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Trial record **1 of 1** for: CAIN457F2201
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Efficacy, Safety and Tolerability of AIN457 in Patients With Rheumatoid Arthritis (RA) Taking Methotrexate (MTX)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT00928512

First received: June 25, 2009
Last updated: October 7, 2015
Last verified: October 2015
History of Changes

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Results First Received: February 12, 2015

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator); Primary Purpose: Treatment
Condition:	Rheumatoid Arthritis
Interventions:	Drug: Secukinmab Drug: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
A total of 16 patients discontinued prior to Week 16.At Week 20, all patients on secukinumab 25-150 mg who were responders continued on their randomized dose regimens. Non-responders in the 25 mg and 75 mg groups were up-titrated to 150 mg and non-responders in the 150 mg group were up-titrated to 300 mg.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk
Secukinumab 75mg	Secukinumab 75mg s.c. q4wk
Secukinumab 25mg	Secukinumab 25mg s.c. q4wk
Secukinumab Placebo	Secukinumab Placebo s.c. q4wk

Participant Flow: Overall Study

	Secukinumab 300mg	Secukinumab 150mg	Secukinumab 75mg	Secukinumab 25mg	Secukinumab Placebo
STARTED	**41**	**43**	**49**	**54**	**50**
Discontinued Prior to Week 16	**3**	**0**	**2**	**6**	**5**
Reassigned at Week 20 (Non-responders)	**0** [1]	**23** [2]	**23** [3]	**27** [4]	**45** [5]

Not Reassigned at Week 20 (Responders)	37	20	23	18	0
New Groups After Reassignment	60 [6]	115	23 [6]	18 [7]	0
Completed Week 16	38	43	47	48	45
Entered/Continued to Week 20 (All)	37	43	46	45	45
COMPLETED	31	37	38	33	35
NOT COMPLETED	10	6	11	21	15
Adverse Event	4	3	2	8	6
Lack of Efficacy	2	0	4	7	3
Protocol Violation	0	1	0	1	3
Withdrawal by Subject	3	0	3	4	0
Lost to Follow-up	1	1	2	1	3
Administrative Problems	0	1	0	0	0

[1] All patients in the 300 mg group at Week 20 remained at this dose in this group.
[2] Non-responders in the AIN457 150 mg group were reassigned treatment to the 300 mg group.
[3] Non-responders in the AIN457 75 mg group were reassigned treatment to the 150 mg group.
[4] Non-responders in the AIN457 25 mg group were reassigned treatment to the 150 mg group.
[5] All placebo patients (responders & non-responders) were reassigned treatment to the 150 mg group.
[6] 1 patient in this group continued at Week 16 but did not receive any study drug at Week 20.
[7] 2 patients in this group continued at Week 16 but did not receive any study drug at Week 20

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The randomized set was defined as all subjects being randomized.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk
Secukinumab 75mg	Secukinumab 75mg s.c. q4wk
Secukinumab 25mg	Secukinumab 25mg s.c. q4wk
Secukinumab Placebo	Secukinumab Placebo s.c. q4wk
Total	Total of all reporting groups

Baseline Measures

	Secukinumab 300mg	Secukinumab 150mg	Secukinumab 75mg	Secukinumab 25mg	Secukinumab Placebo	Total
Number of Participants [units: participants]	41	43	49	54	50	237
Age [units: years] Mean (Standard Deviation)	54.7 (10.61)	57.8 (11.23)	54.3 (9.84)	53.3 (11.44)	55.0 (10.46)	54.9 (10.75)
Age, Customized [units: Participants]						
<18 years	0	0	0	0	0	0
>=18 - < 41 years	3	3	4	6	6	22
>=41 - < 65 years	30	27	37	41	34	169
>=65 - < 75 years	7	11	8	6	9	41
>=75 years	1	2	0	1	1	5

Gender [units: Participants]						
Female	**31**	**35**	**38**	**45**	**34**	**183**
Male	**10**	**8**	**11**	**9**	**16**	**54**
Race/Ethnicity, Customized [units: Participants]						
Caucasian	**32**	**30**	**37**	**38**	**39**	**176**
Black	**0**	**0**	**1**	**1**	**1**	**3**
Asian	**8**	**11**	**9**	**14**	**8**	**50**
Native American	**0**	**0**	**1**	**0**	**0**	**1**
Pacific Islander	**0**	**0**	**0**	**0**	**0**	**0**
Other	**1**	**2**	**1**	**1**	**2**	**7**
Geographical Region [units: Participants]						
East Asia	**8**	**11**	**9**	**13**	**8**	**49**
Non-East Asia	**33**	**32**	**40**	**41**	**42**	**188**
Functional Status [1] [units: Participants]						
Class I	**2**	**3**	**2**	**5**	**4**	**16**
Class II	**28**	**27**	**31**	**37**	**34**	**157**
Class III	**11**	**13**	**16**	**12**	**12**	**64**
Class IV	**0**	**0**	**0**	**0**	**0**	**0**
Weight [units: kg] Mean (Standard Deviation)	**78.9 (23.91)**	**72.1 (16.52)**	**74.3 (15.70)**	**71.3 (14.16)**	**75.9 (15.61)**	**74.3 (17.27)**
Weight Group [units: Participants]						
<90 kg	**32**	**35**	**40**	**50**	**40**	**197**
>=90 kg	**9**	**8**	**9**	**4**	**10**	**40**
Height [units: cm] Mean (Standard Deviation)	**163.3 (10.03)**	**161.9 (10.84)**	**165.4 (9.52)**	**163.2 (7.07)**	**166.1 (7.62)**	**164.0 (9.06)**
BMI (body mass index) [units: kg/m^2] Mean (Standard Deviation)	**29.48 (8.383)**	**27.32 (4.673)**	**27.03 (4.936)**	**26.69 (4.768)**	**24.47 (5.229)**	**27.52 (5.693)**

[1] ACR classification criteria of functional status in rheumatoid arthritis: Class I: completely able to perform usual activities of daily living (self-care, vocational & avocational); Class II: able to perform usual self-care and vocational activities but limited in avocational activities; Class III: able to perform usual self-care activities but limited in vocational and avocational activities; Class IV: limited ability to perform usual self-care, vocational and avocational activities.

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants With American College of Rheumatology Response of 20 (ACR20) at 16 Weeks [Time Frame: 16cweeks]

Measure Type	Primary
Measure Title	Number of Participants With American College of Rheumatology Response of 20 (ACR20) at 16 Weeks
Measure Description	A participant was considered to have achieved the incidence of response (ACR20 criteria) if he/she had at least a 20% improvement in both the tender and swollen 28-joint counts and had at least 20% improvement in at least 3 of the following 5 measures: patient's assessment of rheumatoid athritis (RA) pain, patient's global assessment of disease activity, physician's global assessment of disease activity, patient's self-assesseddisability (Health Assessment Questionnaire [HAQ©] score)and acute phase rectant (C-reactive protein [hsCRP]/ESR).

Time Frame	16cweeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS) all subjects to whom study drug was assigned. Following the intent-to-treat principle, subjects were analyzed according to the treatment they were assigned to at randomization. FAS did not include subjects who have missing values for all post-baseline (visit >=3) assessments on all of the specified efficacy variables.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk
Secukinumab 75mg	Secukinumab 75mg s.c. q4wk
Secukinumab 25mg	Secukinumab 25mg s.c. q4wk
Secukinumab Placebo	Secukinumab Placebo s.c. q4wk

Measured Values

	Secukinumab 300mg	**Secukinumab 150mg**	**Secukinumab 75mg**	**Secukinumab 25mg**	**Secukinumab Placebo**
Number of Participants Analyzed [units: participants]	**41**	**43**	**49**	**53**	**50**
Number of Participants With American College of Rheumatology Response of 20 (ACR20) at 16 Weeks [units: Participants]	**22**	**20**	**23**	**18**	**18**

No statistical analysis provided for Number of Participants With American College of Rheumatology Response of 20 (ACR20) at 16 Weeks

2. Secondary: Number of Participants Who Achieved an ACR50 or ACR70 Response at Week 16 [Time Frame: Week 16]

Measure Type	Secondary
Measure Title	Number of Participants Who Achieved an ACR50 or ACR70 Response at Week 16
Measure Description	A participant was considered as improved according to the ACR50 or ACR70 criteria if he/she had at least a 50% or 70% improvement, respectively, in both the tender and the swollen 28-joint count, and in at least 3 of the following 5 measures: patient's assessment of rheumatoid athritis (RA) pain, patient's global assessment of disease activity, physician's global assessment of disease activity, patient self-assessed disability (Health Assessment Questionnaire [HAQ©] score) and Acute phase reactant (C-reactive protein [hsCRP]/ESR). Participants were defined as ACR50/70 responders at a given post-randomization visit if they satisfied the ACR50/70 criteria, respectively. Participants were considered ACR50/70 nonresponders if they failed the ACR50/70 criteria respectively. Participants who prematurely discontinued from study due to insufficient therapeutic effect were also considered nonresponders.
Time Frame	Week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS) all subjects to whom study drug was assigned. Following the intent-to-treat principle, subjects were analyzed according to the treatment they were assigned to at randomization. FAS did not include subjects who have missing values for all post-baseline (visit >=3) assessments on all of the specified efficacy variables.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk
Secukinumab 75mg	Secukinumab 75mg s.c. q4wk

Secukinumab 25mg	Secukinumab 25mg s.c. q4wk
Secukinumab Placebo	Secukinumab Placebo s.c. q4wk

Measured Values

	Secukinumab 300mg	Secukinumab 150mg	Secukinumab 75mg	Secukinumab 25mg	Secukinumab Placebo
Number of Participants Analyzed [units: participants]	**41**	**43**	**49**	**53**	**50**
Number of Participants Who Achieved an ACR50 or ACR70 Response at Week 16 [units: Participants]					
ACR50 response	**7**	**9**	**9**	**8**	**3**
ACR70 response	**2**	**2**	**1**	**4**	**0**

No statistical analysis provided for Number of Participants Who Achieved an ACR50 or ACR70 Response at Week 16

3. Secondary: Number of Participants Who Achieved an ACR20, ACR50 or ACR70 Response up to Week 16 [Time Frame: at Weeks2, 4, 8, 12, 16]

Measure Type	Secondary
Measure Title	Number of Participants Who Achieved an ACR20, ACR50 or ACR70 Response up to Week 16
Measure Description	A participant was considered as improved according to the ACR20, ACR50 or ACR70 criteria if he/she had as least a 20%, 50% or 70% improvement, respectively, in both the tender and the swollen 28-joint count, and in at least 3 of the following 5 measures: patient's assessment of rheumatoid athritis (RA) pain, patient's global assessment of disease activity, physician's global assessment of disease activity, patient's self-assessed disability and acute phase rectant or Erythrocyte sedimentation rate (ESR).
Time Frame	at Weeks2, 4, 8, 12, 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS) all subjects to whom study drug was assigned. Following the intent-to-treat principle, subjects were analyzed according to the treatment they were assigned to at randomization. FAS did not include subjects who have missing values for all post-baseline (visit >=3) assessments on all of the specified efficacy variables.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk
Secukinumab 75mg	Secukinumab 75mg s.c. q4wk
Secukinumab 25mg	Secukinumab 25mg s.c. q4wk
Secukinumab Placebo	Secukinumab Placebo s.c. q4wk

Measured Values

	Secukinumab 300mg	Secukinumab 150mg	Secukinumab 75mg	Secukinumab 25mg	Secukinumab Placebo
Number of Participants Analyzed [units: participants]	**41**	**43**	**49**	**53**	**50**
Number of Participants Who Achieved an ACR20, ACR50 or ACR70 Response up to Week 16 [units: Participants]					
Week 2: ACR20 response	**7**	**9**	**9**	**9**	**3**
Week 2: ACR50 response	**0**	**2**	**2**	**2**	**1**
Week 2: ACR70 response	**0**	**0**	**0**	**0**	**0**
Week 4: ACR20 response	**7**	**13**	**12**	**13**	**8**

Week 4: ACR50 response	**0**	**1**	**2**	**2**	**2**
Week 4: ACR70 response	**0**	**1**	**1**	**1**	**0**
Week 8: ACR20 response	**16**	**17**	**22**	**15**	**11**
Week 8: ACR50 response	**3**	**5**	**6**	**6**	**1**
Week 8: ACR70 response	**1**	**1**	**2**	**2**	**0**
Week 12: ACR20 response	**20**	**24**	**25**	**17**	**12**
Week 12: ACR50 response	**6**	**7**	**8**	**4**	**1**
Week 12: ACR70 response	**1**	**2**	**2**	**3**	**0**
Week 16: ACR20 response	**22**	**20**	**23**	**18**	**18**
Week 16: ACR50 response	**7**	**9**	**9**	**8**	**3**
Week 16: ACR70 response	**2**	**2**	**1**	**4**	**0**

No statistical analysis provided for Number of Participants Who Achieved an ACR20, ACR50 or ACR70 Response up to Week 16

4. Secondary: Change From Baseline in Disease Activity Score 28 Using CRP (DAS28-CRP) [Time Frame: Baseline, week 16]

Measure Type	Secondary
Measure Title	Change From Baseline in Disease Activity Score 28 Using CRP (DAS28-CRP)
Measure Description	The DAS28 is a measure of disease activity in Rheumatoid Arthritis (RA). The score is calculated by a complex mathematical formula, which includes the number of tender and swollen joints (out of a total of 28), the erythrocyte sedimentation rate (ESR) or hsCRP, and the patient's 'global assessment of global health (indicated by marking a 100 mm line between very good and very bad). A DAS28 score greater than 5.1 implies active disease, less than 3.2 well controlled disease, and less than 2.6 remission. The DAS28-CRP was derived from swollen joint count, tender joint count, hsCRP and patient's global assessment of disease activity.
Time Frame	Baseline, week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS) all subjects to whom study drug was assigned. Following the intent-to-treat principle, subjects were analyzed according to the treatment they were assigned to at randomization. FAS did not include subjects who have missing values for all post-baseline (visit >=3) assessments on all of the specified efficacy variables.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk
Secukinumab 75mg	Secukinumab 75mg s.c. q4wk
Secukinumab 25mg	Secukinumab 25mg s.c. q4wk
Secukinumab Placebo	Secukinumab Placebo s.c. q4wk

Measured Values

	Secukinumab 300mg	**Secukinumab 150mg**	**Secukinumab 75mg**	**Secukinumab 25mg**	**Secukinumab Placebo**
Number of Participants Analyzed [units: participants]	**41**	**43**	**49**	**53**	**50**
Change From Baseline in Disease Activity Score 28 Using CRP (DAS28-CRP) [units: scores on a scale] Least Squares Mean (Standard Error)	**-1.29 (0.186)**	**-1.35 (0.181)**	**-1.46 (0.170)**	**-1.13 (0.165)**	**-0.96 (0.171)**

No statistical analysis provided for Change From Baseline in Disease Activity Score 28 Using CRP (DAS28-CRP)

5. Secondary: Change From Baseline in Medical Outcome Short Form (36) Health Survey (SF-36® v2) [Time Frame: Baseline, week 16]

Measure Type	Secondary
Measure Title	Change From Baseline in Medical Outcome Short Form (36) Health Survey (SF-36® v2)
Measure Description	The SF-36 Scale is a 36-item, patient-reported survey which measures overall quality of life. It consists of 8 subscales (vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, mental health) which can be aggregated to derive a physical-component summary score and a mental-component score. Scores are normally determined with the use of norm-based methods which standardize scores based on an assessment of the general U.S. population free of chronic conditions. The scores range for each subscale from 0 to 10, and the composite score ranges from 0 to 100, with the higher scores indicative of better health.
Time Frame	Baseline, week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS) all subjects to whom study drug was assigned. Following the intent-to-treat principle, subjects were analyzed according to the treatment they were assigned to at randomization. FAS did not include subjects who have missing values for all post-baseline (visit >=3) assessments on all of the specified efficacy variables.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk
Secukinumab 75mg	Secukinumab 75mg s.c. q4wk
Secukinumab 25mg	Secukinumab 25mg s.c. q4wk
Secukinumab Placebo	Secukinumab Placebo s.c. q4wk

Measured Values

	Secukinumab 300mg	**Secukinumab 150mg**	**Secukinumab 75mg**	**Secukinumab 25mg**	**Secukinumab Placebo**
Number of Participants Analyzed [units: participants]	**41**	**43**	**48**	**52**	**47**
Change From Baseline in Medical Outcome Short Form (36) Health Survey (SF-36® v2) [units: scores on a scale-change from baseline] Mean (Standard Deviation)					
SF-36 physical component score	**3.42 (5.574)**	**4.51 (6.800)**	**3.48 (5.961)**	**2.15 (7.176)**	**2.47 (7.481)**
SF-36 mental component score	**-0.76 (11.421)**	**3.59 (9.631)**	**2.58 (11.479)**	**1.06 (9.299)**	**1.10 (10.231)**

No statistical analysis provided for Change From Baseline in Medical Outcome Short Form (36) Health Survey (SF-36® v2)

6. Secondary: Change From Baseline in Functional Assessment of Chronic Illness Therapy - Fatigue (FACIT-Fatigue) at Week 16 [Time Frame: Baseline, Week 16]

Measure Type	Secondary
Measure Title	Change From Baseline in Functional Assessment of Chronic Illness Therapy - Fatigue (FACIT-Fatigue) at Week 16
Measure Description	The Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-Fatigue©) is a 13- item questionnaire that assesses self-reported fatigue and its impact upon daily activities and function. Participants responded to each item on a 5-point Likert-type scale (0 = not at all; 1 = a little bit; 2 = somewhat; 3 = quite a bit; 4 = very much) based on their experience of fatigue during the past 2 weeThe scale score was computed by summing the item scores, after reversing those items that were worded in the negative direction. When there were missing item scores, the subscale score was computed by summing the non-missing item scores, multiplying by 13 (the total number of items in the scale) and dividing by the number of non-missing items. The latter rule applied only when at least half of the items (seven or more) were non-missing. FACIT-Fatigue subscale scores range from 0 to 52, where higher scores represent less fatigue.
Time Frame	Baseline, Week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS) all subjects to whom study drug was assigned. Following the intent-to-treat principle, subjects were analyzed according to the treatment they were assigned to at randomization. FAS did not include subjects who have missing values for all post-baseline (visit >=3) assessments on all of the specified efficacy variables.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk
Secukinumab 75mg	Secukinumab 75mg s.c. q4wk
Secukinumab 25mg	Secukinumab 25mg s.c. q4wk
Secukinumab Placebo	Secukinumab Placebo s.c. q4wk

Measured Values

	Secukinumab 300mg	**Secukinumab 150mg**	**Secukinumab 75mg**	**Secukinumab 25mg**	**Secukinumab Placebo**
Number of Participants Analyzed [units: participants]	**41**	**43**	**49**	**53**	**48**
Change From Baseline in Functional Assessment of Chronic Illness Therapy - Fatigue (FACIT-Fatigue) at Week 16 [units: scores on a scale-change from baseline] Mean (Standard Deviation)	**2.80 (7.181)**	**5.18 (8.470)**	**3.89 (8.368)**	**1.95 (8.232)**	**1.64 (8.464)**

No statistical analysis provided for Change From Baseline in Functional Assessment of Chronic Illness Therapy - Fatigue (FACIT-Fatigue) at Week 16

7. Secondary: Percentage of Participants With European League Against Rheumatism (EULAR) Response at Week 16 [Time Frame: Week 16]

Measure Type	Secondary
Measure Title	Percentage of Participants With European League Against Rheumatism (EULAR) Response at Week 16
Measure Description	The distribution of EULAR response criteria was according to DAS28-CRP at Week 16. EULAR response criteria are based on DAS28-CRP status in combination with DAS28-CRP improvements. The EULAR response criteria are as follows: Week 16 DAS28-CRP <3.2 with DAS28-CRP improvement >1.2 corresponds to 'good response'; Week 16 DAS28-CRP <3.2 with DAS28-CRP improvement between 0.6 to 1.2, or Week 16 DAS28-CRP between 3.2 to 5.1 with DAS28-CRP improvement >1.2 or from 0.6 to 1.2, or WeeK 16 DAS28-CRP >5.1 with DAS28-CRP improvement >1.2 correspond to 'moderate response; Week 16 DAS28-CRP <3.2 with DAS28-CRP improvement <0.6, or Week 16 DAS28-CRP between 3.2 to 5.1 with DAS28-CRP improvement <0.6, or Week 16 DAS28-CRP >5.1 with DAS28-CRP improvement between 0.6 to 1.2 or <0.6 correspond to 'no response'.
Time Frame	Week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS) all subjects to whom study drug was assigned. Following the intent-to-treat principle, subjects were analyzed according to the treatment they were assigned to at randomization. FAS did not include subjects who have missing values for all post-baseline (visit >=3) assessments on all of the specified efficacy variables.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk
Secukinumab 75mg	Secukinumab 75mg s.c. q4wk
Secukinumab 25mg	Secukinumab 25mg s.c. q4wk

Secukinumab Placebo	Secukinumab Placebo s.c. q4wk

Measured Values

	Secukinumab 300mg	Secukinumab 150mg	Secukinumab 75mg	Secukinumab 25mg	Secukinumab Placebo
Number of Participants Analyzed [units: participants]	**41**	**43**	**49**	**53**	**50**
Percentage of Participants With European League Against Rheumatism (EULAR) Response at Week 16 [units: Percentage of participants]					
Good Response	**19.5**	**18.6**	**22.4**	**18.9**	**14.3**
Moderate Response	**43.9**	**41.9**	**46.9**	**30.2**	**40.8**
No Response	**36.6**	**39.5**	**30.6**	**50.9**	**44.9**

No statistical analysis provided for Percentage of Participants With European League Against Rheumatism (EULAR) Response at Week 16

8. Secondary: Change From Baseline in Rheumatoid Factor (RF) Concentrations at Week 16 [Time Frame: Baseline, Week 16]

Measure Type	Secondary
Measure Title	Change From Baseline in Rheumatoid Factor (RF) Concentrations at Week 16
Measure Description	Only values that were above normal range (12 U/mL) were were included.
Time Frame	Baseline, Week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS) all subjects to whom study drug was assigned. Following the intent-to-treat principle, subjects were analyzed according to the treatment they were assigned to at randomization. FAS did not include subjects who have missing values for all post-baseline (visit >=3) assessments on all of the specified efficacy variables.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk
Secukinumab 75mg	Secukinumab 75mg s.c. q4wk
Secukinumab 25mg	Secukinumab 25mg s.c. q4wk
Secukinumab Placebo	Secukinumab Placebo s.c. q4wk

Measured Values

	Secukinumab 300mg	Secukinumab 150mg	Secukinumab 75mg	Secukinumab 25mg	Secukinumab Placebo
Number of Participants Analyzed [units: participants]	**29**	**27**	**34**	**36**	**32**
Change From Baseline in Rheumatoid Factor (RF) Concentrations at Week 16 [units: U/mL] Mean (Standard Deviation)	**-5.66 (210.235)**	**-32.11 (196.574)**	**-77.62 (341.985)**	**66.44 (379.723)**	**85.63 (499.964)**

No statistical analysis provided for Change From Baseline in Rheumatoid Factor (RF) Concentrations at Week 16

9. Secondary: Anti-CCP (Cyclic Citrulinated Peptide) Antibodies Concentrations at Baseline and at Week 16 [Time Frame: Baseline, Week 16]

Measure Type	Secondary

Measure Title	Anti-CCP (Cyclic Citrulinated Peptide) Antibodies Concentrations at Baseline and at Week 16
Measure Description	Only values that were above normal range (20 units) were included.
Time Frame	Baseline, Week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS) all subjects to whom study drug was assigned. Following the intent-to-treat principle, subjects were analyzed according to the treatment they were assigned to at randomization. FAS did not include subjects who have missing values for all post-baseline (visit >=3) assessments on all of the specified efficacy variables.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk
Secukinumab 75mg	Secukinumab 75mg s.c. q4wk
Secukinumab 25mg	Secukinumab 25mg s.c. q4wk
Secukinumab Placebo	Secukinumab Placebo s.c. q4wk

Measured Values

	Secukinumab 300mg	Secukinumab 150mg	Secukinumab 75mg	Secukinumab 25mg	Secukinumab Placebo
Number of Participants Analyzed [units: participants]	**41**	**43**	**49**	**53**	**50**
Anti-CCP (Cyclic Citrulinated Peptide) Antibodies Concentrations at Baseline and at Week 16 [units: Units] Mean (Standard Deviation)					
Concentrations at baseline (n: 33, 32, 43, 46, 38)	**1444.67 (1450.438)**	**1098.81 (1238.627)**	**1178.88 (1390.458)**	**1342.50 (1544.205)**	**1406.79 (1496.032)**
Concentrations at Week 16 (n: 30, 30, 41, 42, 36)	**1478.53 (1767.070)**	**1330.63 (1355.193)**	**1155.27 (1550.003)**	**1443.07 (1640.771)**	**1556.06 (1596.122)**

No statistical analysis provided for Anti-CCP (Cyclic Citrulinated Peptide) Antibodies Concentrations at Baseline and at Week 16

10. Secondary: Change From Baseline in ACR Component: Adjusted Swollen 28-joint Count at Week 16 [Time Frame: Baseline, week 16]

Measure Type	Secondary
Measure Title	Change From Baseline in ACR Component: Adjusted Swollen 28-joint Count at Week 16
Measure Description	Synovial fluid and/or soft tissue swelling but not bony overgrowth represents a positive result for swollen joint count. Joint counts were performed according to the visit schedule by the physician or by well trained personnel. Whenever possible, the same evaluator performed these assessments at all visits. The following 28 joints were assessed for tenderness and swelling: metacarpophalangeal I-V (10), thumb interphalangeal (2), hand proximal interphalangeal II-V (8), wrist (2), elbow (2), shoulders (2), and knees (2). If the number of joints for which data were available (e.g., S) was less than 28, the number of swollen joints (e.g., s) was scaled up proportionately (i.e., 28*(s/S)).
Time Frame	Baseline, week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS) all subjects to whom study drug was assigned. Following the intent-to-treat principle, subjects were analyzed according to the treatment they were assigned to at randomization. FAS did not include subjects who have missing values for all post-baseline (visit >=3) assessments on all of the specified efficacy variables.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk
Secukinumab 75mg	Secukinumab 75mg s.c. q4wk
Secukinumab 25mg	Secukinumab 25mg s.c. q4wk
Secukinumab Placebo	Secukinumab Placebo s.c. q4wk

Measured Values

	Secukinumab 300mg	Secukinumab 150mg	Secukinumab 75mg	Secukinumab 25mg	Secukinumab Placebo
Number of Participants Analyzed [units: participants]	**41**	**43**	**49**	**53**	**50**
Change From Baseline in ACR Component: Adjusted Swollen 28-joint Count at Week 16 [units: swollen joints] Least Squares Mean (Standard Error)	**-5.4 (0.75)**	**-5.2 (0.73)**	**-6.0 (0.68)**	**-4.4 (0.66)**	**-4.6 (0.69)**

No statistical analysis provided for Change From Baseline in ACR Component: Adjusted Swollen 28-joint Count at Week 16

11. Secondary: Change From Baseline in Disease Activity Score 28 Using ESR (DAS28-ESR) at Week 16 [Time Frame: Baseline, week 16]

Measure Type	Secondary
Measure Title	Change From Baseline in Disease Activity Score 28 Using ESR (DAS28-ESR) at Week 16
Measure Description	The DAS28 is a measure of disease activity in Rheumatoid Arthritis (RA). The score is calculated by a complex mathematical formula, which includes the number of tender and swollen joints (out of a total of 28), the erythrocyte sedimentation rate (ESR) or hsCRP, and the patient's 'global assessment of global health (indicated by marking a 100 mm line between very good and very bad). A DAS28 score greater than 5.1 implies active disease, less than 3.2 well controlled disease, and less than 2.6 remission.The DAS28 was also derived using erythrocyte sedimentation rate (ESR) (referred to as DAS28-ESR).
Time Frame	Baseline, week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS) all subjects to whom study drug was assigned. Following the intent-to-treat principle, subjects were analyzed according to the treatment they were assigned to at randomization. FAS did not include subjects who have missing values for all post-baseline (visit >=3) assessments on all of the specified efficacy variables.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk
Secukinumab 75mg	Secukinumab 75mg s.c. q4wk
Secukinumab 25mg	Secukinumab 25mg s.c. q4wk
Secukinumab Placebo	Secukinumab Placebo s.c. q4wk

Measured Values

	Secukinumab 300mg	Secukinumab 150mg	Secukinumab 75mg	Secukinumab 25mg	Secukinumab Placebo
Number of Participants Analyzed [units: participants]	**41**	**43**	**49**	**53**	**50**
Change From Baseline in Disease Activity Score 28 Using ESR (DAS28-ESR) at Week 16	**-1.48 (0.196)**	**-1.55 (0.191)**	**-1.65 (0.179)**	**-1.28 (0.174)**	**-1.14 (0.181)**

[units: scores on a scale] Least Squares Mean (Standard Error)					

No statistical analysis provided for Change From Baseline in Disease Activity Score 28 Using ESR (DAS28-ESR) at Week 16

12. Secondary: Change From Baseline in ACR Component: Adjusted Tender 28-joint Count at Week 16 [Time Frame: Baseline, week 16]

Measure Type	Secondary
Measure Title	Change From Baseline in ACR Component: Adjusted Tender 28-joint Count at Week 16
Measure Description	The ACR tender joint count (28 joints) was done by scoring several different aspects of tenderness as assessed by pressure and joint manipulation on physical examination. Joint counts were performed according to the visit schedule by the physician or by well trained personnel. The following 28 joints were assessed for tenderness and swelling: metacarpophalangeal I-V (10), thumb interphalangeal (2), hand proximal interphalangeal II-V (8), wrist (2), elbow (2), shoulders (2), and knees (2). If the number of joints for which data were available (e.g., T) was less than 28, the number of tender joints (e.g., t) was scaled up proportionately (i.e., 28*(t/T)).
Time Frame	Baseline, week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS) all subjects to whom study drug was assigned. Following the intent-to-treat principle, subjects were analyzed according to the treatment they were assigned to at randomization. FAS did not include subjects who have missing values for all post-baseline (visit >=3) assessments on all of the specified efficacy variables.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk
Secukinumab 75mg	Secukinumab 75mg s.c. q4wk
Secukinumab 25mg	Secukinumab 25mg s.c. q4wk
Secukinumab Placebo	Secukinumab Placebo s.c. q4wk

Measured Values

	Secukinumab 300mg	**Secukinumab 150mg**	**Secukinumab 75mg**	**Secukinumab 25mg**	**Secukinumab Placebo**
Number of Participants Analyzed [units: participants]	**41**	**43**	**49**	**53**	**50**
Change From Baseline in ACR Component: Adjusted Tender 28-joint Count at Week 16 [units: tender joints] Least Squares Mean (Standard Error)	**-6.3 (0.94)**	**-6.5 (0.91)**	**-6.3 (0.86)**	**-5.6 (0.83)**	**-5.0 (0.85)**

No statistical analysis provided for Change From Baseline in ACR Component: Adjusted Tender 28-joint Count at Week 16

13. Secondary: Change From Baseline in ACR Component: Patient's Assessment of RA Pain at Week 16 [Time Frame: Baseline, week 16]

Measure Type	Secondary
Measure Title	Change From Baseline in ACR Component: Patient's Assessment of RA Pain at Week 16
Measure Description	The patient's assessment of pain was performed at all visits using 100 mm visual analog scale (VAS) ranging from "no pain" to "unbearable pain" after the question "Please indicate with a vertical mark (|) through the horizontal line the most pain you had from your rheumatoid arthritis over the last 24 hours.
Time Frame	Baseline, week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS) all subjects to whom study drug was assigned. Following the intent-to-treat principle, subjects were analyzed according to the treatment they were assigned to at randomization. FAS did not include subjects who have missing values for all post-baseline (visit >=3) assessments on all of the specified efficacy variables.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk
Secukinumab 75mg	Secukinumab 75mg s.c. q4wk
Secukinumab 25mg	Secukinumab 25mg s.c. q4wk
Secukinumab Placebo	Secukinumab Placebo s.c. q4wk

Measured Values

	Secukinumab 300mg	Secukinumab 150mg	Secukinumab 75mg	Secukinumab 25mg	Secukinumab Placebo
Number of Participants Analyzed [units: participants]	**41**	**43**	**49**	**53**	**50**
Change From Baseline in ACR Component: Patient's Assessment of RA Pain at Week 16 [units: VAS in mm] Least Squares Mean (Standard Error)	**-9.0 (3.25)**	**-9.1 (3.16)**	**-11.6 (2.97)**	**-9.5 (2.88)**	**-9.1 (2.99)**

No statistical analysis provided for Change From Baseline in ACR Component: Patient's Assessment of RA Pain at Week 16

14. Secondary: Change From Baseline in ACR Component: Patient's Global Assessment of Disease Activity at Week 16 [Time Frame: Baseline, week 16]

Measure Type	Secondary
Measure Title	Change From Baseline in ACR Component: Patient's Global Assessment of Disease Activity at Week 16
Measure Description	The patient’s global assessment of disease activity was performed at the visits on a 100 mm non-anchored visual analog scale, from no arthritis (0) activity to maximal arthritis (100) activity, after the question, "Considering all the ways your arthritis affects you, draw a line on the scale for how well you are doing".
Time Frame	Baseline, week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS) all subjects to whom study drug was assigned. Following the intent-to-treat principle, subjects were analyzed according to the treatment they were assigned to at randomization. FAS did not include subjects who have missing values for all post-baseline (visit >=3) assessments on all of the specified efficacy variables.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk
Secukinumab 75mg	Secukinumab 75mg s.c. q4wk
Secukinumab 25mg	Secukinumab 25mg s.c. q4wk
Secukinumab Placebo	Secukinumab Placebo s.c. q4wk

Measured Values

	Secukinumab 300mg	Secukinumab 150mg	Secukinumab 75mg	Secukinumab 25mg	Secukinumab Placebo

Number of Participants Analyzed [units: participants]	**41**	**43**	**49**	**53**	**50**
Change From Baseline in ACR Component: Patient's Global Assessment of Disease Activity at Week 16 [units: VAS in mm] Least Squares Mean (Standard Error)	**-10.1 (3.27)**	**-10.5 (3.19)**	**-18.4 (2.99)**	**-10.6 (2.90)**	**-9.9 (3.01)**

No statistical analysis provided for Change From Baseline in ACR Component: Patient's Global Assessment of Disease Activity at Week 16

15. Secondary: Change From Baseline in ACR Component: Physician's Global Assessment of Disease Activity at Week 16 [Time Frame: Baseline, week 16]

Measure Type	Secondary
Measure Title	Change From Baseline in ACR Component: Physician's Global Assessment of Disease Activity at Week 16
Measure Description	The physician's global assessment of disease activity was performed at the visits usingon a 100 mm non-anchored visual analog scale, from no arthritis (0) activity to maximal arthritis (100) activity, after the question, "Considering all the ways your arthritis affects you, draw a line on the scale for how well you are doing".
Time Frame	Baseline, week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS) all subjects to whom study drug was assigned. Following the intent-to-treat principle, subjects were analyzed according to the treatment they were assigned to at randomization. FAS did not include subjects who have missing values for all post-baseline (visit >=3) assessments on all of the specified efficacy variables.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk
Secukinumab 75mg	Secukinumab 75mg s.c. q4wk
Secukinumab 25mg	Secukinumab 25mg s.c. q4wk
Secukinumab Placebo	Secukinumab Placebo s.c. q4wk

Measured Values

	Secukinumab 300mg	**Secukinumab 150mg**	**Secukinumab 75mg**	**Secukinumab 25mg**	**Secukinumab Placebo**
Number of Participants Analyzed [units: participants]	**41**	**43**	**49**	**53**	**50**
Change From Baseline in ACR Component: Physician's Global Assessment of Disease Activity at Week 16 [units: VAS in mm] Least Squares Mean (Standard Error)	**-22.8 (2.99)**	**-26.7 (2.91)**	**-25.4 (2.73)**	**-18.1 (2.65)**	**-15.2 (2.74)**

No statistical analysis provided for Change From Baseline in ACR Component: Physician's Global Assessment of Disease Activity at Week 16

16. Secondary: Change From Baseline in ACR Component: Health Assessment Questionnaire (HAQ©) Score at Week 16 [Time Frame: Baseline, week 16]

Measure Type	Secondary
Measure Title	Change From Baseline in ACR Component: Health Assessment Questionnaire (HAQ©) Score at Week 16
Measure Description	HAQ© was used to assess physical ability and functional status of patients as well as quality of life at the visits in these 8 categories assessed by the Disability Index: dressing & grooming, arising, eating, walking, hygiene, reach, grip, and common daily activities. Patients report amount of difficulty they have in performing 2 or 3 specific activities. There are 4 possible responses (0, 1, 2, 3) for these questions which include types of assistance, if any; the participant uses for his/her usual

	activities: 0: without any difficulty- No assistance is needed; 1: with some difficulty - A special device is used by the patient in his/her usual activities; 2: with much difficulty - The patient usually needs help from another person. 3: Unable to do - the patient usually needs both a special device and help from another person. Scores of 0 - 1 are generally considered to represent mild to moderate difficulty, 1-2 moderate to severe disability, and 2 -3 severe to very severe disability.
Time Frame	Baseline, week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS) all subjects to whom study drug was assigned. Following the intent-to-treat principle, subjects were analyzed according to the treatment they were assigned to at randomization. FAS did not include subjects who have missing values for all post-baseline (visit >=3) assessments on all of the specified efficacy variables.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk
Secukinumab 75mg	Secukinumab 75mg s.c. q4wk
Secukinumab 25mg	Secukinumab 25mg s.c. q4wk
Secukinumab Placebo	Secukinumab Placebo s.c. q4wk

Measured Values

	Secukinumab 300mg	Secukinumab 150mg	Secukinumab 75mg	Secukinumab 25mg	Secukinumab Placebo
Number of Participants Analyzed [units: participants]	**41**	**43**	**49**	**53**	**50**
Change From Baseline in ACR Component: Health Assessment Questionnaire (HAQ©) Score at Week 16 [units: scores on a scale] Least Squares Mean (Standard Error)	**-0.297 (0.0698)**	**-0.256 (0.0688)**	**-0.233 (0.0639)**	**-0.202 (0.0627)**	**-0.116 (0.0652)**

No statistical analysis provided for Change From Baseline in ACR Component: Health Assessment Questionnaire (HAQ©) Score at Week 16

17. Secondary: Change From Baseline in ACR Component: High Sensitivity C-reactive Protein (hsCRP) [Time Frame: Baseline, week 16]

Measure Type	Secondary
Measure Title	Change From Baseline in ACR Component: High Sensitivity C-reactive Protein (hsCRP)
Measure Description	Blood for this assessment was obtained at the visits in order to identify the presence of inflammation, to determine its severity, and to monitor response to treatment.Since the results of this test may have unblinded study personnel, results from the central lab were provided for screening and baseline only. The hsCRP results from samples collected during the treatment period were revealed only after final database lock.
Time Frame	Baseline, week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS) all subjects to whom study drug was assigned. Following the intent-to-treat principle, subjects were analyzed according to the treatment they were assigned to at randomization. FAS did not include subjects who have missing values for all post-baseline (visit >=3) assessments on all of the specified efficacy variables.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk

Secukinumab 75mg	Secukinumab 75mg s.c. q4wk
Secukinumab 25mg	Secukinumab 25mg s.c. q4wk
Secukinumab Placebo	Secukinumab Placebo s.c. q4wk

Measured Values

	Secukinumab 300mg	Secukinumab 150mg	Secukinumab 75mg	Secukinumab 25mg	Secukinumab Placebo
Number of Participants Analyzed [units: participants]	**41**	**43**	**49**	**53**	**50**
Change From Baseline in ACR Component: High Sensitivity C-reactive Protein (hsCRP) [units: mg/L] Least Squares Mean (Standard Error)	**-6.54 (2.237)**	**-7.76 (2.175)**	**-9.09 (2.042)**	**-4.08 (1.984)**	**0.30 (2.035)**

No statistical analysis provided for Change From Baseline in ACR Component: High Sensitivity C-reactive Protein (hsCRP)

18. Secondary: Change From Baseline in ACR Component: Erythrocyte Sedimentation Rate (ESR) at Week 16 [Time Frame: Baseline, week 16]

Measure Type	Secondary
Measure Title	Change From Baseline in ACR Component: Erythrocyte Sedimentation Rate (ESR) at Week 16
Measure Description	Blood for ESR, which is helpful to diagnose inflammatory diseases and to monitor disease activity and response to therapy, was obtained at the visits.
Time Frame	Baseline, week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS) all subjects to whom study drug was assigned. Following the intent-to-treat principle, subjects were analyzed according to the treatment they were assigned to at randomization. FAS did not include subjects who have missing values for all post-baseline (visit >=3) assessments on all of the specified efficacy variables.

Reporting Groups

	Description
Secukinumab 300mg	Secukinumab 300mg s.c. q4wk
Secukinumab 150mg	Secukinumab 150mg s.c. q4wk
Secukinumab 75mg	Secukinumab 75mg s.c. q4wk
Secukinumab 25mg	Secukinumab 25mg s.c. q4wk
Secukinumab Placebo	Secukinumab Placebo s.c. q4wk

Measured Values

	Secukinumab 300mg	Secukinumab 150mg	Secukinumab 75mg	Secukinumab 25mg	Secukinumab Placebo
Number of Participants Analyzed [units: participants]	**41**	**43**	**49**	**53**	**50**
Change From Baseline in ACR Component: Erythrocyte Sedimentation Rate (ESR) at Week 16 [units: mm/hr] Least Squares Mean (Standard Error)	**-13.51 (2.630)**	**-15.06 (2.564)**	**-15.43 (2.426)**	**-9.86 (2.331)**	**-6.12 (2.395)**

No statistical analysis provided for Change From Baseline in ACR Component: Erythrocyte Sedimentation Rate (ESR) at Week 16

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
AIN457 25mg	Up to Week 20 - AIN457 25mg
AIN457 75mg	Up to Week 20 - AIN457 75mg
AIN457 150mg	Up to Week 20 - AIN457 150mg
AIN457 300mg	Up to Week 20 - AIN457 300mg
Placebo	Up to Week 20 - Placebo
AIN457 25mg (Wk 20 to End of Study)	From week 20 through end of study - AIN457 25mg
AIN457 75mg (Wk 20 to End of Study)	From week 20 through end of study - AIN457 75mg
AIN457 150mg (Wk 20 to End of Study)	From week 20 through end of study - AIN457 150mg
AIN457 300mg (Wk 20 to End of Study)	From week 20 through end of study - AIN457 300mg

Serious Adverse Events

	AIN457 25mg	AIN457 75mg	AIN457 150mg	AIN457 300mg	Placebo	AIN457 25mg (Wk 20 to End of Study)	AIN457 75mg (Wk 20 to End of Study)	AIN457 150mg (Wk 20 to End of Study)	AIN457 300mg (Wk 20 to End of Study)
Total, serious adverse events									
# participants affected / at risk	**0/54 (0.00%)**	**1/49 (2.04%)**	**0/43 (0.00%)**	**4/41 (9.76%)**	**1/50 (2.00%)**	**1/18 (5.56%)**	**3/23 (13.04%)**	**9/115 (7.83%)**	**8/60 (13.33%)**
Blood and lymphatic system disorders									
Anaemia † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**1/23 (4.35%)**	**0/115 (0.00%)**	**0/60 (0.00%)**
Cardiac disorders									
Cardiac failure † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**1/115 (0.87%)**	**0/60 (0.00%)**
Myocardial infarction † 1									
# participants affected / at risk	**0/54 (0.00%)**	**1/49 (2.04%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**1/115 (0.87%)**	**0/60 (0.00%)**
Pericarditis † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**1/115 (0.87%)**	**0/60 (0.00%)**
Gastrointestinal disorders									
Diarrhoea † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**1/115 (0.87%)**	**0/60 (0.00%)**

Femoral hernia, obstructive † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**1/115 (0.87%)**	**0/60 (0.00%)**
Inguinal hernia † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**1/115 (0.87%)**	**0/60 (0.00%)**
Hepatobiliary disorders									
Cholecystitis chronic † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**1/41 (2.44%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**0/115 (0.00%)**	**0/60 (0.00%)**
Infections and infestations									
Bronchitis † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**1/115 (0.87%)**	**0/60 (0.00%)**
Herpes zoster † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**0/115 (0.00%)**	**1/60 (1.67%)**
Klebsiella bacteraemia † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**1/23 (4.35%)**	**0/115 (0.00%)**	**0/60 (0.00%)**
Lung abscess † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**1/115 (0.87%)**	**0/60 (0.00%)**
Pyelonephritis acute † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**1/41 (2.44%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**0/115 (0.00%)**	**0/60 (0.00%)**
Urinary tract infection † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**0/115 (0.00%)**	**1/60 (1.67%)**
Viral infection † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**1/115 (0.87%)**	**0/60 (0.00%)**
Injury, poisoning and procedural complications									

Clavicle fracture † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**1/115 (0.87%)**	**0/60 (0.00%)**
Tendon rupture † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**1/115 (0.87%)**	**0/60 (0.00%)**
Thoracic vertebral fracture † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**1/50 (2.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**0/115 (0.00%)**	**0/60 (0.00%)**
Metabolism and nutrition disorders									
Hypercalcaemia † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**0/115 (0.00%)**	**1/60 (1.67%)**
Musculoskeletal and connective tissue disorders									
Lumbar spinal stenosis † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**0/115 (0.00%)**	**1/60 (1.67%)**
Osteoarthritis † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**1/41 (2.44%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**0/115 (0.00%)**	**0/60 (0.00%)**
Rheumatoid arthritis † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**0/115 (0.00%)**	**1/60 (1.67%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
Basal cell carcinoma † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**0/115 (0.00%)**	**1/60 (1.67%)**
Ovarian cancer † 1									
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**1/115 (0.87%)**	**0/60 (0.00%)**
Small cell lung									

cancer metastatic † 1									
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	0/23 (0.00%)	0/115 (0.00%)	1/60 (1.67%)
Nervous system disorders									
Cerebrovascular accident † 1									
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	0/23 (0.00%)	0/115 (0.00%)	1/60 (1.67%)
Dementia Alzheimer's type † 1									
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	1/18 (5.56%)	0/23 (0.00%)	0/115 (0.00%)	0/60 (0.00%)
Renal and urinary disorders									
Renal failure acute † 1									
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	0/23 (0.00%)	0/115 (0.00%)	1/60 (1.67%)
Respiratory, thoracic and mediastinal disorders									
Hydrothorax † 1									
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	0/23 (0.00%)	1/115 (0.87%)	0/60 (0.00%)
Vascular disorders									
Deep vein thrombosis † 1									
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	1/41 (2.44%)	0/50 (0.00%)	0/18 (0.00%)	0/23 (0.00%)	0/115 (0.00%)	0/60 (0.00%)
Hypertension † 1									
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	0/23 (0.00%)	0/115 (0.00%)	1/60 (1.67%)
Rheumatoid vasculitis † 1									
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	0/23 (0.00%)	0/115 (0.00%)	1/60 (1.67%)
Varicose ulceration † 1									
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	1/23 (4.35%)	0/115 (0.00%)	0/60 (0.00%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	3%

Reporting Groups

	Description
AIN457 25mg	Up to Week 20 - AIN457 25mg
AIN457 75mg	Up to Week 20 - AIN457 75mg
AIN457 150mg	Up to Week 20 - AIN457 150mg
AIN457 300mg	Up to Week 20 - AIN457 300mg
Placebo	Up to Week 20 - Placebo
AIN457 25mg (Wk 20 to End of Study)	From week 20 through end of study - AIN457 25mg
AIN457 75mg (Wk 20 to End of Study)	From week 20 through end of study - AIN457 75mg
AIN457 150mg (Wk 20 to End of Study)	From week 20 through end of study - AIN457 150mg
AIN457 300mg (Wk 20 to End of Study)	From week 20 through end of study - AIN457 300mg

Other Adverse Events

	AIN457 25mg	AIN457 75mg	AIN457 150mg	AIN457 300mg	Placebo	AIN457 25mg (Wk 20 to End of Study)	AIN457 75mg (Wk 20 to End of Study)	AIN457 150mg (Wk 20 to End of Study)
Total, other (not including serious) adverse events								
# participants affected / at risk	14/54 (25.93%)	21/49 (42.86%)	15/43 (34.88%)	15/41 (36.59%)	24/50 (48.00%)	11/18 (61.11%)	15/23 (65.22%)	52/115 (45.22%)
Blood and lymphatic system disorders								
Anaemia † 1								
# participants affected / at risk	1/54 (1.85%)	1/49 (2.04%)	1/43 (2.33%)	0/41 (0.00%)	2/50 (4.00%)	1/18 (5.56%)	1/23 (4.35%)	4/115 (3.48%)
Granulocytopenia † 1								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	1/23 (4.35%)	0/115 (0.00%)
Leukopenia † 1								
# participants affected / at risk	0/54 (0.00%)	4/49 (8.16%)	0/43 (0.00%)	1/41 (2.44%)	0/50 (0.00%)	0/18 (0.00%)	0/23 (0.00%)	3/115 (2.61%)
Thrombocytosis † 1								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	1/23 (4.35%)	0/115 (0.00%)
Gastrointestinal disorders								
Abdominal pain upper † 1								
# participants affected / at risk	0/54 (0.00%)	2/49 (4.08%)	1/43 (2.33%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	0/23 (0.00%)	1/115 (0.87%)
Constipation † 1								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	0/23 (0.00%)	1/115 (0.87%)

Diarrhoea † [1]								
# participants affected / at risk	0/54 (0.00%)	1/49 (2.04%)	0/43 (0.00%)	0/41 (0.00%)	1/50 (2.00%)	0/18 (0.00%)	1/23 (4.35%)	1/115 (0.87%)
Gingivitis † [1]								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	2/23 (8.70%)	0/115 (0.00%)
Nausea † [1]								
# participants affected / at risk	0/54 (0.00%)	2/49 (4.08%)	1/43 (2.33%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	0/23 (0.00%)	1/115 (0.87%)
General disorders								
Fatigue † [1]								
# participants affected / at risk	1/54 (1.85%)	0/49 (0.00%)	1/43 (2.33%)	1/41 (2.44%)	1/50 (2.00%)	1/18 (5.56%)	0/23 (0.00%)	0/115 (0.00%)
Injection site erythema † [1]								
# participants affected / at risk	1/54 (1.85%)	1/49 (2.04%)	2/43 (4.65%)	1/41 (2.44%)	1/50 (2.00%)	0/18 (0.00%)	0/23 (0.00%)	1/115 (0.87%)
Injection site pain † [1]								
# participants affected / at risk	0/54 (0.00%)	1/49 (2.04%)	0/43 (0.00%)	2/41 (4.88%)	1/50 (2.00%)	0/18 (0.00%)	0/23 (0.00%)	1/115 (0.87%)
Injection site swelling † [1]								
# participants affected / at risk	1/54 (1.85%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	1/18 (5.56%)	0/23 (0.00%)	0/115 (0.00%)
Oedema peripheral † [1]								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	1/23 (4.35%)	0/115 (0.00%)
Hepatobiliary disorders								
Hepatic function abnormal † [1]								
# participants affected / at risk	1/54 (1.85%)	1/49 (2.04%)	0/43 (0.00%)	1/41 (2.44%)	0/50 (0.00%)	0/18 (0.00%)	1/23 (4.35%)	2/115 (1.74%)
Infections and infestations								
Bronchitis † [1]								
# participants affected / at risk	1/54 (1.85%)	1/49 (2.04%)	0/43 (0.00%)	1/41 (2.44%)	1/50 (2.00%)	0/18 (0.00%)	0/23 (0.00%)	5/115 (4.35%)
Gastrointestinal infection † [1]								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	1/18 (5.56%)	0/23 (0.00%)	0/115 (0.00%)
Nasopharyngitis † [1]								
# participants affected / at risk	4/54 (7.41%)	1/49 (2.04%)	4/43 (9.30%)	4/41 (9.76%)	3/50 (6.00%)	1/18 (5.56%)	4/23 (17.39%)	15/115 (13.04%)
Pharyngitis † [1]								
# participants affected / at risk	1/54 (1.85%)	1/49 (2.04%)	0/43 (0.00%)	3/41 (7.32%)	0/50 (0.00%)	0/18 (0.00%)	0/23 (0.00%)	1/115 (0.87%)
Pneumonia viral † [1]								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	1/23 (4.35%)	0/115 (0.00%)
Sinusitis † [1]								
# participants affected / at risk	1/54 (1.85%)	0/49 (0.00%)	1/43 (2.33%)	0/41 (0.00%)	2/50 (4.00%)	0/18 (0.00%)	0/23 (0.00%)	0/115 (0.00%)
Upper respiratory tract infection † [1]								
# participants affected / at risk	1/54 (1.85%)	1/49 (2.04%)	2/43 (4.65%)	0/41 (0.00%)	2/50 (4.00%)	2/18 (11.11%)	0/23 (0.00%)	6/115 (5.22%)
Urinary tract infection † [1]								

# participants affected / at risk	0/54 (0.00%)	2/49 (4.08%)	0/43 (0.00%)	2/41 (4.88%)	0/50 (0.00%)	2/18 (11.11%)	1/23 (4.35%)	5/115 (4.35%)
Injury, poisoning and procedural complications								
Contusion † 1								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	1/41 (2.44%)	0/50 (0.00%)	0/18 (0.00%)	0/23 (0.00%)	0/115 (0.00%)
Excoriation † 1								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	1/23 (4.35%)	1/115 (0.87%)
Limb injury † 1								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	1/18 (5.56%)	0/23 (0.00%)	0/115 (0.00%)
Investigations								
Electrocardiogram abnormal † 1								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	1/18 (5.56%)	0/23 (0.00%)	1/115 (0.87%)
Monocyte count decreased † 1								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	1/23 (4.35%)	1/115 (0.87%)
Weight decreased † 1								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	1/43 (2.33%)	0/41 (0.00%)	0/50 (0.00%)	1/18 (5.56%)	0/23 (0.00%)	0/115 (0.00%)
Metabolism and nutrition disorders								
Decreased appetite † 1								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	2/43 (4.65%)	1/41 (2.44%)	0/50 (0.00%)	0/18 (0.00%)	0/23 (0.00%)	0/115 (0.00%)
Dehydration † 1								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	1/18 (5.56%)	0/23 (0.00%)	0/115 (0.00%)
Dyslipidaemia † 1								
# participants affected / at risk	0/54 (0.00%)	1/49 (2.04%)	0/43 (0.00%)	1/41 (2.44%)	0/50 (0.00%)	0/18 (0.00%)	1/23 (4.35%)	0/115 (0.00%)
Hypercholesterolaemia † 1								
# participants affected / at risk	0/54 (0.00%)	1/49 (2.04%)	1/43 (2.33%)	0/41 (0.00%)	2/50 (4.00%)	0/18 (0.00%)	0/23 (0.00%)	2/115 (1.74%)
Hyperlipidaemia † 1								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	1/43 (2.33%)	1/41 (2.44%)	0/50 (0.00%)	0/18 (0.00%)	1/23 (4.35%)	1/115 (0.87%)
Type 2 diabetes mellitus † 1								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	1/23 (4.35%)	0/115 (0.00%)
Musculoskeletal and connective tissue disorders								
Arthralgia † 1								
# participants affected / at risk	2/54 (3.70%)	1/49 (2.04%)	0/43 (0.00%)	0/41 (0.00%)	1/50 (2.00%)	1/18 (5.56%)	1/23 (4.35%)	5/115 (4.35%)
Back pain † 1								
# participants affected / at risk	1/54 (1.85%)	2/49 (4.08%)	1/43 (2.33%)	2/41 (4.88%)	2/50 (4.00%)	0/18 (0.00%)	0/23 (0.00%)	2/115 (1.74%)
Myalgia † 1								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	2/41 (4.88%)	0/50 (0.00%)	0/18 (0.00%)	0/23 (0.00%)	0/115 (0.00%)

Rheumatoid arthritis † [1]								
# participants affected / at risk	4/54 (7.41%)	0/49 (0.00%)	2/43 (4.65%)	0/41 (0.00%)	2/50 (4.00%)	2/18 (11.11%)	0/23 (0.00%)	6/115 (5.22%)
Synovitis † [1]								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	1/23 (4.35%)	0/115 (0.00%)
Nervous system disorders								
Dizziness † [1]								
# participants affected / at risk	1/54 (1.85%)	0/49 (0.00%)	0/43 (0.00%)	2/41 (4.88%)	0/50 (0.00%)	0/18 (0.00%)	0/23 (0.00%)	1/115 (0.87%)
Headache † [1]								
# participants affected / at risk	0/54 (0.00%)	1/49 (2.04%)	1/43 (2.33%)	0/41 (0.00%)	0/50 (0.00%)	1/18 (5.56%)	0/23 (0.00%)	3/115 (2.61%)
Hypoaesthesia † [1]								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	2/50 (4.00%)	0/18 (0.00%)	0/23 (0.00%)	0/115 (0.00%)
Paraesthesia † [1]								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	1/23 (4.35%)	0/115 (0.00%)
Psychiatric disorders								
Anxiety † [1]								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	1/18 (5.56%)	0/23 (0.00%)	0/115 (0.00%)
Depression † [1]								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	1/41 (2.44%)	0/50 (0.00%)	0/18 (0.00%)	0/23 (0.00%)	0/115 (0.00%)
Renal and urinary disorders								
Haematuria † [1]								
# participants affected / at risk	1/54 (1.85%)	1/49 (2.04%)	1/43 (2.33%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	1/23 (4.35%)	0/115 (0.00%)
Nephrolithiasis † [1]								
# participants affected / at risk	1/54 (1.85%)	0/49 (0.00%)	0/43 (0.00%)	1/41 (2.44%)	0/50 (0.00%)	1/18 (5.56%)	0/23 (0.00%)	0/115 (0.00%)
Proteinuria † [1]								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	1/23 (4.35%)	0/115 (0.00%)
Renal colic † [1]								
# participants affected / at risk	0/54 (0.00%)	1/49 (2.04%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	1/18 (5.56%)	0/23 (0.00%)	0/115 (0.00%)
Reproductive system and breast disorders								
Breast pain † [1]								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	1/18 (5.56%)	0/23 (0.00%)	0/115 (0.00%)
Metrorrhagia † [1]								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	1/18 (5.56%)	0/23 (0.00%)	0/115 (0.00%)
Respiratory, thoracic and mediastinal disorders								
Cough † [1]								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	2/43 (4.65%)	0/41 (0.00%)	3/50 (6.00%)	0/18 (0.00%)	1/23 (4.35%)	0/115 (0.00%)
Pulmonary fibrosis † [1]								
# participants affected / at risk	0/54 (0.00%)	0/49 (0.00%)	0/43 (0.00%)	0/41 (0.00%)	0/50 (0.00%)	0/18 (0.00%)	1/23 (4.35%)	0/115 (0.00%)

Sinus congestion † 1								
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**2/50 (4.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**1/115 (0.87%)**
Skin and subcutaneous tissue disorders								
Dermatitis contact † 1								
# participants affected / at risk	**1/54 (1.85%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**0/115 (0.00%)**
Dyshidrosis † 1								
# participants affected / at risk	**1/54 (1.85%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**1/23 (4.35%)**	**1/115 (0.87%)**
Pruritus † 1								
# participants affected / at risk	**0/54 (0.00%)**	**1/49 (2.04%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**1/23 (4.35%)**	**1/115 (0.87%)**
Rash † 1								
# participants affected / at risk	**0/54 (0.00%)**	**2/49 (4.08%)**	**0/43 (0.00%)**	**2/41 (4.88%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**0/23 (0.00%)**	**1/115 (0.87%)**
Vascular disorders								
Hypertension † 1								
# participants affected / at risk	**0/54 (0.00%)**	**1/49 (2.04%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**2/50 (4.00%)**	**1/18 (5.56%)**	**1/23 (4.35%)**	**3/115 (2.61%)**
Varicose ulceration † 1								
# participants affected / at risk	**0/54 (0.00%)**	**0/49 (0.00%)**	**0/43 (0.00%)**	**0/41 (0.00%)**	**0/50 (0.00%)**	**0/18 (0.00%)**	**1/23 (4.35%)**	**0/115 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. ☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of pooled data (i.e.,data from all sites) in clinical trial or disclosure of trial results in their entirety.

Results Point of Contact:

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No publications provided by Novartis

Publications automatically indexed to this study:

Genovese MC, Durez P, Richards HB, Supronik J, Dokoupilova E, Aelion JA, Lee SH, Codding CE, Kellner H, Ikawa T, Hugot S, Ligozio G, Mpofu S. One-year efficacy and safety results of secukinumab in patients with rheumatoid arthritis: phase II, dose-finding, double-blind, randomized, placebo-controlled study. J Rheumatol. 2014 Mar;41(3):414-21. doi: 10.3899/jrheum.130637. Epub 2014 Jan 15.

Genovese MC, Durez P, Richards HB, Supronik J, Dokoupilova E, Mazurov V, Aelion JA, Lee SH, Codding CE, Kellner H, Ikawa T, Hugot S, Mpofu S. Efficacy and safety of secukinumab in patients with rheumatoid arthritis: a phase II, dose-finding, double-blind, randomised, placebo controlled study. Ann Rheum Dis. 2013 Jun;72(6):863-9. doi: 10.1136/annrheumdis-2012-201601. Epub 2012 Jun 23.

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