0 (63.9 to 90.4)	
Week 284	85.7 (56.2 to 97.5)	95.7 (76.0 to 99.8)	91.9 (77.0 to 97.9)	
Week 308	91.7 (59.8 to 99.6)	88.2 (62.3 to 97.9)	89.7 (71.5 to 97.3)	
Week 312	80.0 (44.2 to 96.5)	83.3 (50.9 to 97.1)	81.8 (59.0 to 94.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with JIA ACR 100 response

End point title	Percentage of participants with JIA ACR 100 response

End point description:

The JIA ACR response criteria consisted of 6 core criteria:
- Physician global assessment of disease activity on a 0-100 mm VAS (0=very good and 100=very poor).
- Parent's or patients' global assessment of overall well-being on a 0-100 mm VAS (0=very well and 100=very poor).
- Functional ability (CHAQ): 30 questions across 8 domains assessing the child’s functional abilities. The total score was calculated as the average of the scores for each domain (0 [no disability] to 3 [very severe disability]).
- Number of joints with active arthritis (as per ACR definition), ranging from 0 to 73.
- Number of joints with limited range of motion, ranging from 0 to 69.
- Index of inflammation: CRP levels

The JIA ACR 100 responses were achieved if 3 of any 6 core set variables improved with 100% from baseline of the core study, and no more than 1 variable worsening > 30%

End point type	Secondary

End point timeframe:

Baseline of the core study, Week 104 (start of extension study), 116, 128, 140, 156, 180, 208, 232, 260, 284 , 308 and 312. Study week is defined with respect to the core study.

End point values	Group 1- Secukinumab 75 mg	Group 2 - Secukinumab 150 mg	Total Secukinumab Dose	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	35	54	
Units: Percentage of participants				
number (confidence interval 95%)				
Week 104	63.2 (38.6 to 82.8)	57.1 (39.5 to 73.2)	59.3 (45.1 to 72.1)	
Week 116	63.2 (38.6 to 82.8)	62.5 (43.7 to 78.3)	62.7 (48.1 to 75.5)	
Week 128	66.7 (41.2 to 85.6)	54.8 (36.3 to 72.2)	59.2 (44.3 to 72.7)	
Week 140	66.7 (41.2 to 85.6)	57.6 (39.4 to 74.0)	60.8 (46.1 to 73.8)	
Week 156	63.2 (38.6 to 82.8)	60.6 (42.2 to 76.6)	61.5 (47.0 to 74.4)	
Week 180	57.9 (34.0 to 78.9)	54.5 (36.6 to 71.5)	55.8 (41.4 to 69.3)	
Week 208	72.2 (46.4 to 89.3)	58.1 (39.3 to 74.9)	63.3 (48.3 to 76.2)	
Week 232	58.8 (33.5 to 80.6)	63.0 (42.5 to 79.9)	61.4 (45.5 to 75.3)	
Week 260	71.4 (42.0 to 90.4)	65.4 (44.4 to 82.1)	67.5 (50.8 to 80.9)	
Week 284	78.6 (48.8 to 94.3)	78.3 (55.8 to 91.7)	78.4 (61.3 to 89.6)	
Week 308	91.7 (59.8 to 99.6)	76.5 (49.8 to 92.2)	82.8 (63.5 to 93.5)	
Week 312	80.0 (44.2 to 96.5)	75.0 (42.8 to 93.3)	77.3 (54.2 to 91.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with inactive disease status

End point title	Number of participants with inactive disease status

End point description:

Inactive disease status was confirmed in a patient when all the following conditions were met:
- No joints with active arthritis
- No uveitis
- CRP value within normal limits for the laboratory where tested or, if elevated, not attributable to JIA
- Physician’s global assessment of disease activity score ≤ 10mm
- Duration of morning stiffness attributable to JIA lasting ≥15 minutes.

End point type	Secondary

End point timeframe:

Baseline of the core study, Week 104 (start of extension study), 116, 128, 140, 156, 180, 208, 232, 260, 284 , 308 and 312. Study week is defined with respect to the core study.

End point values	Group 1- Secukinumab 75 mg	Group 2 - Secukinumab 150 mg	Total Secukinumab Dose	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	35	54	
Units: Percentage of Participants				
number (confidence interval 95%)				
Week 104	63.2 (38.6 to 82.8)	65.7 (47.7 to 80.3)	64.8 (50.6 to 77.0)	
Week 116	68.4 (43.5 to 86.4)	71.9 (53.0 to 85.6)	70.6 (56.0 to 82.1)	
Week 128	66.7 (41.2 to 85.6)	64.5 (45.4 to 80.2)	65.3 (50.3 to 77.9)	
Week 140	72.2 (46.4 to 89.3)	63.6 (45.1 to 79.0)	66.7 (52.0 to 77.9)	
Week 156	68.4 (43.5 to 86.4)	72.7 (54.2 to 86.1)	71.2 (56.7 to 82.5)	
Week 180	68.4 (43.5 to 86.4)	54.5 (36.6 to 71.5)	59.6 (45.1 to 72.7)	
Week 208	61.1 (36.1 to 81.7)	67.7 (48.5 to 82.7)	65.3 (50.3 to 77.9)	
Week 232	70.6 (44.0 to 88.6)	66.7 (46.0 to 82.8)	68.2 (52.3 to 80.9)	
Week 260	71.4 (42.0 to 90.4)	65.4 (44.4 to 82.1)	67.5 (50.8 to 80.9)	
Week 284	78.6 (48.8 to 94.3)	78.3 (55.8 to 91.7)	78.4 (61.3 to 89.6)	
Week 308	83.3 (50.9 to 97.1)	82.4 (55.8 to 95.3)	82.8 (63.5 to 93.5)	
Week 312	70.0 (35.4 to 91.9)	75.0 (42.8 to 93.3)	72.7 (49.6 to 88.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline of core study CAIN457F2304 in JIA ACR Core Component - Physician global assessment of disease activity

End point title	Change from baseline of core study CAIN457F2304 in JIA ACR Core Component - Physician global assessment of disease activity

End point description:

The JIA ACR response criteria consisted of 6 core criteria, one of which was the physician global assessment of disease activity. this assessment was conducted using a 100 mm VAS score, where 0 represented the best disease activity and 100 the worst. The change from baseline of the core study of the physician global assessment of disease activity was measured, with a negative change indicating improvement.

End point type	Secondary

End point timeframe:

Baseline of the core study, Week 104 (start of extension study), 116, 128, 140, 156, 180, 208, 232, 260, 284 , 308 and 312. Study week is defined with respect to the core study.

End point values	Group 1- Secukinumab 75 mg	Group 2 - Secukinumab 150 mg	Total Secukinumab Dose	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	35	54	
Units: Score on a Scale				
arithmetic mean (standard deviation)				
Week 104	-40.0 (± 18.39)	-42.2 (± 20.43)	-41.4 (± 19.59)	
Week 116	-40.3 (± 18.42)	-41.1 (± 20.35)	-40.8 (± 19.46)	
Week 128	-40.4 (± 18.55)	-41.9 (± 21.33)	-41.3 (± 20.17)	
Week 140	-39.0 (± 16.75)	-42.4 (± 19.18)	-41.2 (± 18.26)	
Week 156	-39.7 (± 17.09)	-40.8 (± 20.72)	-40.4 (± 19.50)	
Week 180	-38.5 (± 18.20)	-38.9 (± 21.71)	-38.8 (± 20.31)	
Week 208	-39.0 (± 17.06)	-41.8 (± 19.45)	-40.8 (± 18.48)	
Week 232	-38.4 (± 18.20)	-42.9 (± 20.86)	-41.1 (± 19.78)	
Week 260	-37.6 (± 28.75)	-45.4 (± 20.74)	-42.7 (± 23.78)	
Week 284	-43.6 (± 18.96)	-42.8 (± 20.53)	-43.1 (± 19.68)	
Week 308	-43.8 (± 18.76)	-40.3 (± 20.51)	-41.7 (± 19.53)	
Week 312	-44.2 (± 26.58)	-47.4 (± 22.05)	-46.0 (± 23.67)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline of core study CAIN457F2304 in JIA ACR Core Component - Parent's or patients' global assessment of overall well-being

End point title	Change from baseline of core study CAIN457F2304 in JIA ACR Core Component - Parent's or patients' global assessment of overall well-being

End point description:

The JIA ACR response criteria included six core components, one of which was the parent's or patients' global assessment of overall well-being. This assessment was conducted using a 100 mm VAS score, where 0 represented “very well” and 100 “very poor”. The change from baseline of the core study in the parent's or patients' global assessment of overall well-being was measured, with a negative change indicating improvement

End point type	Secondary

End point timeframe:

Baseline of the core study, Week 104 (start of extension study), 116, 128, 140, 156, 180, 208, 232, 260, 284 , 308 and 312. Study week is defined with respect to the core study.

End point values	Group 1- Secukinumab 75 mg	Group 2 - Secukinumab 150 mg	Total Secukinumab Dose	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	35	54	
Units: Score on a Scale				
arithmetic mean (standard deviation)				
Week 104	-47.1 (± 25.90)	-38.6 (± 27.74)	-41.6 (± 27.17)	
Week 116	-45.4 (± 25.70)	-37.7 (± 26.39)	-40.5 (± 26.15)	
Week 128	-46.8 (± 25.02)	-39.1 (± 26.69)	-41.8 (± 26.11)	
Week 140	-41.1 (± 27.57)	-38.7 (± 27.06)	-38.7 (± 27.06)	
Week 156	-46.1 (± 25.41)	-39.2 (± 27.15)	-41.8 (± 26.49)	
Week 180	-45.5 (± 27.24)	-39.8 (± 27.48)	-41.9 (± 27.27)	
Week 208	-47.6 (± 25.70)	-40.3 (± 28.13)	-43.0 (± 27.23)	
Week 232	-39.6 (± 27.23)	-43.4 (± 28.20)	-41.9 (± 27.57)	
Week 260	-44.8 (± 34.52)	-42.8 (± 29.31)	-43.5 (± 30.80)	
Week 284	-51.6 (± 24.97)	-43.2 (± 31.23)	-46.4 (± 28.96)	
Week 308	-49.8 (± 24.23)	-48.5 (± 31.93)	-49.1 (± 28.53)	
Week 312	-48.9 (± 28.45)	-53.5 (± 30.31)	-51.4 (± 28.87)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline of core study CAIN457F2304 in JIA ACR Core Component - Functional ability (CHAQ)

End point title	Change from baseline of core study CAIN457F2304 in JIA ACR Core Component - Functional ability (CHAQ)

End point description:

The JIA ACR response criteria included six core components, one of which was the functional ability, measured by the CHAQ. The CHAQ questionnaire consisted of 30 questions across 8 domains: dressing/grooming, arising, eating, walking, hygiene, reach, grip, and activities. Each domain was scored on a 4-point scale, and the total score was calculated as the average of the scores for each domain. The total score ranged from 0 (no disability) to 3 (very severe disability). The change from baseline of the core study in the CHAQ was measured, with a negative change indicating improvement.

End point type	Secondary

End point timeframe:

Baseline of the core study, Week 104 (start of extension study), 116, 128, 140, 156, 180, 208, 232, 260, 284 , 308 and 312. Study week is defined with respect to the core study.

End point values	Group 1- Secukinumab 75 mg	Group 2 - Secukinumab 150 mg	Total Secukinumab Dose	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	35	54	
Units: Score on a Scale				
arithmetic mean (standard deviation)				
Week 104	-0.599 (± 0.5490)	-0.636 (± 0.5967)	-0.623 (± 0.5754)	
Week 116	-0.605 (± 0.5469)	-0.617 (± 0.5811)	-0.613 (± 0.5631)	
Week 128	-0.647 (± 0.5196)	-0.685 (± 0.5570)	-0.672 (± 0.5388)	
Week 140	-0.590 (± 0.4809)	-0.648 (± 0.5638)	-0.627 (± 0.5318)	
Week 156	-0.645 (± 0.5275)	-0.644 (± 0.5763)	-0.644 (± 0.5537)	
Week 180	-0.658 (± 0.5541)	-0.625 (± 0.5779)	-0.637 (± 0.5641)	
Week 208	-0.667 (± 0.4832)	-0.625 (± 0.5293)	-0.640 (± 0.5082)	
Week 232	-0.610 (± 0.5411)	-0.681 (± 0.5825)	-0.653 (± 0.5615)	
Week 260	-0.741 (± 0.5035)	-0.649 (± 0.6205)	-0.681 (± 0.5773)	
Week 284	-0.777 (± 0.5052)	-0.652 (± 0.6329)	-0.699 (± 0.5837)	
Week 308	-0.865 (± 0.4811)	-0.794 (± 0.6311)	-0.823 (± 0.5655)	
Week 312	-0.888 (± 0.5050)	-1.000 (± 0.6077)	-0.949 (± 0.5532)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline of core study CAIN457F2304 in JIA ACR Core Component - Number of joints with active arthritis

End point title	Change from baseline of core study CAIN457F2304 in JIA ACR Core Component - Number of joints with active arthritis

End point description:

The JIA ACR response criteria included six core components, one of which was the number of joints with active arthritis. This was determined using the ACR definition, which identifies active arthritis as any joint with swelling or, in the absence of swelling, limitation of motion accompanied by either pain on motion or tenderness not due to deformity. The active joint count ranged from 0 to 73. The change from baseline of the core study in the number of active joints was measured, with a negative change indicating improvement.

End point type	Secondary

End point timeframe:

Baseline of the core study, Week 104 (start of extension study), 116, 128, 140, 156, 180, 208, 232, 260, 284 , 308 and 312. Study week is defined with respect to the core study.

End point values	Group 1- Secukinumab 75 mg	Group 2 - Secukinumab 150 mg	Total Secukinumab Dose	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	35	54	
Units: Joints				
arithmetic mean (standard deviation)				
Week 104	-8.4 (± 11.03)	-6.9 (± 5.26)	-7.4 (± 7.72)	
Week 116	-8.4 (± 11.48)	-6.6 (± 4.50)	-7.3 (± 7.79)	
Week 128	-8.7 (± 11.81)	-7.3 (± 5.35)	-7.8 (± 8.24)	
Week 140	-8.4 (± 11.81)	-7.0 (± 5.44)	-7.5 (± 8.17)	
Week 156	-8.1 (± 9.77)	-7.1 (± 5.61)	-7.5 (± 7.32)	
Week 180	-8.3 (± 11.66)	-7.0 (± 5.69)	-7.5 (± 8.29)	
Week 208	-7.0 (± 6.12)	-6.7 (± 5.38)	-6.8 (± 5.60)	
Week 232	-7.4 (± 8.48)	-7.0 (± 5.68)	-7.1 (± 6.80)	
Week 260	-7.9 (± 10.14)	-7.5 (± 5.57)	-7.7 (± 7.36)	
Week 284	-8.4 (± 11.61)	-7.0 (± 5.57)	-7.5 (± 8.25)	
Week 308	-8.0 (± 9.70)	-6.5 (± 4.52)	-7.1 (± 7.01)	
Week 312	-8.9 (± 11.59)	-7.5 (± 5.14)	-8.1 (± 8.48)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline of core study CAIN457F2304 in JIA ACR Core Component - Number of joints with limited range of motion

End point title	Change from baseline of core study CAIN457F2304 in JIA ACR Core Component - Number of joints with limited range of motion

End point description:

The JIA ACR response criteria included six core components, one of which was the number of joints with limited range of motion. A total of 69 joints were assessed for limitation of motion. The change from baseline of the core study in the number of joints with limited range of motion was measured, with a negative change indicating improvement.

End point type	Secondary

End point timeframe:

Baseline of the core study, Week 104 (start of extension study), 116, 128, 140, 156, 180, 208, 232, 260, 284 , 308 and 312. Study week is defined with respect to the core study.

End point values	Group 1- Secukinumab 75 mg	Group 2 - Secukinumab 150 mg	Total Secukinumab Dose	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	35	54	
Units: Joints				
arithmetic mean (standard deviation)				
Week 104	-5.5 (± 6.20)	-5.3 (± 4.23)	-5.4 (± 4.96)	
Week 116	-5.4 (± 6.24)	-5.7 (± 4.19)	-5.6 (± 4.99)	
Week 128	-5.5 (± 6.41)	-6.0 (± 4.60)	-5.8 (± 5.28)	
Week 140	-5.7 (± 6.31)	-6.0 (± 4.99)	-5.9 (± 5.43)	
Week 156	-5.2 (± 5.68)	-4.3 (± 8.19)	-4.6 (± 7.32)	
Week 180	-5.3 (± 6.37)	-5.5 (± 4.83)	-5.4 (± 5.38)	
Week 208	-5.1 (± 5.61)	-5.3 (± 3.92)	-5.2 (± 4.56)	
Week 232	-4.5 (± 5.42)	-5.6 (± 3.93)	-5.2 (± 4.53)	
Week 260	-5.2 (± 6.47)	-5.9 (± 3.93)	-5.7 (± 4.90)	
Week 284	-5.1 (± 5.72)	-6.0 (± 3.88)	-5.7 (± 4.61)	
Week 308	-5.2 (± 5.46)	-5.8 (± 3.05)	-5.5 (± 4.14)	
Week 312	-5.3 (± 6.77)	-6.3 (± 3.62)	-5.8 (± 5.17)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline of core study CAIN457F2304 in JIA ACR Core Component - CRP levels

End point title	Change from baseline of core study CAIN457F2304 in JIA ACR Core Component - CRP levels

End point description:

The JIA ACR response criteria included six core components, one of which was CRP levels, an inflammation biomarker. Serum concentrations of CRP were determined, and the change from baseline of the core study was assessed, with negative changes indicating improvement.

End point type	Secondary

End point timeframe:

Baseline of the core study, Week 104 (start of extension study), 116, 128, 140, 156, 180, 208, 232, 260, 284 , 308 and 312. Study week is defined with respect to the core study.

End point values	Group 1- Secukinumab 75 mg	Group 2 - Secukinumab 150 mg	Total Secukinumab Dose	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	35	54	
Units: milligram (mg) / liter (L)				
arithmetic mean (standard deviation)				
Week 104	-15.238 (± 38.0680)	-19.788 (± 36.2920)	-18.187 (± 36.6322)	
Week 116	-11.201 (± 40.1619)	-21.795 (± 37.5991)	-17.848 (± 38.5218)	
Week 128	-15.027 (± 40.3989)	-21.446 (± 38.2870)	-19.088 (± 38.7812)	

Week 140	-15.867 (± 36.7306)	-21.211 (± 37.0123)	-19.325 (± 36.6347)	
Week 156	-13.622 (± 34.4677)	-21.325 (± 37.3081)	-18.510 (± 36.1480)	
Week 180	-16.131 (± 38.0479)	-20.788 (± 36.9842)	-19.086 (± 37.0716)	
Week 208	-16.907 (± 40.1651)	-20.694 (± 38.1014)	-19.303 (± 38.4978)	
Week 232	-15.015 (± 41.4765)	-20.365 (± 38.9746)	-18.298 (± 39.5668)	
Week 260	-18.746 (± 48.0621)	-20.715 (± 42.7106)	-20.026 (± 44.0482)	
Week 284	-19.974 (± 47.7822)	-15.530 (± 59.2045)	-17.212 (± 54.5096)	
Week 308	-21.052 (± 53.0822)	-21.458 (± 47.6825)	-21.290 (± 49.0532)	
Week 312	-25.915 (± 55.0448)	-27.892 (± 53.5661)	-26.993 (± 52.9390)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline of core study CAIN457F2304 of 27-joint Juvenile Arthritis Disease Activity Score (JADAS-27)

End point title	Change from baseline of core study CAIN457F2304 of 27-joint Juvenile Arthritis Disease Activity Score (JADAS-27)

End point description:

The JADAS-27 was used for assessment of disease activity, and it included 4 measures:
-Physician global assessment of disease activity (VAS range: 0 to 10; where 0=very good and 100=very poor)
-Parent/participant global assessment of well-being (VAS range: 0 to 10; 0=very well and 100=very poor)
-Count of joints with active disease (range: 0 to 27; where 0= no disease activity and 27= maximum disease activity)
-Index of inflammation determined by CRP concentration, calculated as: (CRP (mg/l) −10)/10. Before calculation, CRP values <10 mg/l were converted to 10 and CRP values >110 mg/l were converted to 110. The normalized scale ranged from 0 to 10; where 0= no disease activity and 10= maximum disease activity.
JADAS-27 score was calculated as the sum of the score of its 4 components, ranging from 0 to 57 where 0= no disease activity and 57= maximum disease activity. The change from baseline of the core study was assessed. A negative change from baseline indicated improvement.

End point type	Secondary

End point timeframe:

Baseline of the core study, Week 104 (start of extension study), 116, 128, 140, 156, 180, 208, 232, 260, 284 , 308 and 312. Study week is defined with respect to the core study.

End point values	Group 1- Secukinumab 75 mg	Group 2 - Secukinumab 150 mg	Total Secukinumab Dose	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	35	54	
Units: Score on a Scale				
arithmetic mean (standard deviation)				

Week 104	-14.436 (± 7.2274)	-13.731 (± 7.4131)	-13.979 (± 7.2876)	
Week 116	-13.984 (± 7.9693)	-13.632 (± 7.0546)	-13.763 (± 7.3314)	
Week 128	-14.478 (± 7.7217)	-14.277 (± 7.3964)	-14.348 (± 7.4314)	
Week 140	-14.050 (± 7.6609)	-14.104 (± 7.3246)	-14.085 (± 7.3683)	
Week 156	-14.027 (± 6.1256)	-14.158 (± 7.4052)	-14.111 (± 6.9032)	
Week 180	-14.235 (± 7.6622)	-13.737 (± 7.5190)	-13.919 (± 7.5002)	
Week 208	-13.501 (± 5.7531)	-13.869 (± 7.3790)	-13.734 (± 6.7665)	
Week 232	-13.064 (± 6.3732)	-14.669 (± 7.6410)	-14.049 (± 7.1443)	
Week 260	-13.454 (± 8.9326)	-15.096 (± 7.9790)	-14.521 (± 8.2484)	
Week 284	-15.358 (± 7.3767)	-14.445 (± 8.4302)	-14.791 (± 7.9550)	
Week 308	-14.437 (± 6.4218)	-14.647 (± 8.3114)	-14.560 (± 7.4623)	
Week 312	-15.310 (± 8.3332)	-17.122 (± 8.2219)	-16.298 (± 8.1255)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline of core study CAIN457F2304 of 71-joint Juvenile Arthritis Disease Activity Score (JADAS-71)

End point title	Change from baseline of core study CAIN457F2304 of 71-joint Juvenile Arthritis Disease Activity Score (JADAS-71)

End point description:

The JADAS-27 was used for assessment of disease activity, and it included 4 measures:
-Physician global assessment of disease activity (VAS range: 0 to 10; where 0=very good and 100=very poor)
-Parent/participant global assessment of well-being (VAS range: 0 to 10; 0=very well and 100=very poor)
-Count of joints with active disease (range: 0 to 71; where 0= no disease activity and 71= maximum disease activity)
-Index of inflammation determined by CRP concentration, calculated as: (CRP (mg/l) −10)/10. Before calculation, CRP values <10 mg/l were converted to 10 and CRP values >110 mg/l were converted to 110. The normalized scale ranged from 0 to 10; where 0= no disease activity and 10= maximum disease activity.
JADAS-27 score was calculated as the sum of the score of its 4 components, ranging from 0 to 101 where 0= no disease activity and 101= maximum disease activity. The change from baseline of the core study was assessed. A negative change from baseline indicated improvement.

End point type	Secondary

End point timeframe:

Baseline of the core study, Week 104 (start of extension study), 116, 128, 140, 156, 180, 208, 232, 260, 284 , 308 and 312. Study week is defined with respect to the core study.

End point values	Group 1- Secukinumab 75 mg	Group 2 - Secukinumab 150 mg	Total Secukinumab Dose	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	35	54	
Units: Score on a Scale				
arithmetic mean (standard deviation)				
Week 104	-17.962 (± 13.2770)	-16.503 (± 9.0939)	-17.016 (± 10.6497)	
Week 116	-17.510 (± 14.0289)	-16.226 (± 8.2331)	-16.704 (± 10.6429)	
Week 128	-18.595 (± 14.2989)	-17.083 (± 9.1148)	-17.619 (± 11.0980)	
Week 140	-17.384 (± 13.8172)	-16.861 (± 9.0858)	-17.046 (± 10.8540)	
Week 156	-17.448 (± 11.6294)	-16.855 (± 9.1102)	-17.072 (± 9.9946)	
Week 180	-17.709 (± 13.9552)	-16.556 (± 9.4998)	-16.977 (± 11.2105)	
Week 208	-16.723 (± 8.8183)	-16.675 (± 9.0536)	-16.693 (± 8.8753)	
Week 232	-16.005 (± 10.7335)	-17.262 (± 9.3685)	-16.776 (± 9.8143)	
Week 260	-17.239 (± 13.8602)	-18.019 (± 9.7594)	-17.746 (± 11.1907)	
Week 284	-19.144 (± 13.7107)	-17.141 (± 10.3338)	-17.899 (± 11.5806)	
Week 308	-18.520 (± 12.0126)	-17.000 (± 9.1449)	-17.629 (± 10.2499)	
Week 312	-19.810 (± 14.3124)	-19.622 (± 9.0748)	-19.707 (± 11.4427)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline of core study CAIN457F2304 in total enthesitis count

End point title	Change from baseline of core study CAIN457F2304 in total enthesitis count

End point description:

The following 16 entheseal sites were assessed for the presence or absence of tenderness (enthesitis) on each side of the body:
• Anterior Entheses: Greater trochanter of the Femur; Medial condyle of the femur; Lateral condyle of the femur
• Posterior Entheses: Greater tuberosity of humerus; medial epicondyle of humerus; lateral epicondyle of humerus, Achilles tendon; and calcaneal insertion of the plantar fascia.
Tenderness on examination was recorded as either present (1) or absent (0) for each of the 16 sites, The total enthesitis count ranged from 0 to 16.
The change from baseline of the core study was assessed. A negative change from baseline indicated improvement

End point type	Secondary

End point timeframe:

Baseline of the core study, Week 104 (start of extension study), 116, 128, 140, 156, 180, 208, 232, 260, 284 , 308 and 312. Study week is defined with respect to the core study.

End point values	Group 1- Secukinumab 75 mg	Group 2 - Secukinumab 150 mg	Total Secukinumab Dose	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	35	54	
Units: Enthesitis count				
arithmetic mean (standard deviation)				
Week 104	-2.5 (± 2.57)	-2.3 (± 2.30)	-2.4 (± 2.37)	
Week 116	-2.4 (± 2.36)	-2.3 (± 2.50)	-2.4 (± 2.42)	
Week 128	-2.4 (± 2.43)	-2.3 (± 1.97)	-2.3 (± 2.13)	
Week 140	-2.5 (± 2.36)	-2.7 (± 2.43)	-2.6 (± 2.38)	
Week 156	-2.7 (± 3.03)	-2.5 (± 2.36)	-2.2 (± 2.62)	
Week 180	-2.6 (± 2.59)	-2.5 (± 2.54)	-2.5 (± 2.53)	
Week 208	-2.4 (± 2.81)	-2.3 (± 2.56)	2.53 (± 2.63)	
Week 232	-2.5 (± 2.85)	-2.0 (± 2.28)	-2.2 (± 2.49)	
Week 260	-2.5 (± 3.54)	-2.0 (± 1.36)	-2.2 (± 2.37)	
Week 284	-2.9 (± 3.05)	-2.0 (± 1.52)	-2.4 (± 2.21)	
Week 308	-3.2 (± 3.07)	-2.1 (± 1.25)	-2.5 (± 2.21)	
Week 312	-2.5 (± 2.32)	-2.1 (± 1.44)	-2.3 (± 1.86)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline of core study CAIN457F2304 in total dactylitis count

End point title	Change from baseline of core study CAIN457F2304 in total dactylitis count

End point description:

The dactylitis count was the number of fingers and toes presenting with swelling and inflammation. Swelling and inflammation on examination was recorded as either present (1) or absent (0) for each of the 20 sites, The total dactylitis count ranged from 0 to 20.
The change from baseline of the core study was assessed. A negative change from baseline indicated improvement

End point type	Secondary

End point timeframe:

Baseline of the core study, Week 104 (start of extension study), 116, 128, 140, 156, 180, 208, 232, 260, 284 , 308 and 312. Study week is defined with respect to the core study.

End point values	Group 1- Secukinumab 75 mg	Group 2 - Secukinumab 150 mg	Total Secukinumab Dose	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	18	35	53	
Units: Dactylitis count				
arithmetic mean (standard deviation)				
Week 104	-1.3 (± 1.94)	-0.4 (± 1.97)	-0.7 (± 1.99)	
Week 116	-1.5 (± 2.04)	-0.5 (± 2.05)	-0.9 (± 2.08)	
Week 128	-1.8 (± 2.39)	-0.5 (± 2.23)	-0.9 (± 2.35)	
Week 140	-1.6 (± 2.42)	-0.6 (± 2.09)	-1.0 (± 2.24)	
Week 156	-1.6 (± 2.23)	-0.7 (± 2.07)	-1.0 (± 2.15)	
Week 180	-1.8 (± 2.41)	0.0 (± 4.15)	-0.6 (± 3.71)	
Week 208	-1.6 (± 2.42)	-0.3 (± 0.87)	-0.8 (± 1.70)	
Week 232	-1.5 (± 2.42)	-0.4 (± 0.88)	-0.8 (± 1.70)	
Week 260	-1.2 (± 2.04)	-0.3 (± 0.84)	-0.6 (± 1.43)	
Week 284	-1.2 (± 2.13)	-0.3 (± 0.95)	-0.6 (± 1.52)	
Week 308	-0.9 (± 1.70)	0.1 (± 0.56)	-0.3 (± 1.22)	
Week 312	-1.1 (± 1.83)	-0.2 (± 0.39)	-0.6 (± 1.29)	

Statistical analyses

No statistical analyses for this end point

Secondary: Serum concentrations of secukinumab over time

End point title	Serum concentrations of secukinumab over time

End point description:

Serum concentration of secukinumab over time. Blood samples for pharmacokinetics were taken pre-dose at the scheduled time points.

End point type	Secondary

End point timeframe:

Pre-dose at Week 128, 140, 156, 180, 208, 232, 260, 284 , 308 and 312. Study week is defined with respect to the core study.

End point values	Group 1- Secukinumab 75 mg	Group 2 - Secukinumab 150 mg	Total Secukinumab Dose	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	16	26	42	
Units: microgram (ug)/milliliter (mL)				
arithmetic mean (standard deviation)				
Week 128	21.4 (± 8.57)	26.4 (± 9.78)	24.8 (± 9.58)	
Week 156	20.8 (± 8.76)	26.6 (± 11.6)	24.3 (± 10.8)	
Week 180	21.0 (± 10.4)	25.2 (± 9.28)	23.7 (± 9.75)	
Week 208	20.5 (± 6.82)	26.7 (± 11.4)	24.3 (± 10.2)	
Week 232	19.7 (± 7.06)	24.2 (± 11.6)	22.5 (± 10.2)	
Week 260	16.0 (± 6.94)	25.4 (± 8.99)	21.5 (± 9.32)	
Week 284	13.5 (± 7.99)	27.5 (± 7.48)	21.7 (± 10.3)	

Week 308	12.5 (± 5.31)	27.5 (± 14.7)	18.8 (± 12.4)	
Week 312	14.6 (± 4.79)	25.4 (± 18.5)	19.5 (± 13.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with treatment-emergent Anti-Drug Antibodies (ADAs) of secukinumab

End point title	Number of participants with treatment-emergent Anti-Drug Antibodies (ADAs) of secukinumab

End point description:

Number of participants with treatment-emergent Anti-Drug Antibodies (ADAs) of secukinumab. Blood samples were collected for immunogenicity (anti-AIN457 antibodies) assessments.

End point type	Secondary

End point timeframe:

From baseline of the core study up to Week 312. Study week is defined with respect to the core study.

End point values	Group 1- Secukinumab 75 mg	Group 2 - Secukinumab 150 mg	Total Secukinumab Dose	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	35	54	
Units: Participants	0	6	6	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From first dose of secukinumab in the extension study up to 84 daysafter last dose of secukinumab, assessed up to approximately 4 years	
Adverse event reporting additional description:	
AEs were reported according to the dose the participants were receiving when the AE started. For non-SAEs, only those with a frequency over 5% are reported.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	27.1

Reporting groups	
Reporting group title	Any secukinumab 75 mg
Reporting group description:	
Participants who received secukinumab 75 mg dose at any point duringthe extension study	
Reporting group title	Any secukinumab 300 mg
Reporting group description:	
Participants who received secukinumab 300 mg dose at any point duringthe extension study	
Reporting group title	Any secukinumab
Reporting group description:	
Participants who received secukinumab, regardless of dose, at any pointduring the extension study	
Reporting group title	Any secukinumab 150 mg
Reporting group description:	
Participants who received secukinumab 150 mg dose at any point duringthe extension study	

Serious adverse events	Any secukinumab 75 mg	Any secukinumab 300 mg	Any secukinumab
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 19 (0.00%)	0 / 16 (0.00%)	4 / 54 (7.41%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	0 / 19 (0.00%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 19 (0.00%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Subdural haematoma			
subjects affected / exposed	0 / 19 (0.00%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Crohn's disease			
subjects affected / exposed	0 / 19 (0.00%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Any secukinumab 150 mg		
Total subjects affected by serious adverse events			

subjects affected / exposed	4 / 43 (9.30%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Head injury			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Crohn's disease			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Urethral haemorrhage			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Any secukinumab 75 mg	Any secukinumab 300 mg	Any secukinumab
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 19 (78.95%)	11 / 16 (68.75%)	43 / 54 (79.63%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Osteochondroma			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 16 (0.00%)	3 / 54 (5.56%)
occurrences (all)	0	0	3
Gait disturbance			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Swelling face			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Respiratory, thoracic and mediastinal disorders			
Pharyngeal erythema			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Oropharyngeal pain			

subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	4 / 54 (7.41%)
occurrences (all)	1	0	10
Cough			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	4 / 54 (7.41%)
occurrences (all)	0	1	7
Bronchospasm			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Psychiatric disorders			
Generalised anxiety disorder			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 19 (0.00%)	2 / 16 (12.50%)	3 / 54 (5.56%)
occurrences (all)	0	2	3
Bacterial test positive			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Basophil count increased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	4	4
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Blood bicarbonate decreased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Blood bilirubin increased			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Blood glucose increased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Blood phosphorus increased			

subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Blood triglycerides increased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Crystal urine present			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Eosinophil count increased			
subjects affected / exposed	0 / 19 (0.00%)	2 / 16 (12.50%)	2 / 54 (3.70%)
occurrences (all)	0	3	3
Eosinophil percentage increased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Protein urine present			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
High density lipoprotein decreased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	2	2
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	4 / 54 (7.41%)
occurrences (all)	1	0	4
Fall			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Ligament sprain			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	2 / 54 (3.70%)
occurrences (all)	1	0	2
Radius fracture			

subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Wrist fracture			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Congenital, familial and genetic disorders			
Familial mediterranean fever			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Nervous system disorders			
Syncope			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	2 / 54 (3.70%)
occurrences (all)	1	0	2
Headache			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	4 / 54 (7.41%)
occurrences (all)	0	2	11
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	2 / 54 (3.70%)
occurrences (all)	1	0	2
Neutropenia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Eye disorders			
Astigmatism			
subjects affected / exposed	0 / 19 (0.00%)	2 / 16 (12.50%)	2 / 54 (3.70%)
occurrences (all)	0	2	2
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 19 (0.00%)	0 / 16 (0.00%)	3 / 54 (5.56%)
occurrences (all)	0	0	21
Diarrhoea			

subjects affected / exposed	1 / 19 (5.26%)	1 / 16 (6.25%)	7 / 54 (12.96%)
occurrences (all)	4	1	11
Colitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Abdominal pain upper			
subjects affected / exposed	3 / 19 (15.79%)	0 / 16 (0.00%)	6 / 54 (11.11%)
occurrences (all)	3	0	15
Vomiting			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	3 / 54 (5.56%)
occurrences (all)	1	0	4
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Acne			
subjects affected / exposed	0 / 19 (0.00%)	0 / 16 (0.00%)	3 / 54 (5.56%)
occurrences (all)	0	0	3
Psoriasis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	5
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	2 / 54 (3.70%)
occurrences (all)	1	0	5
Urinary incontinence			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Musculoskeletal and connective tissue disorders			
Enthesopathy			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	2 / 54 (3.70%)
occurrences (all)	1	0	2
Back pain			
subjects affected / exposed	2 / 19 (10.53%)	0 / 16 (0.00%)	5 / 54 (9.26%)
occurrences (all)	5	0	11
Arthritis			

subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	2 / 54 (3.70%)
occurrences (all)	0	1	3
Arthralgia			
subjects affected / exposed	4 / 19 (21.05%)	3 / 16 (18.75%)	11 / 54 (20.37%)
occurrences (all)	7	7	30
Amplified musculoskeletal pain syndrome			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Exostosis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Groin pain			
subjects affected / exposed	1 / 19 (5.26%)	1 / 16 (6.25%)	2 / 54 (3.70%)
occurrences (all)	1	1	2
Joint swelling			
subjects affected / exposed	0 / 19 (0.00%)	2 / 16 (12.50%)	2 / 54 (3.70%)
occurrences (all)	0	4	7
Temporomandibular pain and dysfunction syndrome			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	2 / 54 (3.70%)
occurrences (all)	1	0	3
Scoliosis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Pain in extremity			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	8 / 54 (14.81%)
occurrences (all)	1	0	15
Juvenile idiopathic arthritis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 16 (0.00%)	3 / 54 (5.56%)
occurrences (all)	0	0	3
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	2 / 54 (3.70%)
occurrences (all)	1	0	2
Bacterial infection			

subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Bronchitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	3 / 54 (5.56%)
occurrences (all)	2	0	4
COVID-19			
subjects affected / exposed	1 / 19 (5.26%)	3 / 16 (18.75%)	13 / 54 (24.07%)
occurrences (all)	1	3	13
Ear infection			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Cystitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	2
Eye infection			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Gastroenteritis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 16 (0.00%)	4 / 54 (7.41%)
occurrences (all)	0	0	5
Gastrointestinal infection			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	2 / 54 (3.70%)
occurrences (all)	0	1	2
Pneumonia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Pharyngitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 16 (0.00%)	4 / 54 (7.41%)
occurrences (all)	0	0	7
Oral herpes			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Nasopharyngitis			
subjects affected / exposed	2 / 19 (10.53%)	4 / 16 (25.00%)	13 / 54 (24.07%)
occurrences (all)	5	6	34
Influenza			

subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	2 / 54 (3.70%)
occurrences (all)	3	0	4
Herpes simplex			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Vaccination site cellulitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Upper respiratory tract infection			
subjects affected / exposed	2 / 19 (10.53%)	0 / 16 (0.00%)	7 / 54 (12.96%)
occurrences (all)	4	0	10
Tooth abscess			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Tonsillitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	4 / 54 (7.41%)
occurrences (all)	0	1	6
Tinea pedis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Sinusitis			
subjects affected / exposed	2 / 19 (10.53%)	1 / 16 (6.25%)	5 / 54 (9.26%)
occurrences (all)	2	1	7
Rhinitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	2 / 54 (3.70%)
occurrences (all)	1	0	2
Varicella			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Metabolism and nutrition disorders			
Malnutrition			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Hypertriglyceridaemia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	2 / 54 (3.70%)
occurrences (all)	1	0	2

Folate deficiency			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Body fat disorder			
subjects affected / exposed	0 / 19 (0.00%)	1 / 16 (6.25%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Vitamin B12 deficiency			
subjects affected / exposed	1 / 19 (5.26%)	0 / 16 (0.00%)	1 / 54 (1.85%)
occurrences (all)	1	0	1
Vitamin D deficiency			
subjects affected / exposed	1 / 19 (5.26%)	1 / 16 (6.25%)	2 / 54 (3.70%)
occurrences (all)	1	2	3

Non-serious adverse events	Any secukinumab 150 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 43 (65.12%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Osteochondroma			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	3		
Gait disturbance			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Swelling face			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Pharyngeal erythema			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			

subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	9		
Cough			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	6		
Bronchospasm			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Generalised anxiety disorder			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
Bacterial test positive			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Basophil count increased			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Blood bicarbonate decreased			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Blood bilirubin increased			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Blood glucose increased			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Blood phosphorus increased			

subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Blood triglycerides increased			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Crystal urine present			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Eosinophil count increased			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Eosinophil percentage increased			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Protein urine present			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
High density lipoprotein decreased			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	3		
Fall			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Ligament sprain			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
Radius fracture			

subjects affected / exposed occurrences (all) Wrist fracture subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0 0 / 43 (0.00%) 0		
Congenital, familial and genetic disorders Familial mediterranean fever subjects affected / exposed occurrences (all)	 0 / 43 (0.00%) 0		
Nervous system disorders Syncope subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all)	 1 / 43 (2.33%) 1 3 / 43 (6.98%) 9		
Blood and lymphatic system disorders Iron deficiency anaemia subjects affected / exposed occurrences (all) Neutropenia subjects affected / exposed occurrences (all)	 1 / 43 (2.33%) 1 0 / 43 (0.00%) 0		
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	 0 / 43 (0.00%) 0		
Eye disorders Astigmatism subjects affected / exposed occurrences (all)	 0 / 43 (0.00%) 0		
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all) Diarrhoea	 3 / 43 (6.98%) 21 		

subjects affected / exposed occurrences (all) Colitis subjects affected / exposed occurrences (all) Abdominal pain upper subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all)	5 / 43 (11.63%) 6 0 / 43 (0.00%) 0 4 / 43 (9.30%) 12 2 / 43 (4.65%) 3		
Skin and subcutaneous tissue disorders Pruritus subjects affected / exposed occurrences (all) Acne subjects affected / exposed occurrences (all) Psoriasis subjects affected / exposed occurrences (all)	 0 / 43 (0.00%) 0 3 / 43 (6.98%) 3 1 / 43 (2.33%) 4		
Renal and urinary disorders Haematuria subjects affected / exposed occurrences (all) Urinary incontinence subjects affected / exposed occurrences (all)	 1 / 43 (2.33%) 4 0 / 43 (0.00%) 0		
Musculoskeletal and connective tissue disorders Enthesopathy subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all) Arthritis	 1 / 43 (2.33%) 1 3 / 43 (6.98%) 6		

subjects affected / exposed	2 / 43 (4.65%)		
occurrences (all)	2		
Arthralgia			
subjects affected / exposed	7 / 43 (16.28%)		
occurrences (all)	16		
Amplified musculoskeletal pain syndrome			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Exostosis			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Groin pain			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Joint swelling			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	3		
Temporomandibular pain and dysfunction syndrome			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	2		
Scoliosis			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	8 / 43 (18.60%)		
occurrences (all)	14		
Juvenile idiopathic arthritis			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	3		
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
Bacterial infection			

subjects affected / exposed	0 / 43 (0.00%)			
occurrences (all)	0			
Bronchitis				
subjects affected / exposed	2 / 43 (4.65%)			
occurrences (all)	2			
COVID-19				
subjects affected / exposed	9 / 43 (20.93%)			
occurrences (all)	9			
Ear infection				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences (all)	0			
Cystitis				
subjects affected / exposed	1 / 43 (2.33%)			
occurrences (all)	1			
Eye infection				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences (all)	0			
Gastroenteritis				
subjects affected / exposed	4 / 43 (9.30%)			
occurrences (all)	5			
Gastrointestinal infection				
subjects affected / exposed	1 / 43 (2.33%)			
occurrences (all)	1			
Pneumonia				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences (all)	0			
Pharyngitis				
subjects affected / exposed	4 / 43 (9.30%)			
occurrences (all)	7			
Oral herpes				
subjects affected / exposed	0 / 43 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	8 / 43 (18.60%)			
occurrences (all)	23			
Influenza				

subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
Herpes simplex			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Vaccination site cellulitis			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	5 / 43 (11.63%)		
occurrences (all)	6		
Tooth abscess			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Tonsillitis			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	5		
Tinea pedis			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Sinusitis			
subjects affected / exposed	2 / 43 (4.65%)		
occurrences (all)	4		
Rhinitis			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		
Varicella			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Malnutrition			
subjects affected / exposed	0 / 43 (0.00%)		
occurrences (all)	0		
Hypertriglyceridaemia			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences (all)	1		

Folate deficiency subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0		
Body fat disorder subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0		
Vitamin B12 deficiency subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0		
Vitamin D deficiency subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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.

One participant, who was enrolled with planned treatment of secukinumab 150 mg, discontinued the study before receiving any treatment. Due to technical limitations of the form, this participant has not been included in the subject disposition tables.

Notes: