# Clinical trial results:
# A Randomized, Double-blind, Placebo-controlled, Phase III Multicenter Study of Subcutaneous Secukinumab (150 mg) With and Without a Subcutaneous Loading Regimen to Assess Efficacy, Safety, and Tolerability up to 2 Years in Patients With Active Ankylosing Spondylitis

## Summary

| | |
|---|---|
| EudraCT number | 2013-005575-41 |
| Trial protocol | CZ DE AT NL FI NO DK GB ES SK BG PL GR IT |
| Global end of trial date | 02 January 2018 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 24 November 2018 |
| First version publication date | 24 November 2018 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | CAIN457F2320 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02159053 |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | Novartis Pharma AG |
| Sponsor organisation address | CH-4002, Basel, Switzerland, |
| Public contact | Novartis Pharma AG, Clinical Disclosure Office, +41 613241111, |
| Scientific contact | Novartis Pharma AG, Clinical Disclosure Office, +41 613241111, |

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 | 02 January 2018 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 02 January 2018 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

To demonstrate that the efficacy of secukinumab 150 mg at Week 16 with or without a loading regimen is superior to placebo based on the proportion of subjects achieving an ASAS20 (Assessment of SpondyloArthritis International Society criteria) response.

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 | 18 May 2015 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Safety, Efficacy |
| Long term follow-up duration | 2 Years |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Netherlands: 15 |
| Country: Number of subjects enrolled | Norway: 5 |
| Country: Number of subjects enrolled | Poland: 49 |
| Country: Number of subjects enrolled | Slovakia: 15 |
| Country: Number of subjects enrolled | Spain: 21 |
| Country: Number of subjects enrolled | United Kingdom: 9 |
| Country: Number of subjects enrolled | Austria: 14 |
| Country: Number of subjects enrolled | Bulgaria: 14 |
| Country: Number of subjects enrolled | Czech Republic: 49 |
| Country: Number of subjects enrolled | Denmark: 5 |
| Country: Number of subjects enrolled | Finland: 10 |
| Country: Number of subjects enrolled | Germany: 56 |
| Country: Number of subjects enrolled | Greece: 6 |
| Country: Number of subjects enrolled | Italy: 12 |
| Country: Number of subjects enrolled | Australia: 5 |
| Country: Number of subjects enrolled | Canada: 3 |
| Country: Number of subjects enrolled | Russian Federation: 35 |

| | |
|---|---|
| Country: Number of subjects enrolled | Switzerland: 3 |
| Country: Number of subjects enrolled | United States: 24 |
| Worldwide total number of subjects | 350 |
| EEA total number of subjects | 280 |

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) | 334 |
| From 65 to 84 years | 16 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

The study was conducted at 85 centers in 19 countries.

### Pre-assignment

Screening details:

A total of 424 subjects were screened, out of which 350 subjects completed the screening phase and were randomized to three treatment groups in 1:1:1 ratio.

### Period 1

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

Blinding implementation details:

Randomized treatment assignments were double-blinded to subjects, investigators, and site personnel. Following the Week 16 database lock, the Sponsor was unblinded to treatment assignment. After the Week 52 database lock and analyses was completed, site personnel and patients were unblinded to the original randomized treatment assignment.

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Secukinumab 150 mg with loading |

Arm description:

Subjects were subcutaneously (s.c.) administered with 150 milligrams (mg) of secukinumab at baseline, Weeks 1, 2, and 3, followed by dosing every four weeks starting at Week 4.

| | |
|---|---|
| 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:

Subjects were administered with 150 mg secukinumab s.c. using pre-filled syringe.

| | |
|---|---|
| **Arm title** | Secukinumab 150 mg without loading dose |

Arm description:

Subjects were s.c. administered with 150 mg of secukinumab at baseline, followed by dosing every four weeks starting at Week 4, and with Placebo at Weeks 1, 2, and 3.

| | |
|---|---|
| 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:

Subjects were administered with 150 mg secukinumab s.c. using pre-filled syringe.

| | |
|---|---|
| **Arm title** | Placebo |

Arm description:

Subjects were s.c. administered with placebo matching to secukinumab at baseline, Weeks 1, 2, 3, 4, 8, and 12. Subjects were further administered with 150 mg of secukinumab every four weeks starting at Week 16.

| | |
|---|---|
| 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:

Subjects were administered with 150 mg secukinumab s.c. using pre-filled syringe.

| **Number of subjects in period 1** | Secukinumab 150 mg with loading | Secukinumab 150 mg without loading dose | Placebo |
|---|---|---|---|
| Started | 116 | 117 | 117 |
| Subjects Week 16 onwards | 116 | 117 | 113 |
| Completed | 96 | 96 | 97 |
| Not completed | 20 | 21 | 20 |
| Physician decision | - | 1 | 1 |
| Adverse event, non-fatal | 7 | 6 | 5 |
| Death | 2 | - | 1 |
| Subject/guardian decision | 8 | 10 | 6 |
| Lack of efficacy | 3 | 4 | 7 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Secukinumab 150 mg with loading |
| Reporting group description: | |
| Subjects were subcutaneously (s.c.) administered with 150 milligrams (mg) of secukinumab at baseline, Weeks 1, 2, and 3, followed by dosing every four weeks starting at Week 4. | |
| Reporting group title | Secukinumab 150 mg without loading dose |
| Reporting group description: | |
| Subjects were s.c. administered with 150 mg of secukinumab at baseline, followed by dosing every four weeks starting at Week 4, and with Placebo at Weeks 1, 2, and 3. | |
| Reporting group title | Placebo |
| Reporting group description: | |
| Subjects were s.c. administered with placebo matching to secukinumab at baseline, Weeks 1, 2, 3, 4, 8, and 12. Subjects were further administered with 150 mg of secukinumab every four weeks starting at Week 16. | |

| Reporting group values | Secukinumab 150 mg with loading | Secukinumab 150 mg without loading dose | Placebo |
|---|---|---|---|
| Number of subjects | 116 | 117 | 117 |
| Age categorical<br>Units: Subjects | | | |
| Adults (18-64 years) | 110 | 114 | 110 |
| From 65-84 years | 6 | 3 | 7 |
| Age continuous<br>Units: years | | | |
| arithmetic mean | 44.5 | 41.2 | 43.4 |
| standard deviation | ± 11.62 | ± 11.07 | ± 12.46 |
| Gender categorical<br>Units: Subjects | | | |
| Female | 35 | 34 | 41 |
| Male | 81 | 83 | 76 |
| Patient's global assessment of disease activity | | | |
| The patient’s global assessment of disease activity was performed using a 0-100 mm visual analog scale (VAS) ranging from not severe to very severe, after the question, "How active was your disease on average during the last week?” | | | |
| Units: Unit on Scale | | | |
| arithmetic mean | 73.5 | 73.2 | 73.7 |
| standard deviation | ± 15.02 | ± 15.99 | ± 15.05 |
| Total back pain (0-100 mm) | | | |
| Total back pain as measured by VAS ≥ 40 mm on a scale of 0-100 mm. | | | |
| Units: Unit on Scale | | | |
| arithmetic mean | 74.9 | 74.2 | 75 |
| standard deviation | ± 13.07 | ± 14.18 | ± 13.80 |
| Bath Ankylosing Spondylitis Disease Activity Index | | | |
| Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) consisted of a 0 through 10 scale (0 being no problem and 10 being the worst problem, captured as a continuous VAS), which was used to answer 6 questions pertaining to the 5 major symptoms of Ankylosing Spondylitis:<br>1. Fatigue<br>2. Spinal pain<br>3. Joint pain / swelling | | | |

| | | | |
|---|---|---|---|
| 4. Areas of localized tenderness (called enthesitis, or inflammation of tendons and ligaments)<br>5. Morning stiffness duration<br>6. Morning stiffness severity | | | |
| Units: Unit on Scale | | | |
| arithmetic mean | 7 | 6.95 | 7.06 |
| standard deviation | ± 1.225 | ± 1.306 | ± 1.271 |
| High sensitivity (hs) C-reactive protein | | | |
| High sensitivity C-reactive protein assessment was performed in order to identify the presence of inflammation, to determine its severity, and to monitor response to treatment. | | | |
| Units: Milligrams per Litre (mg/L) | | | |
| arithmetic mean | 11.78 | 13.84 | 11.67 |
| standard deviation | ± 18.203 | ± 19.795 | ± 16.699 |

| **Reporting group values** | Total | | |
|---|---|---|---|
| Number of subjects | 350 | | |
| Age categorical<br>Units: Subjects | | | |
| Adults (18-64 years) | 334 | | |
| From 65-84 years | 16 | | |
| Age continuous<br>Units: years | | | |
| arithmetic mean | | | |
| standard deviation | - | | |
| Gender categorical<br>Units: Subjects | | | |
| Female | 110 | | |
| Male | 240 | | |
| Patient's global assessment of disease activity | | | |
| The patient’s global assessment of disease activity was performed using a 0-100 mm visual analog scale (VAS) ranging from not severe to very severe, after the question, "How active was your disease on average during the last week?” | | | |
| Units: Unit on Scale | | | |
| arithmetic mean | | | |
| standard deviation | - | | |
| Total back pain (0-100 mm) | | | |
| Total back pain as measured by VAS ≥ 40 mm on a scale of 0-100 mm. | | | |
| Units: Unit on Scale | | | |
| arithmetic mean | | | |
| standard deviation | - | | |
| Bath Ankylosing Spondylitis Disease Activity Index | | | |
| Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) consisted of a 0 through 10 scale (0 being no problem and 10 being the worst problem, captured as a continuous VAS), which was used to answer 6 questions pertaining to the 5 major symptoms of Ankylosing Spondylitis:<br>1. Fatigue<br>2. Spinal pain<br>3. Joint pain / swelling<br>4. Areas of localized tenderness (called enthesitis, or inflammation of tendons and ligaments)<br>5. Morning stiffness duration<br>6. Morning stiffness severity | | | |
| Units: Unit on Scale | | | |
| arithmetic mean | | | |
| standard deviation | - | | |
| High sensitivity (hs) C-reactive protein | | | |
| High sensitivity C-reactive protein assessment was performed in order to identify the presence of | | | |

| inflammation, to determine its severity, and to monitor response to treatment. | | | |
|---|---|---|---|
| Units: Milligrams per Litre (mg/L)<br>arithmetic mean<br>standard deviation | -<br> | | |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | Secukinumab 150 mg with loading |

Reporting group description:

Subjects were subcutaneously (s.c.) administered with 150 milligrams (mg) of secukinumab at baseline, Weeks 1, 2, and 3, followed by dosing every four weeks starting at Week 4.

| | |
|---|---|
| Reporting group title | Secukinumab 150 mg without loading dose |

Reporting group description:

Subjects were s.c. administered with 150 mg of secukinumab at baseline, followed by dosing every four weeks starting at Week 4, and with Placebo at Weeks 1, 2, and 3.

| | |
|---|---|
| Reporting group title | Placebo |

Reporting group description:

Subjects were s.c. administered with placebo matching to secukinumab at baseline, Weeks 1, 2, 3, 4, 8, and 12. Subjects were further administered with 150 mg of secukinumab every four weeks starting at Week 16.

| | |
|---|---|
| Subject analysis set title | All secukinumab 150 mg treated subjects |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

All subjects who were s.c. administered with secukinumab during the study.

### Primary: Percentage of subjects responded for Assessment of Spondyloarthritis International Society 20 criteria (ASAS20) at 16 weeks

| | |
|---|---|
| End point title | Percentage of subjects responded for Assessment of Spondyloarthritis International Society 20 criteria (ASAS20) at 16 weeks[1] |

End point description:

ASAS 20 response is validated composite assessment, defined as improvement of ≥20% and ≥1 unit on scale of 10 in 3 main domains and no worsening of ≥20% and 1 unit on scale of 10 in 4th domain. Four main ASAS domains include:
1. Patient’s global assessment of disease activity, measured on 100mm VAS ranging from not severe to very severe
2. Patient’s assessment of back pain, measured on 100mm VAS ranging from no pain to unbearable pain
3. Function represented by Bath Ankylosing Spondylitis Functional Index (BASFI) average of 10 questions regarding ability to perform specific tasks as measured by 0-10 VAS scale
4. Inflammation represented by average of duration and severity of morning stiffness for last 2 questions on BASDAI scale (0- no problem, 10- worst problem)
The analysis was performed in Full analysis set (FAS) population, defined as all subjects who were randomized and received study treatment. Here, "Number of subjects analysed" signifies subjects evaluable for endpoint.

| | |
|---|---|
| End point type | Primary |

End point timeframe:

16 weeks

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: Only descriptive summary statistics was planned for this outcome measure.

| End point values | Secukinumab 150 mg with loading | Secukinumab 150 mg without loading dose | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 114 | 110 | 112 | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 60.5 (50.9 to 69.4) | 65.5 (55.7 to 74.1) | 49.1 (49.1 to 58.7) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of subjects responded for ASAS 40 response at 16 weeks

| End point title | Percentage of subjects responded for ASAS 40 response at 16 weeks |
|---|---|

End point description:

ASAS 20 response is a validated composite assessment, defined as an improvement of ≥40% and 2 unit on a scale of 10 in three main domains and no worsening at all in the remaining domain within a defined time frame. Four main ASAS domains include:
1. Patient’s global assessment of disease activity measured on a 100 mm VAS ranging from not severe to very severe
2. Patient’s assessment of back pain, measured on a 100 mm VAS ranging from no pain to unbearable pain
3. Function represented by BASFI average of 10 questions regarding ability to perform specific tasks as measured by a 0-10 VAS scale
4. Inflammation represented by average of duration and severity of morning stiffness for last 2 questions on BASDAI scale (0 - no problem, 10 - worst problem)
The analysis was performed in FAS population. Here, "Number of subjects analysed" signifies subjects evaluable for endpoint.

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

End point timeframe:

16 weeks

| **End point values** | Secukinumab 150 mg with loading | Secukinumab 150 mg without loading dose | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 114 | 110 | 112 | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 39.5 (30.6 to 49.1) | 38.2 (29.2 to 48.0) | 29.5 (21.4 to 38.9) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in serum high sensitivity C-reactive protein (hsCRP) at 16 weeks

| End point title | Change From Baseline in serum high sensitivity C-reactive protein (hsCRP) at 16 weeks |
|---|---|

End point description:

Blood levels of C-reactive protein (CRP) is an acute phase reactant, which are indicative of inflammation and of its severity, and can be used to monitor treatment response. A hsCRP test is implemented to assess the efficacy of secukinumab (with or without load) versus placebo in reducing ankylosing spondylitis elicited systemic inflammation over the time. The analysis was performed in FAS population. Here, "Number of subjects analysed" signifies subjects evaluable for endpoint.

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

End point timeframe:

Baseline, 16 weeks

| **End point values** | Secukinumab 150 mg with loading | Secukinumab 150 mg without loading dose | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 113 | 109 | 112 | |
| Units: Ratio | | | | |
| arithmetic mean (standard deviation) | -4.23 (± 15.007) | -6.57 (± 12.778) | 0.62 (± 11.699) | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of subjects responded for ASAS 5/6 response at 16 weeks

| End point title | Percentage of subjects responded for ASAS 5/6 response at 16 weeks |
|---|---|

End point description:

ASAS 5/6 response is validated composite assessment, defined as improvement of ≥20% in score in at least 5 of 6 clinical domains relevant to ankylosing spondylitis and no worsening in remaining domain. ASAS domains includes:
1. Patient’s global assessment of disease activity measured on 100 mm VAS ranging from not to very severe
2. Patient’s assessment of back pain, measured on 100 mm VAS ranging from no to unbearable pain
3. Function represented by BASFI average of 10 questions regarding ability to perform specific tasks as measured by 0-10 VAS scale
4. Inflammation represented by average of duration and severity of morning stiffness for last 2 questions on BASDAI scale (0- no problem, 10- worst problem)
5. Spinal mobility represented by the Bath Ankylosing Spondylitis Metrology Index (BASMI) lateral spinal flexion assessment
6. CRP
The analysis was performed in FAS population. Here, "Number of subjects analysed" signifies subjects evaluable for endpoint.

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

End point timeframe:

16 weeks

| End point values | Secukinumab 150 mg with loading | Secukinumab 150 mg without loading dose | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 114 | 110 | 112 | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 37.7 (29.0 to 47.3) | 45.5 (36.0 to 55.2) | 30.4 (22.2 to 39.9) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) at 16 weeks

| End point title | Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) at 16 weeks |
|---|---|

End point description:

BASDAI is a validated assessment tool using 0 through 10 scales (0- no problem, 10- worst problem) on continuous VAS, to answer 6 questions pertaining to 5 major symptoms of ankylosing spondylitis. Computed composite scores of 4 or greater indicate suboptimal disease control. Questions includes:
1. Fatigue
2. Spinal pain
3. Joint pain / swelling
4. Areas of localized tenderness (called enthesitis, or inflammation of tendons and ligaments)
5. Morning stiffness duration
6. Morning stiffness severity

Each symptom has equal weighting, the mean of two scores related to morning stiffness was taken (questions 5 and 6). The resulting 0 to 10 score was added to the scores from questions 1-4. The resulting 0 to 50 score was divided by 5 to give a final 0–10 BASDAI score.
BASDAI was a quick and simple index taking between 30 seconds and 2 minutes for completion. The analysis was performed in FAS population. Here, "Number of subjects analysed" signifies subjects evaluable for endpoint.

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

End point timeframe:

Baseline, 16 weeks

| End point values | Secukinumab 150 mg with loading | Secukinumab 150 mg without loading dose | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 114 | 110 | 112 | |
| Units: Units on a scale | | | | |
| arithmetic mean (standard deviation) | -2.405 (± 2.1206) | -2.533 (± 2.1463) | -1.917 (± 2.2221) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Physical Function Component summary (PCS) of the Short-form Health Survey (SF-36)

| End point title | Change From Baseline in Physical Function Component summary (PCS) of the Short-form Health Survey (SF-36) |
|---|---|

End point description:

SF-36 is a 36 item questionnaire which measures Quality of Life across eight subscales that were scored individually: Physical Functioning, Role- Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional, and Mental Health. The overall summary scores, SF-36 physical Component Summary (PCS) was used to assess improvement from baseline in the Health-Related Quality Of Life of subjects. The change in SF-36 scores were evaluated using MMRM. The analysis was performed in FAS population. Here, "Number of subjects analysed" signifies subjects evaluable for endpoint.

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

End point timeframe:

Baseline, 16 weeks

| **End point values** | Secukinumab 150 mg with loading | Secukinumab 150 mg without loading dose | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 114 | 112 | 113 | |
| Units: Units on a scale | | | | |
| arithmetic mean (standard deviation) | 6.754 (± 6.9624) | 7.242 (± 8.3627) | 4.7 (± 7.5912) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in Ankylosing Spondylitis Quality of Life Questionnaire (ASQoL) at 16 weeks

| End point title | Change From Baseline in Ankylosing Spondylitis Quality of Life Questionnaire (ASQoL) at 16 weeks |
|---|---|

End point description:

ASQoL is a self-administered 18 item questionnaire that assesses disease-specific quality of life (QoL), consisting of statements that are relevant to the physical and mental conditions for a subject with ankylosing spondylitis: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each statement is answered as a 'Yes' (scored as 1) or 'No' (scored as 0). All item scores are summed to give a total score. Total score ranges from 0 (good QoL) to 18 (poor QoL). The change in ASQoL scores was evaluated using a mixed effect repeated measures model (MMRM). The analysis was performed in FAS population. Here, "Number of subjects analysed" signifies subjects evaluable for endpoint.

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

End point timeframe:

Baseline, 16 weeks

| End point values | Secukinumab 150 mg with loading | Secukinumab 150 mg without loading dose | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 114 | 112 | 113 | |
| Units: Units on a scale | | | | |
| arithmetic mean (standard deviation) | -4.2 (± 4.63) | -4.7 (± 5.05) | -3 (± 4.74) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with adverse events (AEs), deaths, serious adverse events (SAEs) and related discontinuations at 104 weeks

| End point title | Number of subjects with adverse events (AEs), deaths, serious adverse events (SAEs) and related discontinuations at 104 weeks |
|---|---|

End point description:

AEs were defined as any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during study, having been absent at baseline, or, if present at baseline, appears to worsen. SAEs were defined as any untoward medical occurrences that result in death, are life threatening, require (or prolong) hospitalization, cause persistent or significant disability/incapacity, result in congenital anomalies or birth defects, or are other conditions which in judgement of investigators represent significant hazards. The analysis was performed on the safety population, defined as all subjects who took at least one dose of study treatment during the treatment period.

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

End point timeframe:

104 weeks

| End point values | Secukinumab 150 mg with loading | Secukinumab 150 mg without loading dose | Placebo | All secukinumab 150 mg treated subjects |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 116 | 117 | 117 | 346 |
| Units: Number of Subjects | | | | |
| AEs | 100 | 98 | 65 | 289 |
| SAEs | 16 | 11 | 4 | 39 |
| Death | 2 | 0 | 0 | 4 |
| Discontinued study treatment due to any AEs | 9 | 5 | 1 | 20 |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of subjects responded for ASAS 20 at week 4

| End point title | Percentage of subjects responded for ASAS 20 at week 4 |
|---|---|

End point description:

ASAS 20 response is a validated composite assessment, defined as an improvement of ≥20% and 1 unit on a scale of 10 in three main domains and no worsening of ≥20% and 1 unit on a scale of 10 in the fourth domain within a defined time frame. Four main ASAS domains include:
1. Patient's global assessment of disease activity measured on a 100 mm VAS ranging from not severe to very severe
2. Patient's assessment of back pain, measured on a 100 mm VAS ranging from no pain to unbearable pain
3. Function represented by BASFI average of 10 questions regarding ability to perform specific tasks as measured by a 0-10 VAS scale
4. Inflammation represented by average of duration and severity of morning stiffness for last 2 questions on BASDAI scale (0 - no problem, 10 - worst problem)
The analysis was performed in FAS population. Here, "Number of subjects analysed" signifies subjects evaluable for endpoint.

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

End point timeframe:

Week 4

| **End point values** | Secukinumab 150 mg with loading | Secukinumab 150 mg without loading dose | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 116 | 114 | 115 | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 49.1 (39.8 to 58.5) | 55.3 (45.7 to 64.6) | 40.0 (31.1 to 49.6) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of subjects responded for ASAS 40 response at week 4

| End point title | Percentage of subjects responded for ASAS 40 response at week 4 |
|---|---|

End point description:

ASAS 20 response is a validated composite assessment, defined as an improvement of at least 40% and 2 unit on a scale of 10 in three main domains and no worsening at all in the remaining domain within a defined time frame. Four main ASAS domains include:
1. Patient's global assessment of disease activity measured on a 100 mm VAS ranging from not severe to very severe
2. Patient's assessment of back pain, measured on a 100 mm VAS ranging from no pain to unbearable pain
3. Function represented by BASFI average of 10 questions regarding ability to perform specific tasks as measured by a 0-10 VAS scale
4. Inflammation represented by average of duration and severity of morning stiffness for last 2 questions on BASDAI scale (0 - no problem, 10 - worst problem)
The analysis was performed in FAS population. Here, "Number of subjects analysed" signifies subjects evaluable for endpoint.

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

End point timeframe:
Week 4

| **End point values** | Secukinumab 150 mg with loading | Secukinumab 150 mg without loading dose | Placebo | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 116 | 114 | 115 | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 29.3 (21.4 to 38.6) | 27.2 (19.5 to 36.5) | 18.3 (11.9 to 26.8) | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Serious Adverse Events are monitored from date of First Subject First Visit (FSFV) until Last Subject Last Visit (LSLV). All other adverse events are monitored from First Subject First Treatment until LSLV.

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

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 20.1 |

### Reporting groups

| | |
|---|---|
| Reporting group title | Secukinumab 150 mg without loading dose |

Reporting group description:

Subjects were s.c. administered with 150 mg of secukinumab at baseline, followed by dosing every four weeks starting at Week 4, and with Placebo at Weeks 1, 2, and 3.

| | |
|---|---|
| Reporting group title | Secukinumab 150 mg with loading |

Reporting group description:

Subjects were s.c. administered with 150 mg of secukinumab at baseline, Weeks 1, 2, and 3, followed by dosing every four weeks starting at Week 4.

| | |
|---|---|
| Reporting group title | Placebo |

Reporting group description:

Subjects were s.c. administered with placebo matching to secukinumab at baseline, Weeks 1, 2, 3, 4, 8, and 12. Subjects were further administered with 150 mg of secukinumab every four weeks starting at Week 16.

| | |
|---|---|
| Reporting group title | All secukinumab 150 mg treated subjects |

Reporting group description:

All subjects who were s.c. administered with secukinumab during the study.

| Serious adverse events | Secukinumab 150 mg without loading dose | Secukinumab 150 mg with loading | Placebo |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 11 / 117 (9.40%) | 18 / 116 (15.52%) | 4 / 117 (3.42%) |
| number of deaths (all causes) | 0 | 2 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Adenocarcinoma gastric | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Malignant melanoma | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 1 / 117 (0.85%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Prostate cancer | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Testis cancer | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (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 |
| Uterine leiomyoma | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 2 / 116 (1.72%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| Peripheral artery occlusion | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (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 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (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 |
| Reproductive system and breast disorders | | | |
| Rectocele | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Pulmonary embolism | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 117 (0.85%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Psychiatric disorders | | | |
| Depression suicidal | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Somatic symptom disorder | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Investigations | | | |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (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 | 1 / 117 (0.85%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Meniscus injury | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Tendon injury | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 117 (0.85%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Tibia fracture | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 0 / 117 (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 | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 0 / 117 (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 failure acute | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Myocardial infarction | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Myocardial ischaemia | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Pericarditis | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Basal ganglia haemorrhage | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Migraine | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (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 |
| VIth nerve paralysis | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 0 / 116 (0.00%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (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 |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (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 |
| Ear and labyrinth disorders | | | |
| Acute vestibular syndrome | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (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 |
| Eye disorders | | | |
| Papilloedema | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 0 / 116 (0.00%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Retinal detachment | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 0 / 116 (0.00%) | 0 / 117 (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 | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 1 / 117 (0.85%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal fistula | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 0 / 116 (0.00%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Crohn's disease | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 1 / 117 (0.85%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Duodenal ulcer | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (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 |
| Duodenitis | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (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 |
| Gastric ulcer | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (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 |
| Gastritis erosive | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (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 |
| Oesophagitis | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Hepatobiliary disorders | | | |
| Cholelithiasis | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Renal and urinary disorders | | | |
| Bladder diverticulum | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Glomerulonephritis membranous | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 0 / 116 (0.00%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nephrolithiasis | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Proteinuria | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 0 / 116 (0.00%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal colic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 1 / 117 (0.85%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary retention | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Back pain | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Bursitis | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Femoroacetabular impingement | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 1 / 117 (0.85%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Myofascial pain syndrome | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 0 / 116 (0.00%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Osteoarthritis | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 2 / 116 (1.72%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |

| | | | |
|---|---|---|---|
| Appendicitis | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (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 |
| Atypical pneumonia | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Chronic tonsillitis | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 0 / 116 (0.00%) | 0 / 117 (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 |
| Erysipelas | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 2 / 116 (1.72%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tinea pedis | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 0 / 116 (0.00%) | 0 / 117 (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** | All secukinumab 150 mg treated subjects | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 43 / 346 (12.43%) | | |
| number of deaths (all causes) | 4 | | |
| number of deaths resulting from adverse events | 0 | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Adenocarcinoma gastric | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Malignant melanoma | | | |
| subjects affected / exposed | 0 / 346 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Prostate cancer | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Testis cancer | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Uterine leiomyoma | | | |
| subjects affected / exposed | 2 / 346 (0.58%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vascular disorders | | | |
| Peripheral artery occlusion | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | |
|---|---|---|---|
| Reproductive system and breast disorders | | | |
| Rectocele | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Psychiatric disorders | | | |
| Depression suicidal | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Somatic symptom disorder | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Investigations | | | |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Weight decreased | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Injury, poisoning and procedural complications | | | |
| Facial bones fracture | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Meniscus injury | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Tendon injury | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Tibia fracture | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| **Cardiac disorders** | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac failure acute | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Myocardial infarction | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Myocardial ischaemia | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Pericarditis | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| **Nervous system disorders** | | | |

| | | | |
|---|---|---|---|
| Basal ganglia haemorrhage | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Migraine | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| VIth nerve paralysis | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ear and labyrinth disorders | | | |
| Acute vestibular syndrome | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Eye disorders | | | |
| Papilloedema | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 1 / 346 (0.29%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Retinal detachment | | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastrointestinal disorders | | | | |
| Abdominal pain | | | | |
| subjects affected / exposed | 0 / 346 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Anal fistula | | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Colitis ulcerative | | | | |
| subjects affected / exposed | 2 / 346 (0.58%) | | | |
| occurrences causally related to treatment / all | 1 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Crohn's disease | | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Diarrhoea | | | | |
| subjects affected / exposed | 0 / 346 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Duodenal ulcer | | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Duodenitis | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastric ulcer | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastritis erosive | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Oesophagitis | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatobiliary disorders | | | |
| Cholelithiasis | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| Bladder diverticulum | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Glomerulonephritis membranous | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nephrolithiasis | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 1 / 346 (0.29%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Proteinuria | | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Renal colic | | | | |
| subjects affected / exposed | 0 / 346 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Urinary retention | | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Musculoskeletal and connective tissue disorders | | | | |
| Back pain | | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bursitis | | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Femoroacetabular impingement | | | | |
| subjects affected / exposed | 0 / 346 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Intervertebral disc protrusion | | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Myofascial pain syndrome | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Osteoarthritis | | | |
| subjects affected / exposed | 2 / 346 (0.58%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| **Infections and infestations** | | | |
| Appendicitis | | | |
| subjects affected / exposed | 2 / 346 (0.58%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Atypical pneumonia | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Chronic tonsillitis | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Erysipelas | | | |
| subjects affected / exposed | 3 / 346 (0.87%) | | |
| occurrences causally related to treatment / all | 3 / 4 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Otitis media acute | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Tinea pedis | | | |
| subjects affected / exposed | 1 / 346 (0.29%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| **Non-serious adverse events** | Secukinumab 150 mg without loading dose | Secukinumab 150 mg with loading | Placebo |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 89 / 117 (76.07%) | 90 / 116 (77.59%) | 54 / 117 (46.15%) |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 6 / 117 (5.13%) | 9 / 116 (7.76%) | 2 / 117 (1.71%) |
| occurrences (all) | 7 | 9 | 2 |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 3 / 117 (2.56%) | 4 / 116 (3.45%) | 4 / 117 (3.42%) |
| occurrences (all) | 3 | 5 | 5 |
| Influenza like illness | | | |
| subjects affected / exposed | 3 / 117 (2.56%) | 2 / 116 (1.72%) | 0 / 117 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 3 / 117 (2.56%) | 0 / 116 (0.00%) | 1 / 117 (0.85%) |
| occurrences (all) | 3 | 0 | 3 |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 3 / 116 (2.59%) | 1 / 117 (0.85%) |
| occurrences (all) | 1 | 3 | 1 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 4 / 117 (3.42%) | 6 / 116 (5.17%) | 2 / 117 (1.71%) |
| occurrences (all) | 4 | 9 | 2 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 5 / 117 (4.27%) | 7 / 116 (6.03%) | 1 / 117 (0.85%) |
| occurrences (all) | 5 | 10 | 1 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 3 / 117 (2.56%) | 1 / 116 (0.86%) | 0 / 117 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| Psychiatric disorders | | | |
| Depression | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 5 / 117 (4.27%) | 0 / 116 (0.00%) | 0 / 117 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 4 / 117 (3.42%) | 5 / 116 (4.31%) | 1 / 117 (0.85%) |
| occurrences (all) | 4 | 7 | 1 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 4 / 117 (3.42%) | 3 / 116 (2.59%) | 0 / 117 (0.00%) |
| occurrences (all) | 4 | 4 | 0 |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 4 / 117 (3.42%) | 4 / 116 (3.45%) | 0 / 117 (0.00%) |
| occurrences (all) | 5 | 5 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 4 / 116 (3.45%) | 1 / 117 (0.85%) |
| occurrences (all) | 0 | 4 | 1 |
| Cardiac disorders | | | |
| Atrioventricular block first degree | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 4 / 116 (3.45%) | 0 / 117 (0.00%) |
| occurrences (all) | 1 | 4 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 2 / 117 (1.71%) | 10 / 116 (8.62%) | 5 / 117 (4.27%) |
| occurrences (all) | 7 | 11 | 6 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 3 / 117 (2.56%) | 1 / 116 (0.86%) | 0 / 117 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 4 / 116 (3.45%) | 1 / 117 (0.85%) |
| occurrences (all) | 1 | 4 | 1 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 1 / 116 (0.86%) | 0 / 117 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Ear and labyrinth disorders | | | |

| | | | |
|---|---|---|---|
| Vertigo | | | |
| subjects affected / exposed | 3 / 117 (2.56%) | 3 / 116 (2.59%) | 0 / 117 (0.00%) |
| occurrences (all) | 3 | 3 | 0 |
| Eye disorders | | | |
| Iridocyclitis | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 3 / 116 (2.59%) | 0 / 117 (0.00%) |
| occurrences (all) | 2 | 4 | 0 |
| Iritis | | | |
| subjects affected / exposed | 3 / 117 (2.56%) | 1 / 116 (0.86%) | 0 / 117 (0.00%) |
| occurrences (all) | 4 | 2 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 3 / 117 (2.56%) | 3 / 116 (2.59%) | 0 / 117 (0.00%) |
| occurrences (all) | 7 | 3 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 6 / 116 (5.17%) | 0 / 117 (0.00%) |
| occurrences (all) | 1 | 8 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 11 / 117 (9.40%) | 9 / 116 (7.76%) | 6 / 117 (5.13%) |
| occurrences (all) | 17 | 15 | 6 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 3 / 117 (2.56%) | 1 / 116 (0.86%) | 0 / 117 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Mouth ulceration | | | |
| subjects affected / exposed | 2 / 117 (1.71%) | 3 / 116 (2.59%) | 1 / 117 (0.85%) |
| occurrences (all) | 3 | 3 | 2 |
| Nausea | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 8 / 116 (6.90%) | 2 / 117 (1.71%) |
| occurrences (all) | 1 | 9 | 6 |
| Toothache | | | |
| subjects affected / exposed | 3 / 117 (2.56%) | 2 / 116 (1.72%) | 0 / 117 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Alopecia | | | |
| subjects affected / exposed | 4 / 117 (3.42%) | 2 / 116 (1.72%) | 2 / 117 (1.71%) |
| occurrences (all) | 4 | 2 | 2 |
| Eczema | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 117 (2.56%) | 4 / 116 (3.45%) | 3 / 117 (2.56%) |
| occurrences (all) | 4 | 6 | 3 |
| Pruritus | | | |
| subjects affected / exposed | 3 / 117 (2.56%) | 4 / 116 (3.45%) | 2 / 117 (1.71%) |
| occurrences (all) | 4 | 4 | 2 |
| Rash | | | |
| subjects affected / exposed | 3 / 117 (2.56%) | 3 / 116 (2.59%) | 0 / 117 (0.00%) |
| occurrences (all) | 4 | 3 | 0 |
| Renal and urinary disorders | | | |
| Haematuria | | | |
| subjects affected / exposed | 3 / 117 (2.56%) | 0 / 116 (0.00%) | 1 / 117 (0.85%) |
| occurrences (all) | 3 | 0 | 1 |
| Musculoskeletal and connective tissue disorders | | | |
| Ankylosing spondylitis | | | |
| subjects affected / exposed | 11 / 117 (9.40%) | 12 / 116 (10.34%) | 5 / 117 (4.27%) |
| occurrences (all) | 18 | 24 | 5 |
| Arthralgia | | | |
| subjects affected / exposed | 11 / 117 (9.40%) | 2 / 116 (1.72%) | 2 / 117 (1.71%) |
| occurrences (all) | 14 | 2 | 3 |
| Arthritis | | | |
| subjects affected / exposed | 3 / 117 (2.56%) | 0 / 116 (0.00%) | 0 / 117 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Back pain | | | |
| subjects affected / exposed | 7 / 117 (5.98%) | 10 / 116 (8.62%) | 5 / 117 (4.27%) |
| occurrences (all) | 7 | 10 | 6 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 3 / 116 (2.59%) | 2 / 117 (1.71%) |
| occurrences (all) | 1 | 3 | 4 |
| Myalgia | | | |
| subjects affected / exposed | 2 / 117 (1.71%) | 4 / 116 (3.45%) | 0 / 117 (0.00%) |
| occurrences (all) | 2 | 4 | 0 |
| Osteoarthritis | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 3 / 116 (2.59%) | 0 / 117 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Pain in extremity | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 5 / 117 (4.27%) | 2 / 116 (1.72%) | 0 / 117 (0.00%) |
| occurrences (all) | 6 | 2 | 0 |
| Spondylitis | | | |
| subjects affected / exposed | 3 / 117 (2.56%) | 1 / 116 (0.86%) | 1 / 117 (0.85%) |
| occurrences (all) | 3 | 1 | 1 |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 8 / 117 (6.84%) | 13 / 116 (11.21%) | 1 / 117 (0.85%) |
| occurrences (all) | 8 | 17 | 1 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 3 / 116 (2.59%) | 0 / 117 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| Fungal skin infection | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 5 / 116 (4.31%) | 0 / 117 (0.00%) |
| occurrences (all) | 1 | 7 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 3 / 117 (2.56%) | 5 / 116 (4.31%) | 2 / 117 (1.71%) |
| occurrences (all) | 4 | 7 | 2 |
| Herpes simplex | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 3 / 116 (2.59%) | 0 / 117 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| Influenza | | | |
| subjects affected / exposed | 9 / 117 (7.69%) | 7 / 116 (6.03%) | 5 / 117 (4.27%) |
| occurrences (all) | 13 | 11 | 5 |
| Laryngitis | | | |
| subjects affected / exposed | 2 / 117 (1.71%) | 3 / 116 (2.59%) | 0 / 117 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 29 / 117 (24.79%) | 32 / 116 (27.59%) | 10 / 117 (8.55%) |
| occurrences (all) | 44 | 52 | 13 |
| Oral herpes | | | |
| subjects affected / exposed | 3 / 117 (2.56%) | 4 / 116 (3.45%) | 2 / 117 (1.71%) |
| occurrences (all) | 4 | 6 | 2 |
| Pharyngitis | | | |
| subjects affected / exposed | 6 / 117 (5.13%) | 2 / 116 (1.72%) | 3 / 117 (2.56%) |
| occurrences (all) | 6 | 2 | 3 |

| | | | |
|---|---|---|---|
| Pulpitis dental | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 3 / 116 (2.59%) | 0 / 117 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 10 / 117 (8.55%) | 6 / 116 (5.17%) | 3 / 117 (2.56%) |
| occurrences (all) | 14 | 10 | 4 |
| Rhinitis | | | |
| subjects affected / exposed | 7 / 117 (5.98%) | 3 / 116 (2.59%) | 1 / 117 (0.85%) |
| occurrences (all) | 9 | 3 | 1 |
| Sinusitis | | | |
| subjects affected / exposed | 4 / 117 (3.42%) | 4 / 116 (3.45%) | 0 / 117 (0.00%) |
| occurrences (all) | 5 | 6 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 3 / 117 (2.56%) | 1 / 116 (0.86%) | 0 / 117 (0.00%) |
| occurrences (all) | 4 | 1 | 0 |
| Tooth infection | | | |
| subjects affected / exposed | 0 / 117 (0.00%) | 3 / 116 (2.59%) | 0 / 117 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 17 / 117 (14.53%) | 11 / 116 (9.48%) | 6 / 117 (5.13%) |
| occurrences (all) | 24 | 16 | 6 |
| Urinary tract infection | | | |
| subjects affected / exposed | 2 / 117 (1.71%) | 3 / 116 (2.59%) | 0 / 117 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| Metabolism and nutrition disorders | | | |
| Hypercholesterolaemia | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 1 / 116 (0.86%) | 3 / 117 (2.56%) |
| occurrences (all) | 1 | 1 | 3 |
| Hyperlipidaemia | | | |
| subjects affected / exposed | 1 / 117 (0.85%) | 6 / 116 (5.17%) | 1 / 117 (0.85%) |
| occurrences (all) | 1 | 6 | 1 |

| **Non-serious adverse events** | All secukinumab 150 mg treated subjects | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 254 / 346 (73.41%) | | |
| Vascular disorders | | | |

| | | | |
|---|---|---|---|
| Hypertension | | | |
| subjects affected / exposed | 18 / 346 (5.20%) | | |
| occurrences (all) | 19 | | |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 8 / 346 (2.31%) | | |
| occurrences (all) | 9 | | |
| Influenza like illness | | | |
| subjects affected / exposed | 5 / 346 (1.45%) | | |
| occurrences (all) | 5 | | |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 4 / 346 (1.16%) | | |
| occurrences (all) | 5 | | |
| Pyrexia | | | |
| subjects affected / exposed | 8 / 346 (2.31%) | | |
| occurrences (all) | 8 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 18 / 346 (5.20%) | | |
| occurrences (all) | 22 | | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 16 / 346 (4.62%) | | |
| occurrences (all) | 19 | | |
| Rhinorrhoea | | | |
| subjects affected / exposed | 5 / 346 (1.45%) | | |
| occurrences (all) | 6 | | |
| Psychiatric disorders | | | |
| Depression | | | |
| subjects affected / exposed | 6 / 346 (1.73%) | | |
| occurrences (all) | 9 | | |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 10 / 346 (2.89%) | | |
| occurrences (all) | 12 | | |
| Aspartate aminotransferase increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 8 / 346 (2.31%) | | |
| occurrences (all) | 9 | | |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 10 / 346 (2.89%) | | |
| occurrences (all) | 13 | | |
| Fall | | | |
| subjects affected / exposed | 5 / 346 (1.45%) | | |
| occurrences (all) | 5 | | |
| Cardiac disorders | | | |
| Atrioventricular block first degree | | | |
| subjects affected / exposed | 8 / 346 (2.31%) | | |
| occurrences (all) | 8 | | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 18 / 346 (5.20%) | | |
| occurrences (all) | 25 | | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 5 / 346 (1.45%) | | |
| occurrences (all) | 5 | | |
| Leukopenia | | | |
| subjects affected / exposed | 8 / 346 (2.31%) | | |
| occurrences (all) | 9 | | |
| Neutropenia | | | |
| subjects affected / exposed | 7 / 346 (2.02%) | | |
| occurrences (all) | 8 | | |
| Ear and labyrinth disorders | | | |
| Vertigo | | | |
| subjects affected / exposed | 7 / 346 (2.02%) | | |
| occurrences (all) | 8 | | |
| Eye disorders | | | |
| Iridocyclitis | | | |
| subjects affected / exposed | 7 / 346 (2.02%) | | |
| occurrences (all) | 9 | | |
| Iritis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 7 / 346 (2.02%) | | |
| occurrences (all) | 9 | | |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 8 / 346 (2.31%) | | |
| occurrences (all) | 12 | | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 10 / 346 (2.89%) | | |
| occurrences (all) | 13 | | |
| Diarrhoea | | | |
| subjects affected / exposed | 28 / 346 (8.09%) | | |
| occurrences (all) | 42 | | |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 5 / 346 (1.45%) | | |
| occurrences (all) | 5 | | |
| Mouth ulceration | | | |
| subjects affected / exposed | 6 / 346 (1.73%) | | |
| occurrences (all) | 7 | | |
| Nausea | | | |
| subjects affected / exposed | 13 / 346 (3.76%) | | |
| occurrences (all) | 16 | | |
| Toothache | | | |
| subjects affected / exposed | 5 / 346 (1.45%) | | |
| occurrences (all) | 5 | | |
| Skin and subcutaneous tissue disorders | | | |
| Alopecia | | | |
| subjects affected / exposed | 6 / 346 (1.73%) | | |
| occurrences (all) | 6 | | |
| Eczema | | | |
| subjects affected / exposed | 7 / 346 (2.02%) | | |
| occurrences (all) | 10 | | |
| Pruritus | | | |
| subjects affected / exposed | 8 / 346 (2.31%) | | |
| occurrences (all) | 9 | | |
| Rash | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed<br>occurrences (all) | 9 / 346 (2.60%)<br>11 | | |
| Renal and urinary disorders<br>Haematuria<br>subjects affected / exposed<br>occurrences (all) | <br><br>3 / 346 (0.87%)<br>3 | | |
| Musculoskeletal and connective tissue disorders<br>Ankylosing spondylitis<br>subjects affected / exposed<br>occurrences (all)<br>Arthralgia<br>subjects affected / exposed<br>occurrences (all)<br>Arthritis<br>subjects affected / exposed<br>occurrences (all)<br>Back pain<br>subjects affected / exposed<br>occurrences (all)<br>Musculoskeletal pain<br>subjects affected / exposed<br>occurrences (all)<br>Myalgia<br>subjects affected / exposed<br>occurrences (all)<br>Osteoarthritis<br>subjects affected / exposed<br>occurrences (all)<br>Pain in extremity<br>subjects affected / exposed<br>occurrences (all)<br>Spondylitis<br>subjects affected / exposed<br>occurrences (all) | <br><br>29 / 346 (8.38%)<br>49<br><br>15 / 346 (4.34%)<br>23<br><br>4 / 346 (1.16%)<br>7<br><br>23 / 346 (6.65%)<br>25<br><br>6 / 346 (1.73%)<br>6<br><br>8 / 346 (2.31%)<br>8<br><br>5 / 346 (1.45%)<br>5<br><br>10 / 346 (2.89%)<br>11<br><br>4 / 346 (1.16%)<br>4 | | |
| Infections and infestations | | | |

| | | | | |
|---|---|---|---|---|
| Bronchitis | | | | |
| subjects affected / exposed | 31 / 346 (8.96%) | | | |
| occurrences (all) | 37 | | | |
| Ear infection | | | | |
| subjects affected / exposed | 4 / 346 (1.16%) | | | |
| occurrences (all) | 6 | | | |
| Fungal skin infection | | | | |
| subjects affected / exposed | 7 / 346 (2.02%) | | | |
| occurrences (all) | 9 | | | |
| Gastroenteritis | | | | |
| subjects affected / exposed | 10 / 346 (2.89%) | | | |
| occurrences (all) | 13 | | | |
| Herpes simplex | | | | |
| subjects affected / exposed | 5 / 346 (1.45%) | | | |
| occurrences (all) | 5 | | | |
| Influenza | | | | |
| subjects affected / exposed | 19 / 346 (5.49%) | | | |
| occurrences (all) | 31 | | | |
| Laryngitis | | | | |
| subjects affected / exposed | 7 / 346 (2.02%) | | | |
| occurrences (all) | 9 | | | |
| Nasopharyngitis | | | | |
| subjects affected / exposed | 80 / 346 (23.12%) | | | |
| occurrences (all) | 129 | | | |
| Oral herpes | | | | |
| subjects affected / exposed | 9 / 346 (2.60%) | | | |
| occurrences (all) | 15 | | | |
| Pharyngitis | | | | |
| subjects affected / exposed | 10 / 346 (2.89%) | | | |
| occurrences (all) | 12 | | | |
| Pulpitis dental | | | | |
| subjects affected / exposed | 3 / 346 (0.87%) | | | |
| occurrences (all) | 3 | | | |
| Respiratory tract infection | | | | |
| subjects affected / exposed | 22 / 346 (6.36%) | | | |
| occurrences (all) | 33 | | | |

| | | | |
|---|---|---|---|
| Rhinitis<br>subjects affected / exposed<br>occurrences (all) | 15 / 346 (4.34%)<br>17 | | |
| Sinusitis<br>subjects affected / exposed<br>occurrences (all) | 9 / 346 (2.60%)<br>12 | | |
| Tonsillitis<br>subjects affected / exposed<br>occurrences (all) | 10 / 346 (2.89%)<br>11 | | |
| Tooth infection<br>subjects affected / exposed<br>occurrences (all) | 4 / 346 (1.16%)<br>4 | | |
| Upper respiratory tract infection<br>subjects affected / exposed<br>occurrences (all) | 37 / 346 (10.69%)<br>52 | | |
| Urinary tract infection<br>subjects affected / exposed<br>occurrences (all) | 7 / 346 (2.02%)<br>8 | | |
| Metabolism and nutrition disorders<br>Hypercholesterolaemia<br>subjects affected / exposed<br>occurrences (all) | 3 / 346 (0.87%)<br>3 | | |
| Hyperlipidaemia<br>subjects affected / exposed<br>occurrences (all) | 9 / 346 (2.60%)<br>9 | | |

## 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

None reported