Clinical trial results:
A 24-week, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of secukinumab in controlling spinal pain in patients with axial spondyloarthritis

Summary

EudraCT number	2017-000401-21
Trial protocol	ES CZ FI GB LV LT GR BE SE BG PL HR IT
Global end of trial date	15 February 2019

Results information

Result version number	v1
This version publication date	21 February 2020
First version publication date	21 February 2020

Trial information

Trial identification

Sponsor protocol code	CAIN457H3301

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03136861
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	15 February 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 February 2019
Global end of trial reached?	Yes
Global end of trial date	15 February 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to assess the superiority of secukinumab 150 mg compared to placebo in achieving a spinal pain score of < 4 on a 0-10 numerical rating scale (NRS) at Week 8.

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 June 2017
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: 10
Country: Number of subjects enrolled	Bulgaria: 17
Country: Number of subjects enrolled	Croatia: 11
Country: Number of subjects enrolled	Czech Republic: 21
Country: Number of subjects enrolled	Estonia: 24
Country: Number of subjects enrolled	Finland: 8
Country: Number of subjects enrolled	United Kingdom: 11
Country: Number of subjects enrolled	Greece: 21
Country: Number of subjects enrolled	Ireland: 6
Country: Number of subjects enrolled	Italy: 1
Country: Number of subjects enrolled	Latvia: 16
Country: Number of subjects enrolled	Lithuania: 26
Country: Number of subjects enrolled	Poland: 116
Country: Number of subjects enrolled	Russian Federation: 38
Country: Number of subjects enrolled	Spain: 42
Country: Number of subjects enrolled	Sweden: 6
Country: Number of subjects enrolled	Switzerland: 6
Worldwide total number of subjects	380
EEA total number of subjects	336

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)	368
From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study was conducted at 66 centers in 17 countries worldwide: Spain(14), Czech Republic(3), Finland(2), Lithuania(2), Estonia(3), Latvia(3), Switzerland(1), Russia(4), Sweden(4), United Kingdom(5), Belgium(2), Ireland(2), Poland(7), Croatia(3), Bulgaria(5), Greece(5), Italy(1).

Pre-assignment

Screening details:

At Baseline, patients were randomized to either secukinumab 150 mg or placebo (Group A or B). At Week 8, patients were re-randomized or re-assigned respectively to 1 of 5 treatment arms to receive either secukinumab 150 mg or secukinumab 300 mg (Arm A1 to B2).

Period 1

Period 1 title	Treatment Period 1 (TP1)(Baseline-Wk 8)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Secukinumab 150 mg (Group A)

Arm description:

Treatment Period 1: Secukinumab 150 mg (1 x 1.0 mL) s.c. administered at Baseline, Week 1, 2, 3 and 4

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

Dosage and administration details:

Secukinumab sc injections weekly up to week 4.

Arm title	Placebo (Group B)

Arm description:

Treatment Period 1: Placebo (1 x 1.0 mL) s.c. administered at Baseline and Week 1, 2, 3 and 4

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

Dosage and administration details:

Placebo sc injections weekly up to week 4.

Number of subjects in period 1	Secukinumab 150 mg (Group A)	Placebo (Group B)
Started	285	95
Completed	278	89
Not completed	7	6
Adverse event, non-fatal	3	2
Protocol Deviation	2	1
Subject/Guardian Decision	-	1
Lost to follow-up	1	1
Withdrawal of Informed Consent	1	1

Period 2	
Period 2 title	Treatment Period 2 (TP2) (Wk 8-Wk 24)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms	
Are arms mutually exclusive?	Yes
Arm title	Arm A1

Arm description:

Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20

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

Dosage and administration details:

Secukinumab sc injections every 4 weeks between week 8 and week 20.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	Placebo
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo sc injections every 4 weeks between week 8 and week 20.

Arm title	Arm A2

Arm description:

Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20

Arm type	Active comparator

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

Dosage and administration details:

Secukinumab sc injections every 4 weeks between week 8 and week 20.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	Placebo
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo sc injections every 4 weeks between week 8 and week 20.

Arm title	Arm A3

Arm description:

Treatment Period 2: Secukinumab 300 mg (2 x 1.0 mL) administered at Week 8, 12, 16, and 20

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

Dosage and administration details:

2 secukinumab sc injections every 4 weeks between week 8 and week 20.

Arm title	Arm B1

Arm description:

Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20

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

Dosage and administration details:

Secukinumab sc injections every 4 weeks between week 8 and week 20.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	Placebo
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo sc injections every 4 weeks between week 8 and week 20.

Arm title	Arm B2

Arm description:

Treatment Period 2: Secukinumab 300 mg (2 x 1.0 mL) administered at Week 8, 12, 16, and 20

Arm type	Active comparator

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

Dosage and administration details:

2 secukinumab sc injections every 4 weeks between week 8 and week 20.

Number of subjects in period 2	Arm A1	Arm A2	Arm A3
Started	90	94	94
Completed	88	93	92
Not completed	2	1	2
Adverse event, non-fatal	-	1	2
Lost to follow-up	1	-	-
Withdrawal of Informed Consent	1	-	-

Number of subjects in period 2	Arm B1	Arm B2
Started	45	44
Completed	45	43
Not completed	0	1
Adverse event, non-fatal	-	1
Lost to follow-up	-	-
Withdrawal of Informed Consent	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Secukinumab 150 mg (Group A)
Reporting group description:	
Treatment Period 1: Secukinumab 150 mg (1 x 1.0 mL) s.c. administered at Baseline, Week 1, 2, 3 and 4	
Reporting group title	Placebo (Group B)
Reporting group description:	
Treatment Period 1: Placebo (1 x 1.0 mL) s.c. administered at Baseline and Week 1, 2, 3 and 4	

Reporting group values	Secukinumab 150 mg (Group A)	Placebo (Group B)	Total
Number of subjects	285	95	380
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)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	274	94	368
From 65-84 years	11	1	12
85 years and over	0	0	0
Age Continuous			
Age continuous at Baseline Treatment Period 1			
Units: Years			
arithmetic mean	42.3	40.9	
standard deviation	± 11.88	± 12.20	-
Sex: Female, Male			
Gender at Baseline Treatment Period 1			
Units: Participants			
Female	106	39	145
Male	179	56	235
Race/Ethnicity, Customized			
Race at Baseline Treatment Period 1			
Units: Subjects			
Caucasian	267	93	360
Asian	2	1	3
Other	16	1	17

End points

End points reporting groups

Reporting group title	Secukinumab 150 mg (Group A)
Reporting group description:	
Treatment Period 1: Secukinumab 150 mg (1 x 1.0 mL) s.c. administered at Baseline, Week 1, 2, 3 and 4	
Reporting group title	Placebo (Group B)
Reporting group description:	
Treatment Period 1: Placebo (1 x 1.0 mL) s.c. administered at Baseline and Week 1, 2, 3 and 4	
Reporting group title	Arm A1
Reporting group description:	
Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20	
Reporting group title	Arm A2
Reporting group description:	
Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20	
Reporting group title	Arm A3
Reporting group description:	
Treatment Period 2: Secukinumab 300 mg (2 x 1.0 mL) administered at Week 8, 12, 16, and 20	
Reporting group title	Arm B1
Reporting group description:	
Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20	
Reporting group title	Arm B2
Reporting group description:	
Treatment Period 2: Secukinumab 300 mg (2 x 1.0 mL) administered at Week 8, 12, 16, and 20	

Primary: Percentage of participants with a spinal pain numerical rating scale (NRS) score below 4 at Week 8

End point title	Percentage of participants with a spinal pain numerical rating scale (NRS) score below 4 at Week 8
End point description:	
The spinal pain numerical rating scale (NRS) is an 11-point scale to assess pain intensity in patients who are able to self-report. To calculate the average spinal pain, the patient is asked to answer 2 questions to get 2 pain ratings, the total spinal pain corresponding to the intensity of spinal pain experienced on an average over 24 hours during the previous week and the nocturnal back pain corresponding to the intensity of spinal pain experienced on an average over the night during the previous week.	
End point type	Primary
End point timeframe:	
Week 8	

End point values	Secukinumab 150 mg (Group A)	Placebo (Group B)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	279	92		
Units: Participants				
Average Spinal Pain Score|Yes	91	19		
Total Spinal Pain Score|Yes	92	16		
Nocturnal Spinal Pain Score|Yes	77	17		
Average Spinal Pain Score|No	188	73		
Total Spinal Pain Score|No	187	76		
Nocturnal Spinal Pain Score|No	202	75		

Statistical analyses

Statistical analysis title	Average Spinal Pain Score <4 at Week 8
Comparison groups	Secukinumab 150 mg (Group A) v Placebo (Group B)
Number of subjects included in analysis	371
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0264
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.08
upper limit	3.33

Statistical analysis title	Total Spinal Pain Score <4 at Week 8
Comparison groups	Secukinumab 150 mg (Group A) v Placebo (Group B)
Number of subjects included in analysis	371
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0043
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.31
upper limit	4.31

Statistical analysis title	Nocturnal Spinal Pain Score
Comparison groups	Secukinumab 150 mg (Group A) v Placebo (Group B)
Number of subjects included in analysis	371
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.072
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	3.1

Secondary: Percentage of participants with a Bath ankylosing spondylitis disease activity index score below 4 at Week 8

End point title	Percentage of participants with a Bath ankylosing spondylitis disease activity index score below 4 at Week 8

End point description:

The Bath ankylosing spondylitis disease activity index (BASDAI) consists of a 0 through 10 scale, which is used to answer 6 questions pertaining to the 5 major symptoms of ankylosing spondylitis. To give each symptom equal weighting, the mean (average) of the 2 scores relating to morning stiffness (questions 5 and 6) is taken. The mean of questions 5 and 6 is added to the scores from questions 1-4. The resulting 0 to 50 score is divided by 5 to give a final 0 – 10 BASDAI score.

End point type	Secondary

End point timeframe:

Week 8

End point values	Secukinumab 150 mg (Group A)	Placebo (Group B)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	280	92		
Units: Participants				
Yes (n=95,22)	95	22		
No (n=185,70)	185	70		

Statistical analyses

Statistical analysis title	BASDAI Score <4 at Week 8
Comparison groups	Secukinumab 150 mg (Group A) v Placebo (Group B)

Number of subjects included in analysis	372
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0466
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.01
upper limit	3.04

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment emergent adverse events were collected from first dose of study treatment until end of study treatment plus 12 weeks, up to a maximum duration of 32 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	21.0

Reporting groups

Reporting group title	Secukinumab 150 mg

Reporting group description:

Treatment Period 1: Secukinumab 150 mg (1 x 1.0 mL) s.c. administered at Baseline, Week 1, 2, 3 and 4

Reporting group title	Placebo

Reporting group description:

Treatment Period 1: Placebo (1 x 1.0 mL) s.c. administered at Baseline and Week 1, 2, 3 and 4

Reporting group title	Arm A1

Reporting group description:

Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20

Reporting group title	Arm A2

Reporting group description:

Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20

Reporting group title	Arm A3

Reporting group description:

Treatment Period 2: Secukinumab 300 mg (2 x 1.0 mL) administered at Week 8, 12, 16, and 20

Reporting group title	Arm B1

Reporting group description:

Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20

Reporting group title	Arm B2

Reporting group description:

Treatment Period 2: Secukinumab 300 mg (2 x 1.0 mL) administered at Week 8, 12, 16, and 20

Serious adverse events	Secukinumab 150 mg	Placebo	Arm A1
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 285 (1.40%)	0 / 95 (0.00%)	3 / 90 (3.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Malignant melanoma			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Facial bones fracture			
subjects affected / exposed	1 / 285 (0.35%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 285 (0.35%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	1 / 285 (0.35%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Hemiparesis			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	1 / 90 (1.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	1 / 90 (1.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal impairment			

subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	1 / 90 (1.11%)
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 mass			
subjects affected / exposed	1 / 285 (0.35%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal abscess			
subjects affected / exposed	1 / 285 (0.35%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Arm A2	Arm A3	Arm B1
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 94 (1.06%)	1 / 94 (1.06%)	0 / 45 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma			
subjects affected / exposed	0 / 94 (0.00%)	1 / 94 (1.06%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Facial bones fracture			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			

subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Hemiparesis			
subjects affected / exposed	1 / 94 (1.06%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal impairment			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal mass			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Arm B2		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 44 (0.00%)		

number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Facial bones fracture			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Hemiparesis			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Renal and urinary disorders			
Renal impairment			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal mass			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Secukinumab 150 mg	Placebo	Arm A1
Total subjects affected by non-serious adverse events			
subjects affected / exposed	59 / 285 (20.70%)	23 / 95 (24.21%)	21 / 90 (23.33%)
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 285 (1.05%)	1 / 95 (1.05%)	0 / 90 (0.00%)
occurrences (all)	3	1	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	6 / 285 (2.11%)	0 / 95 (0.00%)	1 / 90 (1.11%)
occurrences (all)	6	0	1
Injection site pain			
subjects affected / exposed	2 / 285 (0.70%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	2	0	0
Reproductive system and breast disorders			
Vulvovaginal pruritus			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0

Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	2 / 285 (0.70%)	0 / 95 (0.00%)	3 / 90 (3.33%)
occurrences (all)	2	0	3
Oropharyngeal pain			
subjects affected / exposed	8 / 285 (2.81%)	1 / 95 (1.05%)	4 / 90 (4.44%)
occurrences (all)	9	1	4
Rhinorrhoea			
subjects affected / exposed	1 / 285 (0.35%)	1 / 95 (1.05%)	0 / 90 (0.00%)
occurrences (all)	1	1	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 285 (0.35%)	1 / 95 (1.05%)	0 / 90 (0.00%)
occurrences (all)	1	2	0
Blood creatinine increased			
subjects affected / exposed	4 / 285 (1.40%)	0 / 95 (0.00%)	3 / 90 (3.33%)
occurrences (all)	4	0	3
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 285 (0.00%)	1 / 95 (1.05%)	0 / 90 (0.00%)
occurrences (all)	0	1	0
Limb injury			
subjects affected / exposed	1 / 285 (0.35%)	0 / 95 (0.00%)	2 / 90 (2.22%)
occurrences (all)	1	0	2
Nervous system disorders			

Headache			
subjects affected / exposed	10 / 285 (3.51%)	1 / 95 (1.05%)	2 / 90 (2.22%)
occurrences (all)	12	1	2
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	1 / 285 (0.35%)	1 / 95 (1.05%)	1 / 90 (1.11%)
occurrences (all)	1	1	1
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Iritis			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Vitreous haemorrhage			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	3 / 285 (1.05%)	1 / 95 (1.05%)	0 / 90 (0.00%)
occurrences (all)	3	1	0
Diarrhoea			
subjects affected / exposed	6 / 285 (2.11%)	1 / 95 (1.05%)	0 / 90 (0.00%)
occurrences (all)	9	1	0
Frequent bowel movements			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hypertransaminasaemia			

subjects affected / exposed	1 / 285 (0.35%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	2 / 285 (0.70%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	2	0	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	1 / 285 (0.35%)	0 / 95 (0.00%)	1 / 90 (1.11%)
occurrences (all)	1	0	1
Proteinuria			
subjects affected / exposed	3 / 285 (1.05%)	1 / 95 (1.05%)	0 / 90 (0.00%)
occurrences (all)	3	1	0
Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	4 / 285 (1.40%)	2 / 95 (2.11%)	0 / 90 (0.00%)
occurrences (all)	4	2	0
Back pain			
subjects affected / exposed	1 / 285 (0.35%)	3 / 95 (3.16%)	0 / 90 (0.00%)
occurrences (all)	1	5	0
Bursitis			
subjects affected / exposed	1 / 285 (0.35%)	0 / 95 (0.00%)	1 / 90 (1.11%)
occurrences (all)	1	0	1
Foot deformity			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Muscle contracture			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			

subjects affected / exposed	6 / 285 (2.11%)	0 / 95 (0.00%)	1 / 90 (1.11%)
occurrences (all)	6	0	1
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 285 (0.00%)	1 / 95 (1.05%)	1 / 90 (1.11%)
occurrences (all)	0	1	1
Conjunctivitis			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	2 / 90 (2.22%)
occurrences (all)	0	0	2
Herpes simplex			
subjects affected / exposed	1 / 285 (0.35%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	6 / 285 (2.11%)	1 / 95 (1.05%)	1 / 90 (1.11%)
occurrences (all)	7	1	1
Otitis externa			
subjects affected / exposed	1 / 285 (0.35%)	0 / 95 (0.00%)	1 / 90 (1.11%)
occurrences (all)	1	0	2
Pharyngitis			
subjects affected / exposed	3 / 285 (1.05%)	0 / 95 (0.00%)	2 / 90 (2.22%)
occurrences (all)	3	0	2
Rhinitis			
subjects affected / exposed	1 / 285 (0.35%)	0 / 95 (0.00%)	2 / 90 (2.22%)
occurrences (all)	1	0	2
Tooth infection			
subjects affected / exposed	0 / 285 (0.00%)	2 / 95 (2.11%)	0 / 90 (0.00%)
occurrences (all)	0	2	0
Upper respiratory tract infection			
subjects affected / exposed	4 / 285 (1.40%)	5 / 95 (5.26%)	1 / 90 (1.11%)
occurrences (all)	4	5	1
Viral pharyngitis			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Lactose intolerance			
subjects affected / exposed	0 / 285 (0.00%)	0 / 95 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Arm A2	Arm A3	Arm B1
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 94 (25.53%)	23 / 94 (24.47%)	9 / 45 (20.00%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 94 (1.06%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Injection site pain			
subjects affected / exposed	0 / 94 (0.00%)	3 / 94 (3.19%)	0 / 45 (0.00%)
occurrences (all)	0	4	0
Reproductive system and breast disorders			
Vulvovaginal pruritus			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 94 (1.06%)	1 / 94 (1.06%)	0 / 45 (0.00%)
occurrences (all)	1	1	0
Oropharyngeal pain			
subjects affected / exposed	2 / 94 (2.13%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	2	0	0
Rhinorrhoea			

subjects affected / exposed	0 / 94 (0.00%)	2 / 94 (2.13%)	0 / 45 (0.00%)
occurrences (all)	0	2	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	2 / 94 (2.13%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	2	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 94 (1.06%)	2 / 94 (2.13%)	1 / 45 (2.22%)
occurrences (all)	1	2	1
Blood creatinine increased			
subjects affected / exposed	1 / 94 (1.06%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Limb injury			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 94 (2.13%)	3 / 94 (3.19%)	0 / 45 (0.00%)
occurrences (all)	2	3	0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Eye disorders			

Blepharitis			
subjects affected / exposed	2 / 94 (2.13%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	2	0	0
Iritis			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Vitreous haemorrhage			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 94 (1.06%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	0 / 94 (0.00%)	1 / 94 (1.06%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
Frequent bowel movements			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	2 / 94 (2.13%)	1 / 94 (1.06%)	0 / 45 (0.00%)
occurrences (all)	2	1	0
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 94 (0.00%)	1 / 94 (1.06%)	1 / 45 (2.22%)
occurrences (all)	0	1	1
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 94 (0.00%)	3 / 94 (3.19%)	1 / 45 (2.22%)
occurrences (all)	0	3	1
Proteinuria			
subjects affected / exposed	2 / 94 (2.13%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	3	0	0

Musculoskeletal and connective tissue disorders			
Ankylosing spondylitis			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Arthralgia			
subjects affected / exposed	3 / 94 (3.19%)	1 / 94 (1.06%)	0 / 45 (0.00%)
occurrences (all)	3	1	0
Back pain			
subjects affected / exposed	2 / 94 (2.13%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	2	0	0
Bursitis			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Foot deformity			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Muscle contracture			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 94 (1.06%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 94 (1.06%)	0 / 94 (0.00%)	1 / 45 (2.22%)
occurrences (all)	1	0	1
Conjunctivitis			
subjects affected / exposed	2 / 94 (2.13%)	1 / 94 (1.06%)	0 / 45 (0.00%)
occurrences (all)	2	1	0
Herpes simplex			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			

subjects affected / exposed	3 / 94 (3.19%)	4 / 94 (4.26%)	2 / 45 (4.44%)
occurrences (all)	3	4	2
Otitis externa			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	2 / 94 (2.13%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	2	0	0
Rhinitis			
subjects affected / exposed	2 / 94 (2.13%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	2	0	0
Tooth infection			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 94 (0.00%)	3 / 94 (3.19%)	0 / 45 (0.00%)
occurrences (all)	0	3	0
Viral pharyngitis			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 94 (1.06%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Lactose intolerance			
subjects affected / exposed	0 / 94 (0.00%)	0 / 94 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Arm B2		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 44 (29.55%)		
Vascular disorders			

Hypertension			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences (all)	1		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences (all)	0		
Injection site pain			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Vulvovaginal pruritus			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences (all)	1		
Cough			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences (all)	0		
Blood creatinine increased			

subjects affected / exposed	2 / 44 (4.55%)		
occurrences (all)	2		
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences (all)	1		
Foot fracture			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences (all)	0		
Limb injury			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences (all)	2		
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences (all)	1		
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences (all)	0		
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences (all)	0		
Iritis			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences (all)	0		
Vitreous haemorrhage			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences (all)	1		
Gastrointestinal disorders			

Abdominal pain subjects affected / exposed occurrences (all)	1 / 44 (2.27%) 1		
Diarrhoea subjects affected / exposed occurrences (all)	0 / 44 (0.00%) 0		
Frequent bowel movements subjects affected / exposed occurrences (all)	1 / 44 (2.27%) 1		
Toothache subjects affected / exposed occurrences (all)	0 / 44 (0.00%) 0		
Hepatobiliary disorders Hypertransaminasaemia subjects affected / exposed occurrences (all)	0 / 44 (0.00%) 0		
Skin and subcutaneous tissue disorders Pruritus subjects affected / exposed occurrences (all)	0 / 44 (0.00%) 0		
Renal and urinary disorders Haematuria subjects affected / exposed occurrences (all)	0 / 44 (0.00%) 0		
Proteinuria subjects affected / exposed occurrences (all)	0 / 44 (0.00%) 0		
Musculoskeletal and connective tissue disorders Ankylosing spondylitis subjects affected / exposed occurrences (all)	0 / 44 (0.00%) 0		
Arthralgia subjects affected / exposed occurrences (all)	0 / 44 (0.00%) 0		
Back pain			

subjects affected / exposed	0 / 44 (0.00%)		
occurrences (all)	0		
Bursitis			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences (all)	1		
Foot deformity			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences (all)	1		
Muscle contracture			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences (all)	1		
Osteoarthritis			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences (all)	1		
Pain in extremity			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences (all)	0		
Herpes simplex			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences (all)	1		
Nasopharyngitis			
subjects affected / exposed	2 / 44 (4.55%)		
occurrences (all)	2		
Otitis externa			
subjects affected / exposed	1 / 44 (2.27%)		
occurrences (all)	1		
Pharyngitis			
subjects affected / exposed	0 / 44 (0.00%)		
occurrences (all)	0		

Rhinitis subjects affected / exposed occurrences (all)	0 / 44 (0.00%) 0		
Tooth infection subjects affected / exposed occurrences (all)	0 / 44 (0.00%) 0		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 44 (0.00%) 0		
Viral pharyngitis subjects affected / exposed occurrences (all)	1 / 44 (2.27%) 1		
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 44 (2.27%) 1		
Metabolism and nutrition disorders Hypercholesterolaemia subjects affected / exposed occurrences (all)	1 / 44 (2.27%) 1		
Lactose intolerance subjects affected / exposed occurrences (all)	1 / 44 (2.27%) 1		

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.

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: