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Trial record **1 of 1** for: CACZ885A2201

Previous Study | Return to List | Next Study

Efficacy, Safety and Tolerability of ACZ885 in Patients With Active Rheumatoid Arthritis

This study has been completed.

Sponsor:
Novartis

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT00424346

First received: January 17, 2007
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History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: April 2, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Rheumatoid Arthritis
Interventions:	Drug: Canakinumab 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
277 patients were randomized in core (CACZ885A2201): 71 were assigned to ACZ885 600 mg intravenous(iv) + 300 mg subcutaneous each 2 weeks(sc q2wk), 66 to ACZ885 300 mg sc q2wk, 69 to ACZ885 150 mg sc q4wk, 71 to placebo. 3 were randomized but not treated. All other 274 (98.9%) were treated and had post-baseline efficacy data.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Enrollment in core & CACZ885A2201E2 was determined by how many entered first extension study. Study protocols did not mandate that patients continue treatment in the extension phase and furthermore the reason for not continuing from the Core to the Extension phase was not capture. A total of 6.6% completed extensions.

Reporting Groups

	Description
Canakinumab 600 mg IV + 300 mg q2wk	Participants received canakinumab 600 mg intravenous (IV) loading dose on Day 1 and 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg every 4 weeks. Participants in this treatment group who participated in the Extension Phase are represented in the 'Canakinumab 300 mg q2wk' treatment group in the Extension Phase table below.

Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Participant Flow for 2 periods

Period 1: Core Study

	Canakinumab 600 mg IV + 300 mg q2wk	Canakinumab 300 mg q2wk	Canakinumab 150 mg q4wk	Placebo
STARTED	71	64	69	70
COMPLETED	62	56	65	63
NOT COMPLETED	9	8	4	7
Adverse Event	5	3	1	1
Abnormal Laboratory Values	0	1	0	0
Lack of Efficacy	1	3	0	4
Withdrawal by Subject	1	0	0	2
Lost to Follow-up	1	1	0	0
Administrative Problems	1	0	1	0
Protocol Violation	0	0	2	0

Period 2: Extension Phase

	Canakinumab 600 mg IV + 300 mg q2wk	Canakinumab 300 mg q2wk	Canakinumab 150 mg q4wk	Placebo
STARTED	0 [1]	110 [2]	59	58
COMPLETED	0	8	4	3
NOT COMPLETED	0	102	55	55
Adverse Event	0	9	5	4
Lack of Efficacy	0	16	14	11
Withdrawal by Subject	0	5	3	4
Lost to Follow-up	0	2	0	0
Administrative Problems	0	69	32	35
Death	0	0	0	1

Protocol Violation	**0**	**1**	**1**	**0**

[1] Participants are represented in the Canakinumab 300 mg q2wk treatment group.
[2] Includes participants who completed the Core phase in the Canakinumab 600 mg IV + 300 mg q2wk group.

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.
No text entered.

Reporting Groups

	Description
Canakinumab 600 mg IV + 300 mg q2wk	Participants received canakinumab 600 mg intravenous (IV) loading dose on Day 1 and 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg every 4 weeks.
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Total	Total of all reporting groups

Baseline Measures

	Canakinumab 600 mg IV + 300 mg q2wk	**Canakinumab 300 mg q2wk**	**Canakinumab 150 mg q4wk**	**Placebo**	**Total**
Number of Participants [units: participants]	**71**	**64**	**69**	**70**	**274**
Age, Customized [1] [units: participants]					
≥18 - <41 years	**5**	**5**	**7**	**7**	**24**
≥41 - <65 years	**50**	**31**	**43**	**43**	**167**
≥65 - <75 years	**11**	**18**	**16**	**16**	**61**
≥75 years	**5**	**10**	**3**	**4**	**22**
Age, Customized [2] [units: participants]					
≥18 - <41 years	**NA [3]**	**7**	**6**	**6**	**19**
≥41 - <65 years	**NA [3]**	**66**	**39**	**38**	**143**

≥65 - <75 years	NA [3]	25	12	12	49
≥75 years	NA [3]	12	2	2	16
Gender [4] [units: participants]					
Female	60	57	56	52	225
Male	11	7	13	18	49
Gender [5] [units: participants]					
Female	0	94	47	44	185
Male	0	16	12	14	42

[1] Demographics for the Core Study population. The number of patients in the core phase was 274.
[2] Demographics for the Extension study population. The number of participants in the optional extension phase was less than the overall number of baseline participants who started the study. Total number of patients is 227.
[3] This group did not exist in the extension studies, only in core.
[4] Demographics for the Core Study population.
[5] Demographics for the Extension study population. The number of patients in the optional extension phase was less than the overall number of baseline participants who started the study. Total number of patients is 227.

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of American College of Rheumatology [ACR] 50 Criteria Responders at Week 12 [Time Frame: Baseline and Week 12]

Measure Type	Primary
Measure Title	Percentage of American College of Rheumatology [ACR] 50 Criteria Responders at Week 12
Measure Description	Participants were defined as ACR50 responders if they had at least a 50% improvement from Baseline in both the tender and the swollen 28-joint count, and in at least 3 of the following 5 measures: • Patient's pain assessment (assessed using a 100 mm Visual Analog Scale [VAS]); • Patient's global assessment of disease activity (VAS 100 mm); • Physician's global assessment of disease activity (VAS 100 mm); • Patient self-assessed disability (Health Assessment Questionnaire (HAQ) score); • Acute phase reactant (high sensitivity C-reactive Protein [hsCRP]). Details on each of these components are provided in Outcome Measures 10-16. Participants were considered as non-responders if they failed the ACR50 criteria. Participants who prematurely discontinued due to insufficient therapeutic effect were also considered non-responders.
Time Frame	Baseline and Week 12
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.
The intent-to-treat (ITT) population consisted of all patients as randomized that received at least one dose of study drug and had at least one post-baseline efficacy assessment. The number of patients in the analysis includes those with ACR50 evaluation. Last observation carried forward was applied for all the component variables.

Reporting Groups

	Description
Canakinumab 600 mg IV + 300 mg q2wk	Participants received canakinumab 600 mg intravenous (IV) loading dose on Day 1 and 300 mg

	subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg every 4 weeks.
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 600 mg IV + 300 mg q2wk	Canakinumab 300 mg q2wk	Canakinumab 150 mg q4wk	Placebo
Number of Participants Analyzed [units: participants]	**71**	**64**	**68**	**70**
Percentage of American College of Rheumatology [ACR] 50 Criteria Responders at Week 12 [units: percentage of participants]	**9.9**	**23.4**	**26.5**	**11.4**

No statistical analysis provided for Percentage of American College of Rheumatology [ACR] 50 Criteria Responders at Week 12

2. Primary: Percentage of American College of Rheumatology [ACR] 20 Criteria Responders During the Extension Phase [Time Frame: Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124]

Measure Type	Primary
Measure Title	Percentage of American College of Rheumatology [ACR] 20 Criteria Responders During the Extension Phase
Measure Description	Participants were defined as ACR20 responders if they had at least a 20% improvement from Baseline in both the tender and the swollen 28-joint count, and in at least 3 of the following 5 measures: • Patient's pain assessment (assessed using a 100 mm Visual Analog Scale [VAS]) • Patient's global assessment of disease activity (VAS 100 mm) • Physician's global assessment of disease activity (VAS 100 mm) • Patient self-assessed disability (Health Assessment Questionnaire (HAQ) score) • Acute phase reactant (high sensitivity C-reactive Protein [hsCRP]). Participants were considered as non-responders if they failed the ACR20 criteria. Participants who prematurely discontinued due to insufficient therapeutic effect were also considered non-responders.
Time Frame	Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124
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.
The Extension Study intent-to-treat (ITT) population consisted of all patients who entered the extension study and who received at least one dose of study drug in the extension studies. The number of patients in the analysis at each time point (N) includes those with ACR20 evaluation data available.

Reporting Groups

	Description
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks. Includes participants who received the 600 mg intravenous loading dose on Day 1 of the Core phase.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 300 mg q2wk	Canakinumab 150 mg q4wk	Placebo
Number of Participants Analyzed [units: participants]	**110**	**59**	**58**
Percentage of American College of Rheumatology [ACR] 20 Criteria Responders During the Extension Phase [units: percentage of participants]			
Week 24 [N=105, 57, 56]	**52.4**	**64.9**	**66.1**
Week 36 [N=100, 48, 49]	**57.0**	**66.7**	**63.3**
Week 48 [N=95, 43, 47]	**66.3**	**81.4**	**72.3**
Week 60 [N=87, 40, 42]	**60.9**	**75.0**	**73.8**
Week 72 [N=66, 34, 27]	**62.1**	**76.5**	**74.1**
Week 88 [N=43, 25, 23]	**67.4**	**72.0**	**82.6**
Week 100 [N=21, 12, 14]	**81.0**	**75.0**	**91.7**
Week 112 [N=13, 8, 6]	**76.9**	**75.0**	**66.7**
Week 124 [N=2, 1, 1]	**100.0**	**100.0**	**100.0**
End of Study Visit [N=103, 53, 54]	**51.5**	**54.7**	**61.1**

No statistical analysis provided for Percentage of American College of Rheumatology [ACR] 20 Criteria Responders During the Extension Phase

3. Primary: Percentage of American College of Rheumatology [ACR] 50 Criteria Responders During the Extension Phase [Time Frame: Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124]

Measure Type	Primary
Measure Title	Percentage of American College of Rheumatology [ACR] 50 Criteria Responders During the Extension Phase
Measure Description	Participants were defined as ACR50 responders if they had at least a 50% improvement from Baseline in both the tender and the swollen 28-joint count, and in at least 3 of the following 5 measures: • Patient's pain assessment (assessed using a 100 mm Visual Analog Scale [VAS]) • Patient's global assessment of disease activity (VAS 100 mm) • Physician's global assessment of disease activity (VAS 100 mm) • Patient self-assessed disability (Health Assessment Questionnaire (HAQ) score) • Acute phase reactant (high sensitivity C-reactive Protein [hsCRP]).

	Participants were considered as non-responders if they failed the ACR50 criteria. Participants who prematurely discontinued due to insufficient therapeutic effect were also considered non-responders.
Time Frame	Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124
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.
The Extension Study intent-to-treat (ITT) population consisted of all patients who entered the extension study and who received at least one dose of study drug in the extension studies. The number of patients in the analysis at each time point (N) includes those with ACR50 evaluation data available.

Reporting Groups

	Description
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks. Includes participants who received the 600 mg intravenous loading dose on Day 1 of the Core phase.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 300 mg q2wk	**Canakinumab 150 mg q4wk**	**Placebo**
Number of Participants Analyzed [units: participants]	**110**	**59**	**58**
Percentage of American College of Rheumatology [ACR] 50 Criteria Responders During the Extension Phase [units: percentage of participants]			
Week 24 [N=106, 57, 56]	**18.9**	**29.8**	**37.5**
Week 36 [N=100, 48, 49]	**24.0**	**31.3**	**32.7**
Week 48 [N=95, 43, 47]	**34.7**	**48.8**	**34.0**
Week 60 [N=87, 40, 42]	**34.5**	**42.5**	**42.9**
Week 72 [N=66, 34, 27]	**37.9**	**58.8**	**48.1**
Week 88 [N=43, 25, 23]	**39.5**	**44.0**	**52.2**
Week 100 [N=21, 13, 14]	**47.6**	**30.8**	**57.1**
Week 112 [N=13, 8, 6]	**23.1**	**62.5**	**66.7**
Week 124 [N=2, 1, 1]	**50.0**	**100.0**	**100.0**
End of Study Visit [N=103, 53, 54]	**23.3**	**35.8**	**35.2**

No statistical analysis provided for Percentage of American College of Rheumatology [ACR] 50 Criteria Responders During the Extension Phase

4. Primary: Percentage of American College of Rheumatology [ACR] 70 Criteria Responders During the Extension Phase [Time Frame: Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124]

Measure Type	Primary
Measure Title	Percentage of American College of Rheumatology [ACR] 70 Criteria Responders During the Extension Phase
Measure Description	Participants were defined as ACR70 responders if they had at least a 70% improvement from Baseline in both the tender and the swollen 28-joint count, and in at least 3 of the following 5 measures: • Patient's pain assessment (assessed using a 100 mm Visual Analog Scale [VAS]) • Patient's global assessment of disease activity (VAS 100 mm) • Physician's global assessment of disease activity (VAS 100 mm) • Patient self-assessed disability (Health Assessment Questionnaire (HAQ) score) • Acute phase reactant (high sensitivity C-reactive Protein [hsCRP]). Participants were considered as non-responders if they failed the ACR70 criteria. Participants who prematurely discontinued due to insufficient therapeutic effect were also considered non-responders.
Time Frame	Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124
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.
The Extension Study intent-to-treat (ITT) population consisted of all patients who entered the extension study and who received at least one dose of study drug in the extension studies. The number of patients in the analysis at each time point (N) includes those with ACR70 evaluation data available.

Reporting Groups

	Description
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks. Includes participants who received the 600 mg intravenous loading dose on Day 1 of the Core phase.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 300 mg q2wk	**Canakinumab 150 mg q4wk**	**Placebo**
Number of Participants Analyzed [units: participants]	**110**	**59**	**58**
Percentage of American College of Rheumatology [ACR] 70 Criteria Responders During the Extension Phase [units: percentage of participants]			
Week 24 [N=106, 57, 56]	**5.7**	**10.5**	**14.3**
Week 36 [N=100, 48, 49]	**7.0**	**4.2**	**12.2**
Week 48 [N=96, 43, 47]	**10.4**	**9.3**	**6.4**
Week 60 [N=87, 40, 42]	**16.1**	**17.5**	**19.0**

Week 72 [N=66, 34, 27]	**15.2**	**20.6**	**14.8**
Week 88 [N=44, 25, 23]	**15.9**	**16.0**	**17.4**
Week 100 [N=21, 14, 14]	**14.3**	**21.4**	**28.6**
Week 112 [N=13, 8, 6]	**7.7**	**37.5**	**33.3**
Week 124 [N=2, 1, 1]	**50.0**	**100.0**	**0.0**
End of Study Visit [N=103, 54, 54]	**13.6**	**16.7**	**13.0**

No statistical analysis provided for Percentage of American College of Rheumatology [ACR] 70 Criteria Responders During the Extension Phase

5. Primary: Change From Baseline in Disease Activity Score (DAS) 28 During the Extension Phase [Time Frame: Baseline and Weeks 24, 72 and 112]

Measure Type	Primary
Measure Title	Change From Baseline in Disease Activity Score (DAS) 28 During the Extension Phase
Measure Description	The Disease Activity Score (DAS) 28 is a combined index to measure the disease activity in patients with rheumatoid arthritis, and includes the following variables: • The number of swollen and tender joints assessed using the 28-joint count; • C-reactive protein (CRP) in mg/L; • Patient's global assessment of disease activity measured on a 100 mm visual analog scale. The DAS28 score ranges from zero to ten. DAS28 above 5.1 means high disease activity whereas a DAS28 below 3.2 indicates low disease activity. Remission is achieved by a DAS28 lower than 2.6
Time Frame	Baseline and Weeks 24, 72 and 112
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.
The Extension Study intent-to-treat (ITT) population consisted of all patients who entered the extension study and who received at least one dose of study drug in the extension studies. At each timepoint, only patients with a value at both Baseline and that timepoint are included (N).

Reporting Groups

	Description
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks. Includes participants who received the 600 mg intravenous loading dose on Day 1 of the Core phase.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 300 mg q2wk	**Canakinumab 150 mg q4wk**	**Placebo**
Number of Participants Analyzed			

[units: participants]	110	59	58
Change From Baseline in Disease Activity Score (DAS) 28 During the Extension Phase [units: scores on a scale] Mean (Standard Deviation)			
Week 24 [N=103, 56, 54]	-1.60 (1.171)	-1.82 (1.333)	-1.93 (1.474)
Week 72 [N=63, 31, 26]	-2.18 (1.302)	-2.58 (1.232)	-2.21 (1.132)
Week 112 [N=13, 8, 6]	-2.00 (1.110)	-2.73 (1.252)	-2.59 (1.916)
End of Study Visit [N=100, 52, 49}	-1.83 (1.434)	-1.79 (1.551)	-1.86 (1.621)

No statistical analysis provided for Change From Baseline in Disease Activity Score (DAS) 28 During the Extension Phase

6. Secondary: Percentage of American College of Rheumatology [ACR] 50 Criteria Responders at Weeks 2, 4 and 8 [Time Frame: Baseline and Weeks 2, 4 and 8]

Measure Type	Secondary
Measure Title	Percentage of American College of Rheumatology [ACR] 50 Criteria Responders at Weeks 2, 4 and 8
Measure Description	Participants were defined as ACR50 responders if they had at least a 50% improvement from Baseline in both the tender and the swollen 28-joint count, and in at least 3 of the following 5 measures: • Patient's pain assessment (assessed using a 100 mm Visual Analog Scale [VAS]); • Patient's global assessment of disease activity (VAS 100 mm); • Physician's global assessment of disease activity (VAS 100 mm); • Patient self-assessed disability (Health Assessment Questionnaire (HAQ) score); • Acute phase reactant (high sensitivity C-reactive Protein [hsCRP]). Participants were considered as non-responders if they failed the ACR50 criteria. Participants who prematurely discontinued due to insufficient therapeutic effect were also considered non-responders.
Time Frame	Baseline and Weeks 2, 4 and 8
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.
The intent-to-treat (ITT) population. The number of patients in the analysis includes those with ACR50 evaluation. Last observation carried forward was applied for all the component variables. "N" indicates the number of patients included at each time point.

Reporting Groups

	Description
Canakinumab 600 mg IV + 300 mg q2wk	Participants received canakinumab 600 mg intravenous (IV) loading dose on Day 1 and 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg every 4 weeks.
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab

	every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 600 mg IV + 300 mg q2wk	Canakinumab 300 mg q2wk	Canakinumab 150 mg q4wk	Placebo
Number of Participants Analyzed [units: participants]	**71**	**64**	**69**	**70**
Percentage of American College of Rheumatology [ACR] 50 Criteria Responders at Weeks 2, 4 and 8 [units: percentage of participants]				
Responders at Week 2 [N=70, 64, 69, 70]	**2.9**	**1.6**	**5.8**	**4.3**
Responders at Week 4 [N=71, 64, 69, 70]	**1.4**	**7.8**	**7.2**	**4.3**
Responders at Week 8 [N=71, 64, 69, 70]	**4.2**	**17.2**	**17.4**	**7.1**

No statistical analysis provided for Percentage of American College of Rheumatology [ACR] 50 Criteria Responders at Weeks 2, 4 and 8

7. Secondary: Percentage of American College of Rheumatology [ACR] 20 Criteria Responders [Time Frame: Baseline and Weeks 2, 4, 8 and 12]

Measure Type	Secondary
Measure Title	Percentage of American College of Rheumatology [ACR] 20 Criteria Responders
Measure Description	Participants were defined as ACR20 responders if they had at least a 20% improvement from Baseline in both the tender and the swollen 28-joint count, and in at least 3 of the following 5 measures: • Patient's pain assessment (assessed using a 100 mm Visual Analog Scale [VAS]); • Patient's global assessment of disease activity (VAS 100 mm); • Physician's global assessment of disease activity (VAS 100 mm); • Patient self-assessed disability (Health Assessment Questionnaire (HAQ) score); • Acute phase reactant (high sensitivity C-reactive Protein [hsCRP]). Participants were considered ACR20 non-responders if they failed the ACR20 criteria. Patients who prematurely discontinued the study due to insufficient therapeutic effect were also considered non responders.
Time Frame	Baseline and Weeks 2, 4, 8 and 12
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.
The intent-to-treat (ITT) population. The number of patients in the analysis includes those with ACR20 evaluation. Last observation carried forward was applied for all the component variables. "N" indicates the number of patients included at each time point.

Reporting Groups

	Description
Canakinumab 600 mg IV + 300 mg q2wk	Participants received canakinumab 600 mg intravenous (IV) loading dose on Day 1 and 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol

	amendment in January 2009 decreased the dose to 150 mg every 4 weeks.
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 600 mg IV + 300 mg q2wk	Canakinumab 300 mg q2wk	Canakinumab 150 mg q4wk	Placebo
Number of Participants Analyzed [units: participants]	**71**	**64**	**69**	**70**
Percentage of American College of Rheumatology [ACR] 20 Criteria Responders [units: percentage of participants]				
Responders at Week 2 [N=70, 64, 69, 70]	**17.1**	**29.7**	**23.2**	**14.3**
Responders at Week 4 [N=71, 64, 68, 70]	**29.6**	**37.5**	**39.7**	**20.0**
Responders at Week 8 [N=71, 64, 68, 70]	**35.2**	**43.8**	**42.6**	**27.1**
Responders at Week 12 [N=71, 64, 68, 70]	**43.7**	**48.4**	**50.0**	**28.6**

No statistical analysis provided for Percentage of American College of Rheumatology [ACR] 20 Criteria Responders

8. Secondary: Percentage of American College of Rheumatology [ACR] 70 Criteria Responders [Time Frame: Baseline and Weeks 2, 4, 8 and 12]

Measure Type	Secondary
Measure Title	Percentage of American College of Rheumatology [ACR] 70 Criteria Responders
Measure Description	Participants were defined as ACR70 responders if they had at least a 70% improvement from Baseline in both the tender and the swollen 28-joint count, and in at least 3 of the following 5 measures: • Patient's pain assessment (assessed using a 100 mm Visual Analog Scale [VAS]); • Patient's global assessment of disease activity (VAS 100 mm); • Physician's global assessment of disease activity (VAS 100 mm); • Patient self-assessed disability (Health Assessment Questionnaire (HAQ) score); • Acute phase reactant (high sensitivity C-reactive Protein [hsCRP]). Participants were considered ACR70 non-responders if they failed the ACR70 criteria. Patients who prematurely discontinued the study due to insufficient therapeutic effect were also considered non responders.
Time Frame	Baseline and Weeks 2, 4, 8 and 12
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.

The intent-to-treat (ITT) population. The number of patients in the analysis includes those with ACR70 evaluation. Last observation carried forward was applied for all the component variables. "N" indicates the number of patients included at each time point.

Reporting Groups

	Description
Canakinumab 600 mg IV + 300 mg q2wk	Participants received canakinumab 600 mg intravenous (IV) loading dose on Day 1 and 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg every 4 weeks.
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 600 mg IV + 300 mg q2wk	Canakinumab 300 mg q2wk	Canakinumab 150 mg q4wk	Placebo
Number of Participants Analyzed [units: participants]	**71**	**64**	**69**	**70**
Percentage of American College of Rheumatology [ACR] 70 Criteria Responders [units: percentage of participants]				
Responders at Week 2 [N=70, 64, 69, 70]	**0.0**	**1.6**	**0.0**	**0.0**
Responders at Week 4 [N=71, 64, 69, 70]	**0.0**	**1.6**	**4.3**	**0.0**
Responders at Week 8 [N=71, 64, 69, 70]	**0.0**	**4.7**	**5.8**	**2.9**
Responders at Week 12 [N=71, 64, 69, 70]	**4.2**	**3.1**	**5.8**	**2.9**

No statistical analysis provided for Percentage of American College of Rheumatology [ACR] 70 Criteria Responders

9. Secondary: Number of Distinct Responders According to ACR20, ACR50 and ACR70 Criteria at Week 12 [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Number of Distinct Responders According to ACR20, ACR50 and ACR70 Criteria at Week 12
Measure Description	To assess differences between the level of clinical response attained and not just whether the patient did or did not achieve a particular level of response, participants were categorized as follows: 1. Did not attain an ACR20 response; 2. Attained a 20% but not a 50% response; 3. Attained a 50% but not a 70% response; 4. Attained a 70% or greater response. A participant was considered as improved according to the ACR20, ACR50 or ACR70 criteria if they had at least a 20, 50 or 70% improvement from Baseline, respectively, in both the tender and the swollen 28-joint count, and in at least 3 of the following 5 measures:

	• Patient's pain assessment (100 mm visual analog scale [VAS]); • Patient's global assessment of disease activity (VAS 100 mm); • Physician's global assessment of disease activity (VAS 100 mm); • Patient self-assessed disability (Health Assessment Questionnaire [HAQ] score); • Acute phase reactant (high sensitivity C-reactive Protein [hsCRP]).
Time Frame	Baseline and Week 12
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.
The intent-to-treat (ITT) population. The number of patients in the analysis includes those with ACR evaluation. Last observation carried forward was applied for all the component variables.

Reporting Groups

	Description
Canakinumab 600 mg IV + 300 mg q2wk	Participants received canakinumab 600 mg intravenous (IV) loading dose on Day 1 and 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg every 4 weeks.
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 600 mg IV + 300 mg q2wk	**Canakinumab 300 mg q2wk**	**Canakinumab 150 mg q4wk**	**Placebo**
Number of Participants Analyzed [units: participants]	**71**	**64**	**68**	**70**
Number of Distinct Responders According to ACR20, ACR50 and ACR70 Criteria at Week 12 [units: participants]				
No response	**40**	**33**	**34**	**50**
ACR20 - not ACR50 response	**24**	**16**	**16**	**12**
ACR50 - not ACR70 response	**4**	**13**	**14**	**6**
ACR70 response	**3**	**2**	**4**	**2**

No statistical analysis provided for Number of Distinct Responders According to ACR20, ACR50 and ACR70 Criteria at Week 12

10. Secondary: Change From Baseline in Swollen 28-joint Count [Time Frame: Baseline and Weeks 2, 4, 8 and 12]

Measure Type	Secondary
Measure Title	Change From Baseline in Swollen 28-joint Count
Measure Description	The following 28 joints were assessed by the physician for swelling: metacarpophalangeal I-V (10), thumb interphalangeal (2), hand proximal interphalangeal II-V (8), wrist (2), elbow (2), shoulders (2), and knees (2). Least squares means (LSM) were derived from an Analysis of Covariance (ANCOVA) model adjusting for treatment and center with baseline value as a covariate.
Time Frame	Baseline and Weeks 2, 4, 8 and 12
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.
ITT Population, the number of patients included in the analysis at each time point is indicated by "N". Last observation carried forward was utilized.

Reporting Groups

	Description
Canakinumab 600 mg IV + 300 mg q2wk	Participants received canakinumab 600 mg intravenous (IV) loading dose on Day 1 and 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg every 4 weeks.
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 600 mg IV + 300 mg q2wk	**Canakinumab 300 mg q2wk**	**Canakinumab 150 mg q4wk**	**Placebo**
Number of Participants Analyzed [units: participants]	**71**	**64**	**69**	**70**
Change From Baseline in Swollen 28-joint Count [units: swollen joints] Least Squares Mean (Standard Error)				
Week 2 [N=70, 64, 69, 70]	**-2.4 (0.53)**	**-2.7 (0.56)**	**-3.1 (0.54)**	**-2.3 (0.54)**
Week 4 [N=71, 64, 69, 70]	**-3.4 (0.55)**	**-4.0 (0.58)**	**-4.6 (0.56)**	**-3.0 (0.56)**
Week 8 [N=71, 64, 69, 70]	**-4.0 (0.58)**	**-4.4 (0.61)**	**-4.9 (0.59)**	**-3.3 (0.59)**
Week 12 [N=71, 64, 69, 70]	**-4.6 (0.64)**	**-5.3 (0.67)**	**-5.2 (0.65)**	**-3.4 (0.65)**

No statistical analysis provided for Change From Baseline in Swollen 28-joint Count

11. Secondary: Change From Baseline in Tender 28-joint Count [Time Frame: Baseline and Weeks 2, 4, 8 and 12]

Measure Type	Secondary
Measure Title	Change From Baseline in Tender 28-joint Count
Measure Description	The following 28 joints were assessed by the physician for tenderness: metacarpophalangeal I-V (10), thumb interphalangeal (2), hand proximal interphalangeal II-V (8), wrist (2), elbow (2), shoulders (2), and knees (2). Least squares means (LSM) were derived from an Analysis of Covariance (ANCOVA) model adjusting for treatment and center with baseline value as a covariate.
Time Frame	Baseline and Weeks 2, 4, 8 and 12
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.
ITT Population, the number of patients included in the analysis at each time point is indicated by "N". Last observation carried forward was utilized.

Reporting Groups

	Description
Canakinumab 600 mg IV + 300 mg q2wk	Participants received canakinumab 600 mg intravenous (IV) loading dose on Day 1 and 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg every 4 weeks.
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 600 mg IV + 300 mg q2wk	**Canakinumab 300 mg q2wk**	**Canakinumab 150 mg q4wk**	**Placebo**
Number of Participants Analyzed [units: participants]	**71**	**64**	**69**	**70**
Change From Baseline in Tender 28-joint Count [units: tender joints] Least Squares Mean (Standard Error)				
Week 2 [N=70, 64, 69, 70]	**-3.0 (0.68)**	**-2.1 (0.71)**	**-3.6 (0.68)**	**-3.2 (0.69)**
Week 4 [N=71, 64, 69, 70]	**-4.1 (0.77)**	**-4.0 (0.80)**	**-5.0 (0.78)**	**-4.2 (0.78)**

Week 8 [N=71, 64, 69, 70]	**-4.6 (0.79)**	**-4.7 (0.83)**	**-5.4 (0.80)**	**-4.7 (0.80)**
Week 12 [N=71, 64, 69, 70]	**-4.3 (0.86)**	**-4.8 (0.90)**	**-6.3 (0.87)**	**-4.5 (0.87)**

No statistical analysis provided for Change From Baseline in Tender 28-joint Count

12. Secondary: Change From Baseline in Patient's Pain Intensity [Time Frame: Baseline and Weeks 2, 4, 8 and 12]

Measure Type	Secondary
Measure Title	Change From Baseline in Patient's Pain Intensity
Measure Description	The patient's assessment of pain was performed using a 100 mm visual analog scale (VAS) ranging from no pain (0) to unbearable pain (100). The distance in mm from the left edge of the scale was measured. A negative change from Baseline score indicates improvement in pain intensity. Least squares means (LSM) were derived from an Analysis of Covariance (ANCOVA) model adjusting for treatment and center with baseline value as a covariate.
Time Frame	Baseline and Weeks 2, 4, 8 and 12
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.
ITT Population, only patients with a value at both Baseline and post-baseline are included in the analysis. The number of patients included at each time point is indicated by

Reporting Groups

	Description
Canakinumab 600 mg IV + 300 mg q2wk	Participants received canakinumab 600 mg intravenous (IV) loading dose on Day 1 and 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg every 4 weeks.
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 600 mg IV + 300 mg q2wk	**Canakinumab 300 mg q2wk**	**Canakinumab 150 mg q4wk**	**Placebo**
Number of Participants Analyzed [units: participants]	**71**	**64**	**68**	**70**
Change From Baseline in Patient's Pain Intensity				

[units: scores on a scale] Least Squares Mean (Standard Error)				
Week 2 [N=70, 64, 68, 70]	-6.7 (2.20)	-8.0 (2.29)	-8.3 (2.23)	-4.2 (2.22)
Week 4 [N=71, 64, 68, 70]	-9.1 (2.40)	-9.6 (2.52)	-11.4 (2.45)	-5.6 (2.45)
Week 8 [N=71, 64, 68, 70]	-12.2 (2.66)	-12.5 (2.80)	-14.0 (2.72)	-7.6 (2.72)
Week 12 [N=71, 64, 68, 70]	-14.2 (2.72)	-15.1 (2.87)	-17.0 (2.78)	-10.5 (2.78)

No statistical analysis provided for Change From Baseline in Patient's Pain Intensity

13. Secondary: Change From Baseline in Patient's Global Assessment of Disease Activity [Time Frame: Baseline and Weeks 2, 4, 8 and 12]

Measure Type	Secondary
Measure Title	Change From Baseline in Patient's Global Assessment of Disease Activity
Measure Description	The patient's global assessment of disease activity was performed using a 100 mm visual analog scale (VAS) ranging from no arthritis activity (0) to maximal arthritis activity (100), after the question "Considering all the ways your arthritis affects you, draw a line on the scale for how well you are doing". The distance in mm from the left edge of the scale was measured. A negative change from Baseline score indicates improvement in assessment of disease activity. Least squares means (LSM) were derived from an Analysis of Covariance (ANCOVA) model adjusting for treatment and center with baseline value as a covariate.
Time Frame	Baseline and Weeks 2, 4, 8 and 12
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.
ITT Population, only patients with a value at both Baseline and post-baseline are included in the analysis. The number of patients included at each time point is indicated by

Reporting Groups

	Description
Canakinumab 600 mg IV + 300 mg q2wk	Participants received canakinumab 600 mg intravenous (IV) loading dose on Day 1 and 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg every 4 weeks.
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 600 mg IV + 300 mg q2wk	Canakinumab 300 mg q2wk	Canakinumab 150 mg q4wk	Placebo
Number of Participants Analyzed [units: participants]	**71**	**64**	**68**	**70**
Change From Baseline in Patient's Global Assessment of Disease Activity [units: scores on a scale] Least Squares Mean (Standard Error)				
Week 2 [N=70, 64, 68, 70]	**-6.4 (2.12)**	**-7.5 (2.21)**	**-7.9 (2.15)**	**-5.0 (2.15)**
Week 4 [N= 71, 64, 68, 70]	**-9.4 (2.28)**	**-11.2 (2.39)**	**-12.8 (2.33)**	**-6.1 (2.33)**
Week 8 [N= 71, 64, 68, 70]	**-13.9 (2.63)**	**-15.7 (2.76)**	**-13.8 (2.68)**	**-6.9 (2.68)**
Week 12 [N= 71, 64, 68, 70]	**-14.5 (2.61)**	**-17.5 (2.74)**	**-17.6 (2.66)**	**-10.1 (2.66)**

No statistical analysis provided for Change From Baseline in Patient's Global Assessment of Disease Activity

14. Secondary: Change From Baseline in Physician's Global Assessment of Disease Activity [Time Frame: Baseline and Weeks 2, 4, 8 and 12]

Measure Type	Secondary
Measure Title	Change From Baseline in Physician's Global Assessment of Disease Activity
Measure Description	The physician's global assessment of disease activity was performed using a 100 mm visual analog scale (VAS) ranging from no arthritis activity (0) to maximal arthritis activity (100). To enhance objectivity, the physician was not aware of the specific patient's global assessment of disease activity when performing their own assessment on that patient. The distance in mm from the left edge of the scale was measured. A negative change from Baseline score indicates improvement in assessment of disease activity. Least squares means (LSM) were derived from an Analysis of Covariance (ANCOVA) model adjusting for treatment and center with baseline value as a covariate.
Time Frame	Baseline and Weeks 2, 4, 8 and 12
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.
ITT Population, only patients with a value at both Baseline and post-baseline are included in the analysis. The number of patients included at each time point is indicated by

Reporting Groups

	Description
Canakinumab 600 mg IV + 300 mg q2wk	Participants received canakinumab 600 mg intravenous (IV) loading dose on Day 1 and 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg every 4 weeks.
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 600 mg IV + 300 mg q2wk	Canakinumab 300 mg q2wk	Canakinumab 150 mg q4wk	Placebo
Number of Participants Analyzed [units: participants]	**71**	**64**	**68**	**70**
Change From Baseline in Physician's Global Assessment of Disease Activity [units: scores on a scale] Least Squares Mean (Standard Error)				
Week 2 [N=70, 64, 68, 69]	**-13.3 (2.21)**	**-14.8 (2.34)**	**-15.2 (2.25)**	**-9.3 (2.25)**
Week 4 [N=71, 64, 68, 70]	**-17.7 (2.40)**	**-20.1 (2.55)**	**-20.3 (2.46)**	**-12.2 (2.45)**
Week 8 [N=71, 64, 68, 70]	**-20.8 (2.68)**	**-22.6 (2.86)**	**-23.6 (2.75)**	**-16.5 (2.74)**
Week 12 [N=71, 64, 68, 70]	**-21.6 (2.82)**	**-24.0 (3.01)**	**-26.4 (2.90)**	**-17.6 (2.88)**

No statistical analysis provided for Change From Baseline in Physician's Global Assessment of Disease Activity

15. Secondary: Change From Baseline in Health Assessment Questionnaire (HAQ) Score [Time Frame: Baseline and Weeks 2, 4, 8 and 12]

Measure Type	Secondary
Measure Title	Change From Baseline in Health Assessment Questionnaire (HAQ) Score
Measure Description	The patient health assessment questionnaire (HAQ) was used to assess the physical ability and functional status of participants as well as quality of life. The disability dimension consists of 20 multiple choice items concerning difficulty in performing eight common activities of daily living; dressing and grooming, arising, eating, walking, reaching, personal hygiene, gripping and activities. Participants choose from four response categories, ranging from 'without any difficulty' (Score=0) to 'unable to do' (Score=3). The overall score is the average of each of the 8 category scores and ranges from 0 to 3, where zero represents no disability and three very severe, high-dependency disability. A negative change from Baseline score indicates improvement in disability status. Least squares means (LSM) were derived from an Analysis of Covariance (ANCOVA) model adjusting for treatment and center with baseline value as a covariate.
Time Frame	Baseline and Weeks 2, 4, 8 and 12
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.
ITT Population, only patients with a value at both Baseline and post-baseline are included in the analysis. The number of patients included at each time point is indicated by "N". Last observation carried forward was utilized.

Reporting Groups

	Description
Canakinumab 600 mg IV + 300 mg q2wk	Participants received canakinumab 600 mg intravenous (IV) loading dose on Day 1 and 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg every 4 weeks.
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 600 mg IV + 300 mg q2wk	Canakinumab 300 mg q2wk	Canakinumab 150 mg q4wk	Placebo
Number of Participants Analyzed [units: participants]	**71**	**64**	**69**	**70**
Change From Baseline in Health Assessment Questionnaire (HAQ) Score [units: scores on a scale] Least Squares Mean (Standard Error)				
Week 2 [N=70, 64, 69, 70]	**-0.1 (0.04)**	**0.0 (0.05)**	**-0.1 (0.04)**	**-0.1 (0.04)**
Week 4 [N=71, 64, 69, 70]	**-0.1 (0.05)**	**-0.1 (0.05)**	**-0.2 (0.05)**	**-0.1 (0.05)**
Week 8 [N=71, 64, 69, 70]	**-0.2 (0.06)**	**-0.1 (0.06)**	**-0.2 (0.06)**	**-0.1 (0.06)**
Week 12 [N=71, 64, 69, 70]	**-0.2 (0.06)**	**-0.2 (0.06)**	**-0.2 (0.06)**	**-0.1 (0.06)**

No statistical analysis provided for Change From Baseline in Health Assessment Questionnaire (HAQ) Score

16. Secondary: Change From Baseline in High-sensitive C-Reactive Protein (hsCRP) Levels [Time Frame: Baseline and Weeks 2, 4, 8 and 12]

Measure Type	Secondary
Measure Title	Change From Baseline in High-sensitive C-Reactive Protein (hsCRP) Levels
Measure Description	HsCRP is a marker for inflammation and was measured from blood samples to identify the presence of inflammation, to determine its severity, and to monitor response to treatment. Least squares means (LSMs) were derived from an Analysis of Covariance (ANCOVA) model adjusting for treatment and center with baseline value as a covariate.
Time Frame	Baseline and Weeks 2, 4, 8 and 12
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.
ITT Population, only patients with a value at both Baseline and post-baseline are included in the analysis. The number of patients included at each time point is indicated by "N". Last observation carried forward was utilized.

Reporting Groups

	Description
Canakinumab 600 mg IV + 300 mg q2wk	Participants received canakinumab 600 mg intravenous (IV) loading dose on Day 1 and 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg every 4 weeks.
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 600 mg IV + 300 mg q2wk	**Canakinumab 300 mg q2wk**	**Canakinumab 150 mg q4wk**	**Placebo**
Number of Participants Analyzed [units: participants]	**71**	**64**	**69**	**70**
Change From Baseline in High-sensitive C-Reactive Protein (hsCRP) Levels [units: mg/L] Least Squares Mean (Standard Error)				
Week 2 [N=69, 64, 67, 70]	**-5.6 (1.72)**	**-5.8 (1.79)**	**-4.7 (1.75)**	**-1.7 (1.74)**
Week 4 [N=71, 64, 69, 70]	**-5.2 (1.69)**	**-7.4 (1.78)**	**-6.5 (1.72)**	**-1.7 (1.73)**
Week 8 [N=71, 64, 69, 70]	**-4.3 (1.72)**	**-6.9 (1.82)**	**-3.5 (1.75)**	**0.0 (1.77)**
Week 12 [N=71, 64, 69, 70]	**-5.6 (1.89)**	**-3.4 (1.99)**	**-8.0 (1.92)**	**-0.7 (1.94)**

No statistical analysis provided for Change From Baseline in High-sensitive C-Reactive Protein (hsCRP) Levels

17. Secondary: Change From Baseline in Disease Activity Score (DAS) 28 [Time Frame: Baseline and Weeks 2, 4, 8 and 12]

Measure Type	Secondary
Measure Title	Change From Baseline in Disease Activity Score (DAS) 28
Measure Description	The Disease Activity Score (DAS) 28 is a combined index to measure the disease activity in patients with rheumatoid

	arthritis, and includes the following variables: • The number of swollen and tender joints assessed using the 28-joint count; • C-reactive protein (CRP) in mg/L; • Patient's global assessment of disease activity measured on a 100 mm visual analog scale. The DAS28 score ranges from zero to ten. DAS28 above 5.1 means high disease activity whereas a DAS28 below 3.2 indicates low disease activity. Remission is achieved by a DAS28 lower than 2.6. Least squares means (LSMs) were derived from an Analysis of Covariance (ANCOVA) model adjusting for treatment and center with baseline DAS28 value as a covariate.
Time Frame	Baseline and Weeks 2, 4, 8 and 12
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.
ITT Population, only patients with a value at both Baseline and post-baseline are included in the analysis. The number of patients included at each time point is indicated by "N". Last observation carried forward was utilized.

Reporting Groups

	Description
Canakinumab 600 mg IV + 300 mg q2wk	Participants received canakinumab 600 mg intravenous (IV) loading dose on Day 1 and 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg every 4 weeks.
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 600 mg IV + 300 mg q2wk	**Canakinumab 300 mg q2wk**	**Canakinumab 150 mg q4wk**	**Placebo**
Number of Participants Analyzed [units: participants]	**71**	**64**	**68**	**70**
Change From Baseline in Disease Activity Score (DAS) 28 [units: scores on a scale] Least Squares Mean (Standard Error)				
Week 2 [N=69, 64, 66, 70]	**-0.7 (0.11)**	**-0.7 (0.11)**	**-0.8 (0.11)**	**-0.5 (0.11)**
Week 4 [N=71, 64, 68, 70]	**-0.9 (0.13)**	**-1.0 (0.13)**	**-1.1 (0.13)**	**-0.7 (0.13)**
Week 8 [N=71, 64, 68, 70]	**-1.1 (0.14)**	**-1.2 (0.15)**	**-1.2 (0.14)**	**-0.8 (0.14)**
Week 12 [N=71, 64, 68, 70]	**-1.2 (0.15)**	**-1.3 (0.16)**	**-1.5 (0.15)**	**-0.9 (0.15)**

No statistical analysis provided for Change From Baseline in Disease Activity Score (DAS) 28

18. Secondary: Change From Baseline in Erythrocyte Sedimentation Rate [Time Frame: Baseline and Weeks 2, 4, 8 and 12]

Measure Type	Secondary
Measure Title	Change From Baseline in Erythrocyte Sedimentation Rate
Measure Description	Erythrocyte sedimentation rate (ESR) indirectly measures how much inflammation is in the body. A higher ESR is indicative of increased inflammation. A negative change from Baseline score indicates improvement.
Time Frame	Baseline and Weeks 2, 4, 8 and 12
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.
ITT Population, only patients with a value at both Baseline and post-baseline are included in the analysis. The number of patients included at each time point is indicated by "N". Last observation carried forward was utilized.

Reporting Groups

	Description
Canakinumab 600 mg IV + 300 mg q2wk	Participants received canakinumab 600 mg intravenous (IV) loading dose on Day 1 and 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg every 4 weeks.
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 600 mg IV + 300 mg q2wk	**Canakinumab 300 mg q2wk**	**Canakinumab 150 mg q4wk**	**Placebo**
Number of Participants Analyzed [units: participants]	**71**	**64**	**69**	**70**
Change From Baseline in Erythrocyte Sedimentation Rate [units: mm/hr] Mean (Standard Deviation)				
Week 2 [N=68, 64, 67, 69]	**-9.0 (12.85)**	**-8.2 (15.97)**	**-9.0 (12.43)**	**-2.9 (11.62)**
Week 4 [N=71, 64, 69, 70]	**-9.2 (15.11)**	**-9.6 (17.43)**	**-11.8 (14.71)**	**-2.6 (12.94)**
Week 8 [N=71, 64, 69, 70]	**-11.3 (16.28)**	**-12.3 (16.02)**	**-12.8 (13.89)**	**-4.4 (15.65)**

Week 12 [N=71, 64, 69, 70]	**-11.2 (18.20)**	**-11.1 (18.12)**	**-15.1 (14.96)**	**-4.1 (16.73)**

No statistical analysis provided for Change From Baseline in Erythrocyte Sedimentation Rate

19. Secondary: Change From Baseline in Rheumatoid Factor Concentration [Time Frame: Baseline and Weeks 4, 8 and 12]

Measure Type	Secondary
Measure Title	Change From Baseline in Rheumatoid Factor Concentration
Measure Description	Rheumatoid factor (RF) is an autoantibody (antibody directed against an organism's own tissues) that is an indicator of inflammation and rheumatoid arthritis.
Time Frame	Baseline and Weeks 4, 8 and 12
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.
ITT Population, only patients with a value at both Baseline and post-baseline are included in the analysis. The number of patients included at each time point is indicated by "N". Last observation carried forward was utilized.

Reporting Groups

	Description
Canakinumab 600 mg IV + 300 mg q2wk	Participants received canakinumab 600 mg intravenous (IV) loading dose on Day 1 and 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg every 4 weeks.
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 600 mg IV + 300 mg q2wk	**Canakinumab 300 mg q2wk**	**Canakinumab 150 mg q4wk**	**Placebo**
Number of Participants Analyzed [units: participants]	**71**	**64**	**69**	**70**
Change From Baseline in Rheumatoid Factor Concentration [units: kIU/L] Mean (Standard Deviation)				
Week 4 [N=70, 62, 68, 67]	**-6.7 (71.53)**	**-10.6 (99.36)**	**-16.1 (144.18)**	**-0.9 (85.28)**
				6.0

Week 8 [N=70, 63, 69, 70]	**-2.6 (117.30)**	**22.7 (134.66)**	**-57.1 (442.24)**	**(91.51)**
Week 12 [N=70, 64, 69, 70]	**2.0 (135.70)**	**29.7 (144.91)**	**-50.7 (531.68)**	**16.9 (110.03)**

No statistical analysis provided for Change From Baseline in Rheumatoid Factor Concentration

20. Secondary: Change From Baseline in Short Form 36 Health Survey (SF-36) [Time Frame: Baseline and Weeks 2, 4, 8 and 12]

Measure Type	Secondary
Measure Title	Change From Baseline in Short Form 36 Health Survey (SF-36)
Measure Description	The SF-36 measures the impact of disease on overall quality of life and consists of eight subscales (physical function, pain, general and mental health, vitality, social function, physical and emotional health) which can be aggregated to derive a physical-component summary score and a mental-component summary score. Scores for each subscale range from 0 to 10, and the composite scores range from 0 to 100, with higher scores indicating better health. A positive change from Baseline score indicates improvement in quality of life.
Time Frame	Baseline and Weeks 2, 4, 8 and 12
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.
ITT Population, only patients with a value at both Baseline and post-baseline are included in the analysis. The number of patients included at each time point is indicated by "N". Last observation carried forward was utilized.

Reporting Groups

	Description
Canakinumab 600 mg IV + 300 mg q2wk	Participants received canakinumab 600 mg intravenous (IV) loading dose on Day 1 and 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg every 4 weeks.
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 600 mg IV + 300 mg q2wk	**Canakinumab 300 mg q2wk**	**Canakinumab 150 mg q4wk**	**Placebo**
Number of Participants Analyzed [units: participants]	**71**	**64**	**69**	**70**
Change From Baseline in Short Form 36 Health Survey (SF-36) [units: scores on a scale] Mean (Standard Deviation)				

Physical component: Week 2 [N=61, 61, 59, 64]	**1.73 (5.013)**	**0.27 (5.648)**	**2.85 (4.999)**	**2.03 (6.996)**
Physical component: Week 4 [N=65, 62, 63, 67]	**2.71 (6.582)**	**2.30 (6.972)**	**3.21 (6.406)**	**2.43 (7.134)**
Physical component: Week 8 [N=67, 62, 63, 68]	**2.62 (6.528)**	**2.75 (7.331)**	**4.29 (8.757)**	**1.96 (7.464)**
Physical component: Week 12 [N=68, 62, 63, 68]	**4.03 (6.519)**	**3.05 (7.847)**	**5.73 (8.612)**	**2.69 (7.846)**
Mental component: Week 2 [N=61, 61, 59, 64]	**0.56 (8.831)**	**2.64 (8.425)**	**1.21 (8.486)**	**0.63 (9.234)**
Mental component: Week 4 [N=65, 62, 63, 67]	**2.18 (9.660)**	**2.75 (11.364)**	**2.23 (8.634)**	**1.75 (8.331)**
Mental component: Week 8 [N=67, 62, 63, 68]	**2.29 (10.505)**	**2.83 (11.760)**	**3.04 (9.307)**	**1.18 (9.580)**
Mental component: Week 12 [N=68, 62, 63, 68]	**1.44 (9.988)**	**3.34 (11.927)**	**4.06 (10.952)**	**0.35 (9.294)**

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

21. Secondary: Change From Baseline in Functional Assessment of Chronic Illness Therapy- Fatigue (FACIT-F) [Time Frame: Baseline and Weeks 2, 4, 8 and 12]

Measure Type	Secondary
Measure Title	Change From Baseline in Functional Assessment of Chronic Illness Therapy- Fatigue (FACIT-F)
Measure Description	The fatigue subscale of the FACIT is a 13-item questionnaire that assesses self-reported fatigue and its impact upon daily activities and function. Participants respond 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 weeks. The scale score is computed by summing the item scores, after reversing those items that are worded in the negative direction. FACIT Fatigue subscale scores range from 0 to 52, where higher scores represent less fatigue. Least squares means (LSMs) were derived from an Analysis of Covariance (ANCOVA) model adjusting for treatment and center with baseline FACIT-F value as a covariate.
Time Frame	Baseline and Weeks 2, 4, 8 and 12
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.
ITT Population, only patients with a value at both Baseline and post-baseline are included in the analysis. The number of patients included at each time point is indicated by "N". Last observation carried forward was utilized.

Reporting Groups

	Description
Canakinumab 600 mg IV + 300 mg q2wk	Participants received canakinumab 600 mg intravenous (IV) loading dose on Day 1 and 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg every 4 weeks.
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 600 mg IV + 300 mg q2wk	Canakinumab 300 mg q2wk	Canakinumab 150 mg q4wk	Placebo
Number of Participants Analyzed [units: participants]	**71**	**64**	**69**	**70**
Change From Baseline in Functional Assessment of Chronic Illness Therapy- Fatigue (FACIT-F) [units: scores on a scale] Least Squares Mean (Standard Error)				
Week 2 [N=62, 63, 63, 64]	**2.5 (0.90)**	**1.6 (0.87)**	**3.7 (0.89)**	**2.5 (0.89)**
Week 4 [N=66, 64, 66, 67]	**3.8 (0.99)**	**3.3 (0.99)**	**4.9 (0.98)**	**2.1 (1.00)**
Week 8 [N=67, 64, 66, 67]	**4.2 (1.13)**	**4.0 (1.15)**	**4.6 (1.13)**	**2.1 (1.15)**
Week 12 [N=67, 64, 66, 67]	**4.9 (1.14)**	**3.8 (1.15)**	**5.7 (1.14)**	**1.4 (1.16)**

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

22. Secondary: Number of Distinct Responders According to ACR20, ACR50 and ACR70 Criteria at the End of the Extension Study [Time Frame: Baseline and End of Study (up to 124 weeks)]

Measure Type	Secondary
Measure Title	Number of Distinct Responders According to ACR20, ACR50 and ACR70 Criteria at the End of the Extension Study
Measure Description	To assess differences between the level of clinical response attained and not just whether the patient did or did not achieve a particular level of response, patients were categorized as follows: 1. Did not attain an ACR20 response; 2. Attained a 20% but not a 50% response; 3. Attained a 50% but not a 70% response; 4. Attained a 70% or greater response. A participant was considered as improved according to the ACR20, ACR50 or ACR70 criteria if they had at least a 20, 50 or 70% improvement from Baseline, respectively, in both the tender and the swollen 28-joint count, and in at least 3 of the following 5 measures: • Patient's pain assessment (100 mm visual analog scale [VAS]); • Patient's global assessment of disease activity (VAS 100 mm); • Physician's global assessment of disease activity (VAS 100 mm); • Patient self-assessed disability (Health Assessment Questionnaire [HAQ] score); • Acute phase reactant (high sensitivity C-reactive Protein [hsCRP]).
Time Frame	Baseline and End of Study (up to 124 weeks)
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.
Extension Study ITT population.

Reporting Groups

	Description
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks. Includes participants who received the 600 mg intravenous loading dose on Day 1 of the Core phase.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 300 mg q2wk	**Canakinumab 150 mg q4wk**	**Placebo**
Number of Participants Analyzed [units: participants]	**103**	**53**	**54**
Number of Distinct Responders According to ACR20, ACR50 and ACR70 Criteria at the End of the Extension Study [units: participants]			
No response	**50**	**24**	**21**
ACR20 - not ACR50 response	**29**	**10**	**14**
ACR50 - not ACR70 response	**10**	**10**	**12**
ACR70 response	**14**	**9**	**7**

No statistical analysis provided for Number of Distinct Responders According to ACR20, ACR50 and ACR70 Criteria at the End of the Extension Study

23. Secondary: Change From Baseline in Swollen 28-joint Count During the Extension Study [Time Frame: Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124.]

Measure Type	Secondary
Measure Title	Change From Baseline in Swollen 28-joint Count During the Extension Study
Measure Description	The following 28 joints were assessed by the physician for swelling: metacarpophalangeal I-V (10), thumb interphalangeal (2), hand proximal interphalangeal II-V (8), wrist (2), elbow (2), shoulders (2), and knees (2).
Time Frame	Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124.
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.

The Extension Study ITT population. At each timepoint, only patients with a value at both Baseline and that timepoint are included (N).

Reporting Groups

	Description
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks. Includes participants who received the 600 mg intravenous loading dose on Day 1 of the Core phase.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 300 mg q2wk	Canakinumab 150 mg q4wk	Placebo
Number of Participants Analyzed [units: participants]	**110**	**59**	**58**
Change From Baseline in Swollen 28-joint Count During the Extension Study [units: swollen joints] Mean (Standard Deviation)			
Week 24 [N=105, 58, 55]	**-6.04 (4.892)**	**-5.70 (5.119)**	**-6.93 (5.300)**
Week 36 [N=100, 49, 49]	**-7.12 (4.828)**	**-6.79 (4.365)**	**-7.05 (4.726)**
Week 48 [N=95, 44, 47]	**-7.72 (4.171)**	**-7.52 (3.622)**	**-7.74 (4.454)**
Week 60 [N=89, 40, 43]	**-7.69 (4.670)**	**-7.38 (3.737)**	**-8.65 (4.825)**
Week 72 [N=66, 35, 27]	**-7.41 (5.311)**	**-7.94 (4.143)**	**-7.60 (3.678)**
Week 88 [N=44, 25, 22]	**-8.38 (4.369)**	**-7.24 (3.666)**	**-7.50 (3.389)**
Week 100 [N=21, 13, 14]	**-8.29 (4.285)**	**-8.15 (2.824)**	**-7.56 (2.974)**
Week 112 [N=13, 8, 6]	**-7.39 (5.308)**	**-9.50 (2.976)**	**-5.83 (5.636)**
Week 124 [N=2, 1, 1]	**-6.50 (0.707)**	**-16.00** [1]	**-4.00** [1]
End of Study Visit [N=103, 55, 53]	**-6.36 (5.477)**	**-5.99 (4.937)**	**-6.67 (6.350)**

[1] Mean based on 1 participant. Standard deviation can not be calculated.

No statistical analysis provided for Change From Baseline in Swollen 28-joint Count During the Extension Study

24. Secondary: Change From Baseline in Tender 28-joint Count During the Extension Study [Time Frame: Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124.]

Measure Type	Secondary
Measure Title	Change From Baseline in Tender 28-joint Count During the Extension Study
Measure Description	The following 28 joints were assessed by the physician for tenderness: metacarpophalangeal I-V (10), thumb interphalangeal (2), hand proximal interphalangeal II-V (8), wrist (2), elbow (2), shoulders (2), and knees (2).
Time Frame	Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124.
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.
The Extension Study ITT population. At each timepoint, only patients with a value at both Baseline and that timepoint are included (N).

Reporting Groups

	Description
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks. Includes participants who received the 600 mg intravenous loading dose on Day 1 of the Core phase.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 300 mg q2wk	**Canakinumab 150 mg q4wk**	**Placebo**
Number of Participants Analyzed [units: participants]	**105**	**58**	**55**
Change From Baseline in Tender 28-joint Count During the Extension Study [units: tender joints] Mean (Standard Deviation)			
Week 24 [N=105, 58, 55]	**-6.93 (7.078)**	**-8.27 (7.555)**	**-8.49 (7.298)**
Week 36 [N=100, 49, 49]	**-7.92 (6.793)**	**-9.83 (6.459)**	**-8.95 (7.154)**
Week 48 [N=95, 44, 47]	**-8.64 (7.193)**	**-10.75 (5.948)**	**-10.05 (6.321)**
Week 60 [N=89, 40, 43]	**-8.52 (6.915)**	**-11.10 (6.484)**	**-10.76 (6.185)**
Week 72 [N=66, 35, 27]	**-8.71 (7.556)**	**-11.37 (7.436)**	**-9.56 (4.722)**
Week 88 [N=44, 25, 22]	**-10.34 (5.995)**	**-10.76 (7.184)**	**-9.98 (4.964)**
Week 100 [N=21, 13, 14]	**-8.53 (5.780)**	**-12.00 (5.307)**	**-9.08 (4.989)**
			-9.17 (5.981)

Week 112 [N=13, 8, 6]	**-8.47 (6.205)**	**-13.63 (6.435)**	
Week 124 [N=2, 1, 1]	**-9.00 (4.243)**	**-23.00** [1]	**-8.00** [1]
End of Study Visit [N=103, 55, 53]	**-7.93 (7.857)**	**-8.43 (8.331)**	**-8.83 (7.573)**

[1] Mean based on 1 participant. Standard deviation can not be calculated.

No statistical analysis provided for Change From Baseline in Tender 28-joint Count During the Extension Study

25. Secondary: Change From Baseline in Patient's Pain Intensity During the Extension Study [Time Frame: Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124.]

Measure Type	Secondary
Measure Title	Change From Baseline in Patient's Pain Intensity During the Extension Study
Measure Description	The patient's assessment of pain was performed using a 100 mm visual analog scale (VAS) ranging from no pain (0) to unbearable pain (100). The distance in mm from the left edge of the scale was measured. A negative change from Baseline score indicates improvement in pain intensity.
Time Frame	Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124.
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.
The Extension Study ITT population. At each timepoint, only patients with a value at both Baseline and that timepoint are included (N).

Reporting Groups

	Description
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks. Includes participants who received the 600 mg intravenous loading dose on Day 1 of the Core phase.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 300 mg q2wk	**Canakinumab 150 mg q4wk**	**Placebo**
Number of Participants Analyzed [units: participants]	**106**	**57**	**56**
Change From Baseline in Patient's Pain Intensity During the Extension Study [units: scores on a scale] Mean (Standard Deviation)			
Week 24 [N=106, 57, 56]	**-22.8 (26.44)**	**-24.1 (25.69)**	**-20.8 (25.61)**

Week 36 [N=100, 48, 48]	**-21.7 (29.00)**	**-28.2 (22.05)**	**-24.0 (24.13)**
Week 48 [N=96, 43, 47]	**-25.1 (28.08)**	**-30.6 (21.94)**	**-21.1 (23.02)**
Week 60 [N=87, 40, 42]	**-26.3 (27.09)**	**-27.8 (25.63)**	**-30.0 (23.04)**
Week 72 [N=66, 34, 27]	**-29.0 (27.42)**	**-35.2 (26.06)**	**-26.2 (27.63)**
Week 88 [N=43, 25, 23]	**-28.5 (30.42)**	**-29.0 (30.23)**	**-32.3 (24.84)**
Week 100 [N=21, 13, 14]	**-30.7 (23.60)**	**-27.6 (26.14)**	**-32.0 (26.15)**
Week 112 [N=13, 8, 6]	**-33.3 (20.38)**	**-17.5 (25.39)**	**-31.7 (38.93)**
Week 124 [N=2, 1, 1]	**-55.0 (15.56)**	**-17.0** [1]	**-24.0** [1]
End of Study Visit [N=103, 53, 54]	**-19.1 (28.14)**	**-21.9 (27.19)**	**-20.9 (27.45)**

[1] Mean based on 1 participant. Standard deviation can not be calculated.

No statistical analysis provided for Change From Baseline in Patient's Pain Intensity During the Extension Study

26. Secondary: Change From Baseline in Patient's Global Assessment of Disease Activity During the Extension Study [Time Frame: Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124.]

Measure Type	Secondary
Measure Title	Change From Baseline in Patient's Global Assessment of Disease Activity During the Extension Study
Measure Description	The patient's global assessment of disease activity was performed using a 100 mm visual analog scale (VAS) ranging from no arthritis activity (0) to maximal arthritis activity (100), after the question "Considering all the ways your arthritis affects you, draw a line on the scale for how well you are doing". The distance in mm from the left edge of the scale was measured. A negative change from Baseline score indicates improvement in assessment of disease activity.
Time Frame	Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124.
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.
The Extension Study ITT population. At each timepoint, only patients with a value at both Baseline and that timepoint are included (N).

Reporting Groups

	Description
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks. Includes participants who received the 600 mg intravenous loading dose on Day 1 of the Core phase.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol

	amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 300 mg q2wk	Canakinumab 150 mg q4wk	Placebo
Number of Participants Analyzed [units: participants]	**105**	**57**	**56**
Change From Baseline in Patient's Global Assessment of Disease Activity During the Extension Study [units: scores on a scale] Mean (Standard Deviation)			
Week 24 [N=105, 57, 56]	**-23.2 (26.12)**	**-21.9 (23.21)**	**-18.6 (24.42)**
Week 36 [N=100, 48, 48]	**-22.5 (28.61)**	**-23.8 (23.11)**	**-20.0 (25.52)**
Week 48 [N=96, 43, 47]	**-25.8 (27.92)**	**-27.2 (21.44)**	**-23.6 (25.23)**
Week 60 [N=87, 40, 42]	**-27.7 (29.08)**	**-24.4 (24.23)**	**-26.5 (25.63)**
Week 72 [N=66, 33, 27]	**-28.6 (24.54)**	**-32.1 (26.56)**	**-24.1 (32.14)**
Week 88 [N=43, 25, 23]	**-28.4 (27.77)**	**-30.9 (25.59)**	**-29.2 (23.95)**
Week 100 [N=21, 13, 14]	**-34.1 (20.69)**	**-27.6 (21.85)**	**-31.9 (24.45)**
Week 112 [N=13, 8, 6]	**-29.9 (23.05)**	**-28.5 (19.01)**	**-36.8 (38.84)**
Week 124 [N=2, 1, 1]	**-59.5 (20.51)**	**-20.0** [1]	**-21.0** [1]
End of Study Visit [N=103, 52, 54]	**-20.4 (27.93)**	**-19.7 (26.29)**	**-18.6 (27.61)**

[1] Mean based on 1 participant. Standard deviation can not be calculated.

No statistical analysis provided for Change From Baseline in Patient's Global Assessment of Disease Activity During the Extension Study

27. Secondary: Change From Baseline in Physician's Global Assessment of Disease Activity During the Extension Study [Time Frame: Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124.]

Measure Type	Secondary
Measure Title	Change From Baseline in Physician's Global Assessment of Disease Activity During the Extension Study
Measure Description	The physician's global assessment of disease activity was performed using a 100 mm visual analog scale (VAS) ranging from no arthritis activity (0) to maximal arthritis activity (100). To enhance objectivity, the physician was not aware of the specific patient's global assessment of disease activity when performing their own assessment on that patient. The distance in mm from the left edge of the scale was measured. A negative change from Baseline score indicates improvement in assessment of disease activity.
Time Frame	Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124.
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.

The Extension Study ITT population. At each timepoint, only patients with a value at both Baseline and that timepoint are included (N).

Reporting Groups

	Description
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks. Includes participants who received the 600 mg intravenous loading dose on Day 1 of the Core phase.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 300 mg q2wk	Canakinumab 150 mg q4wk	Placebo
Number of Participants Analyzed [units: participants]	**105**	**57**	**55**
Change From Baseline in Physician's Global Assessment of Disease Activity During the Extension Study [units: scores on a scale] Mean (Standard Deviation)			
Week 24 [N=105, 57, 55]	**-30.9 (23.58)**	**-36.1 (25.59)**	**-36.0 (23.94)**
Week 36 [N=98, 48, 48]	**-31.1 (22.69)**	**-41.6 (18.24)**	**-37.3 (24.17)**
Week 48 [N=93, 43, 47]	**-34.3 (22.60)**	**-45.6 (18.09)**	**-38.8 (24.99)**
Week 60 [N=89, 40, 43]	**-34.9 (23.57)**	**-41.9 (22.92)**	**-42.3 (24.00)**
Week 72 [N=66, 34, 27]	**-37.7 (25.64)**	**-44.6 (22.32)**	**-43.8 (18.34)**
Week 88 [N=42, 25, 22]	**-41.9 (23.81)**	**-44.8 (19.42)**	**-45.4 (19.00)**
Week 100 [N=21, 12, 13]	**-45.2 (18.56)**	**-42.2 (12.93)**	**-47.6 (17.04)**
Week 112 [N=13, 8, 6]	**-45.2 (22.11)**	**-51.4 (13.11)**	**-29.0 (33.15)**
Week 124 [N=2, 1, 1]	**-54.5 (0.71)**	**-49.0** [1]	**-39.0** [1]
End of Study Visit [N=102, 53, 53]	**-25.6 (27.23)**	**-29.7 (25.95)**	**-31.8 (29.28)**

[1] Mean based on 1 participant. Standard deviation can not be calculated.

No statistical analysis provided for Change From Baseline in Physician's Global Assessment of Disease Activity During the Extension Study

28. Secondary: Change From Baseline in Health Assessment Questionnaire (HAQ) Score During the Extension Study [Time Frame: Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124.]

Measure Type	Secondary
Measure Title	Change From Baseline in Health Assessment Questionnaire (HAQ) Score During the Extension Study
Measure Description	The patient health assessment questionnaire (HAQ) was used to assess the physical ability and functional status of participants as well as quality of life. The disability dimension consists of 20 multiple choice items concerning difficulty in performing eight common activities of daily living; dressing and grooming, arising, eating, walking, reaching, personal hygiene, gripping and activities. Participants choose from four response categories, ranging from 'without any difficulty' (Score=0) to 'unable to do' (Score=3). The overall score is the average of each of the 8 category scores and ranges from 0 to 3, where zero represents no disability and three very severe, high-dependency disability. A negative change from Baseline score indicates improvement in disability status.
Time Frame	Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124.
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.
The Extension Study ITT population. At each timepoint, only patients with a value at both Baseline and that timepoint are included (N).

Reporting Groups

	Description
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks. Includes participants who received the 600 mg intravenous loading dose on Day 1 of the Core phase.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 300 mg q2wk	**Canakinumab 150 mg q4wk**	**Placebo**
Number of Participants Analyzed [units: participants]	**107**	**58**	**56**
Change From Baseline in Health Assessment Questionnaire (HAQ) Score During the Extension Study [units: scores on a scale] Mean (Standard Deviation)			
Week 24 [N=106, 58, 56]	**-0.241 (0.5430)**	**-0.304 (0.4895)**	**-0.239 (0.5142)**
Week 36 [N=99, 49, 48]	**-0.266 (0.5418)**	**-0.347 (0.5066)**	**-0.302 (0.5511)**
Week 48 [N=96, 44, 47]	**-0.322 (0.5446)**	**-0.324 (0.4988)**	**-0.293 (0.5375)**
Week 60 [N=86, 40, 42]	**-0.347 (0.5552)**	**-0.419 (0.5819)**	**-0.425 (0.6047)**
Week 72 [N=65, 34, 27]	**-0.398 (0.6047)**	**-0.441 (0.5849)**	**-0.449 (0.6338)**
Week 88 [N=44, 25, 23]	**-0.472 (0.5985)**	**-0.440 (0.5218)**	**-0.451 (0.5823)**

Week 100 [N=21, 13, 14]	**-0.613 (0.5504)**	**-0.298 (0.4692)**	**-0.563 (0.7448)**
Week 112 [N=13, 8, 6]	**-0.538 (0.5410)**	**-0.406 (0.6640)**	**-0.542 (0.7100)**
Week 124 [N=2, 1, 1]	**-0.938 (0.6187)**	**-0.625** [1]	**-1.250** [1]
End of Study Visit [N=101, 54, 54]	**-0.260 (0.6051)**	**-0.322 (0.5724)**	**-0.291 (0.6259)**

[1] Mean based on 1 participant. Standard deviation can not be calculated.

No statistical analysis provided for Change From Baseline in Health Assessment Questionnaire (HAQ) Score During the Extension Study

29. Secondary: Change From Baseline in High-sensitive C-Reactive Protein (hsCRP) Levels During the Extension Study [Time Frame: Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124.]

Measure Type	Secondary
Measure Title	Change From Baseline in High-sensitive C-Reactive Protein (hsCRP) Levels During the Extension Study
Measure Description	HsCRP is a marker for inflammation and was measured from blood samples to identify the presence of inflammation, to determine its severity, and to monitor response to treatment.
Time Frame	Baseline and Weeks 24, 36, 48, 60, 72, 88, 100, 112 and 124.
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.
The Extension Study ITT population. At each timepoint, only patients with a value at both Baseline and that timepoint are included (N).

Reporting Groups

	Description
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks. Includes participants who received the 600 mg intravenous loading dose on Day 1 of the Core phase.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 300 mg q2wk	**Canakinumab 150 mg q4wk**	**Placebo**
Number of Participants Analyzed [units: participants]	**106**	**58**	**55**
Change From Baseline in High-sensitive C-Reactive Protein (hsCRP) Levels During the Extension Study [units: mg/L] Mean (Standard Deviation)			
Week 24 [N=106, 58, 55]	**-4.82 (17.914)**	**-6.45 (14.556)**	**-9.59**

			(18.388)
Week 36 [N=97, 49, 50]	-7.76 (16.771)	-4.57 (14.393)	0.50 (71.610)
Week 48 [N=95, 44, 47]	-5.61 (22.335)	-4.63 (13.521)	-11.04 (20.261)
Week 60 [N=88, 40, 43]	-6.93 (21.160)	0.49 (47.139)	-7.04 (18.638)
Week 72 [N=63, 33, 26]	-9.02 (18.067)	-5.29 (15.219)	-7.70 (18.221)
Week 88 [N=44, 24, 22]	-8.45 (19.060)	-7.31 (13.035)	-7.65 (18.098)
Week 100 [N=21, 14, 12]	-7.29 (12.850)	-2.74 (17.273)	-10.74 (24.539)
Week 112 [N=13, 9, 6]	-5.75 (10.438)	-1.80 (18.838)	-19.33 (35.567)
Week 124 [N=2, 1, 1]	4.95 (13.364)	-22.70 [1]	0.20 [1]
End of Study Visit [N=101, 57, 52]	-7.01 (17.934)	-2.94 (15.735)	-9.74 (20.766)

[1] Mean based on 1 participant. Standard deviation can not be calculated.

No statistical analysis provided for Change From Baseline in High-sensitive C-Reactive Protein (hsCRP) Levels During the Extension Study

30. Secondary: Change From Baseline in Erythrocyte Sedimentation Rate During the Extension Study [Time Frame: Baseline and Weeks 24, 36, 48, 60, 72 and 88.]

Measure Type	Secondary
Measure Title	Change From Baseline in Erythrocyte Sedimentation Rate During the Extension Study
Measure Description	Erythrocyte sedimentation rate (ESR) indirectly measures how much inflammation is in the body. A higher ESR is indicative of increased inflammation. A negative change from Baseline score indicates improvement.
Time Frame	Baseline and Weeks 24, 36, 48, 60, 72 and 88.
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.
The Extension Study ITT population. At each timepoint, only patients with a value at both Baseline and that timepoint are included (N).

Reporting Groups

	Description
Canakinumab 300 mg q2wk	Participants received canakinumab 300 mg subcutaneous injections every 2 weeks (q2wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks. Includes participants who received the 600 mg intravenous loading dose on Day 1 of the Core phase.
Canakinumab 150 mg q4wk	Participants received canakinumab 150 mg subcutaneous injections every 4 weeks (q4wk) for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.
Placebo	Participants received placebo subcutaneous injections every 2 weeks for 12 weeks in the Core Phase. In the Extension Phase, participants received 300 mg canakinumab every 4 weeks subcutaneously, until a protocol

	amendment in January 2009 decreased the dose to 150 mg subcutaneous injection every 4 weeks.

Measured Values

	Canakinumab 300 mg q2wk	Canakinumab 150 mg q4wk	Placebo
Number of Participants Analyzed [units: participants]	**105**	**58**	**54**
Change From Baseline in Erythrocyte Sedimentation Rate During the Extension Study [units: mm/hr] Mean (Standard Deviation)			
Week 24 [N=105, 58, 54]	**-14.9 (17.31)**	**-18.3 (14.96)**	**-16.8 (17.10)**
Week 36 [N=95, 46, 48]	**-14.5 (18.99)**	**-13.6 (19.09)**	**-11.3 (25.94)**
Week 48 [N=91, 42, 47]	**-15.6 (20.13)**	**-16.6 (13.44)**	**-17.0 (18.81)**
Week 60 [N=85, 39, 43]	**-17.2 (19.07)**	**-15.8 (19.08)**	**-16.7 (19.09)**
Week 72 [N=64, 34, 26]	**-18.6 (17.83)**	**-15.3 (16.39)**	**-14.1 (23.10)**
Week 88 [N=42, 24, 23]	**-19.7 (17.46)**	**-13.5 (16.38)**	**-13.3 (20.89)**
End of Study Visit [N=98, 55, 55]	**-14.9 (18.09)**	**-14.0 (17.51)**	**-15.9 (18.10)**

No statistical analysis provided for Change From Baseline in Erythrocyte Sedimentation Rate During the Extension Study

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
ACZ885 600mg iv + 300mg sc q2wk	ACZ885 600mg iv + 300mg sc q2wk
ACZ885 300mg sc q2wk	ACZ885 300mg sc q2wk
ACZ885 150mg sc q4wk	ACZ885 150mg sc q4wk
Placebo	Placebo

Serious Adverse Events

	ACZ885 600mg iv + 300mg sc q2wk	ACZ885 300mg sc q2wk	ACZ885 150mg sc q4wk	Placebo
Total, serious adverse events				
# participants affected / at risk	**11/71 (15.49%)**	**16/64 (25.00%)**	**12/69 (17.39%)**	**16/70 (22.86%)**
Blood and lymphatic system disorders				

Anaemia † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**1/69 (1.45%)**	**0/70 (0.00%)**
Cardiac disorders				
Atrial fibrillation † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**1/70 (1.43%)**
Tachyarrhythmia † 1				
# participants affected / at risk	**0/71 (0.00%)**	**1/64 (1.56%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Ear and labyrinth disorders				
Sudden hearing loss † 1				
# participants affected / at risk	**1/71 (1.41%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Eye disorders				
Cataract † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**1/70 (1.43%)**
Gastrointestinal disorders				
Abdominal hernia obstructive † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**1/70 (1.43%)**
Ascites † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**1/70 (1.43%)**
Colitis † 1				
# participants affected / at risk	**1/71 (1.41%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Diarrhoea † 1				
# participants affected / at risk	**1/71 (1.41%)**	**0/64 (0.00%)**	**1/69 (1.45%)**	**0/70 (0.00%)**
Duodenal ulcer † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**1/70 (1.43%)**
Dyspepsia † 1				
# participants affected / at risk	**0/71 (0.00%)**	**1/64 (1.56%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Gastric ulcer haemorrhage † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**1/69 (1.45%)**	**1/70 (1.43%)**
Gastritis † 1				
# participants affected / at risk	**1/71 (1.41%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Intestinal perforation † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**1/70 (1.43%)**
Large intestine perforation † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**1/69 (1.45%)**	**0/70 (0.00%)**
General disorders				
Chest pain † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**1/69 (1.45%)**	**0/70 (0.00%)**
Malaise † 1				
# participants affected / at risk	**1/71 (1.41%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Infections and infestations				
Abscess limb † 1				
# participants affected / at risk	**0/71 (0.00%)**	**1/64 (1.56%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Appendicitis † 1				
# participants affected / at risk	**1/71 (1.41%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**0/70 (0.00%)**

Arthritis bacterial † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**1/70 (1.43%)**
Bronchitis † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**1/69 (1.45%)**	**0/70 (0.00%)**
Cellulitis † 1				
# participants affected / at risk	**0/71 (0.00%)**	**1/64 (1.56%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Chronic sinusitis † 1				
# participants affected / at risk	**1/71 (1.41%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Device related infection † 1				
# participants affected / at risk	**0/71 (0.00%)**	**1/64 (1.56%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Diverticulitis † 1				
# participants affected / at risk	**0/71 (0.00%)**	**1/64 (1.56%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Erysipelas † 1				
# participants affected / at risk	**1/71 (1.41%)**	**0/64 (0.00%)**	**1/69 (1.45%)**	**0/70 (0.00%)**
Infected epidermal cyst † 1				
# participants affected / at risk	**1/71 (1.41%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Meningitis † 1				
# participants affected / at risk	**0/71 (0.00%)**	**1/64 (1.56%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Respiratory tract infection † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**1/69 (1.45%)**	**0/70 (0.00%)**
Soft tissue infection † 1				
# participants affected / at risk	**0/71 (0.00%)**	**1/64 (1.56%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Subcutaneous abscess † 1				
# participants affected / at risk	**1/71 (1.41%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Urinary tract infection † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**1/70 (1.43%)**
Urosepsis † 1				
# participants affected / at risk	**1/71 (1.41%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Wound infection † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**1/70 (1.43%)**
Injury, poisoning and procedural complications				
Epicondylitis † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**1/70 (1.43%)**
Radius fracture † 1				
# participants affected / at risk	**0/71 (0.00%)**	**1/64 (1.56%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Seroma † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**1/69 (1.45%)**	**0/70 (0.00%)**
Tendon rupture † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**1/70 (1.43%)**
Thoracic vertebral fracture † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**1/69 (1.45%)**	**0/70 (0.00%)**
Investigations				
Tumour marker increased † 1				

# participants affected / at risk	0/71 (0.00%)	0/64 (0.00%)	1/69 (1.45%)	0/70 (0.00%)
Metabolism and nutrition disorders				
Dehydration † 1				
# participants affected / at risk	0/71 (0.00%)	0/64 (0.00%)	1/69 (1.45%)	0/70 (0.00%)
Musculoskeletal and connective tissue disorders				
Cervical spinal stenosis † 1				
# participants affected / at risk	0/71 (0.00%)	1/64 (1.56%)	0/69 (0.00%)	0/70 (0.00%)
Foot deformity † 1				
# participants affected / at risk	0/71 (0.00%)	0/64 (0.00%)	0/69 (0.00%)	1/70 (1.43%)
Hand deformity † 1				
# participants affected / at risk	0/71 (0.00%)	1/64 (1.56%)	0/69 (0.00%)	0/70 (0.00%)
Intervertebral disc protrusion † 1				
# participants affected / at risk	0/71 (0.00%)	0/64 (0.00%)	1/69 (1.45%)	0/70 (0.00%)
Lumbar spinal stenosis † 1				
# participants affected / at risk	0/71 (0.00%)	0/64 (0.00%)	1/69 (1.45%)	0/70 (0.00%)
Osteoarthritis † 1				
# participants affected / at risk	0/71 (0.00%)	1/64 (1.56%)	2/69 (2.90%)	0/70 (0.00%)
Rheumatoid arthritis † 1				
# participants affected / at risk	1/71 (1.41%)	1/64 (1.56%)	1/69 (1.45%)	3/70 (4.29%)
Rheumatoid nodule † 1				
# participants affected / at risk	1/71 (1.41%)	0/64 (0.00%)	0/69 (0.00%)	0/70 (0.00%)
Spinal osteoarthritis † 1				
# participants affected / at risk	0/71 (0.00%)	0/64 (0.00%)	0/69 (0.00%)	1/70 (1.43%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Angiomyolipoma † 1				
# participants affected / at risk	0/71 (0.00%)	0/64 (0.00%)	0/69 (0.00%)	1/70 (1.43%)
Lung adenocarcinoma † 1				
# participants affected / at risk	0/71 (0.00%)	1/64 (1.56%)	0/69 (0.00%)	0/70 (0.00%)
Lung adenocarcinoma metastatic † 1				
# participants affected / at risk	1/71 (1.41%)	0/64 (0.00%)	0/69 (0.00%)	0/70 (0.00%)
Non-Hodgkin's lymphoma † 1				
# participants affected / at risk	0/71 (0.00%)	0/64 (0.00%)	1/69 (1.45%)	0/70 (0.00%)
Squamous cell carcinoma of skin † 1				
# participants affected / at risk	0/71 (0.00%)	0/64 (0.00%)	1/69 (1.45%)	0/70 (0.00%)
Nervous system disorders				
Cervical myelopathy † 1				
# participants affected / at risk	0/71 (0.00%)	1/64 (1.56%)	0/69 (0.00%)	0/70 (0.00%)
Ischaemic stroke † 1				
# participants affected / at risk	1/71 (1.41%)	0/64 (0.00%)	0/69 (0.00%)	0/70 (0.00%)
Transient ischaemic attack † 1				
# participants affected / at risk	0/71 (0.00%)	1/64 (1.56%)	0/69 (0.00%)	0/70 (0.00%)
Psychiatric disorders				
Depression † 1				

# participants affected / at risk	**0/71 (0.00%)**	**1/64 (1.56%)**	**0/69 (0.00%)**	**1/70 (1.43%)**
Renal and urinary disorders				
Renal colic † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**1/69 (1.45%)**	**0/70 (0.00%)**
Reproductive system and breast disorders				
Ovarian cyst † 1				
# participants affected / at risk	**1/71 (1.41%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Uterine haemorrhage † 1				
# participants affected / at risk	**1/71 (1.41%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Respiratory, thoracic and mediastinal disorders				
Chronic obstructive pulmonary disease † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**1/69 (1.45%)**	**0/70 (0.00%)**
Dyspnoea † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**1/70 (1.43%)**
Pulmonary embolism † 1				
# participants affected / at risk	**0/71 (0.00%)**	**1/64 (1.56%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Respiratory failure † 1				
# participants affected / at risk	**1/71 (1.41%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Vascular disorders				
Deep vein thrombosis † 1				
# participants affected / at risk	**0/71 (0.00%)**	**1/64 (1.56%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Hypertension † 1				
# participants affected / at risk	**0/71 (0.00%)**	**1/64 (1.56%)**	**1/69 (1.45%)**	**0/70 (0.00%)**
Peripheral arterial occlusive disease † 1				
# participants affected / at risk	**1/71 (1.41%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Thromboangiitis obliterans † 1				
# participants affected / at risk	**0/71 (0.00%)**	**0/64 (0.00%)**	**0/69 (0.00%)**	**1/70 (1.43%)**
Thrombophlebitis † 1				
# participants affected / at risk	**0/71 (0.00%)**	**1/64 (1.56%)**	**0/69 (0.00%)**	**0/70 (0.00%)**
Venous thrombosis limb † 1				
# participants affected / at risk	**0/71 (0.00%)**	**1/64 (1.56%)**	**0/69 (0.00%)**	**0/70 (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	5%

Reporting Groups

	Description
ACZ885 600mg iv + 300mg sc q2wk	ACZ885 600mg iv + 300mg sc q2wk
ACZ885 300mg sc q2wk	ACZ885 300mg sc q2wk
ACZ885 150mg sc q4wk	ACZ885 150mg sc q4wk
Placebo	Placebo

Other Adverse Events

	ACZ885 600mg iv + 300mg sc q2wk	ACZ885 300mg sc q2wk	ACZ885 150mg sc q4wk	Placebo
Total, other (not including serious) adverse events				
# participants affected / at risk	**42/71 (59.15%)**	**38/64 (59.38%)**	**39/69 (56.52%)**	**40/70 (57.14%)**
Gastrointestinal disorders				
Diarrhoea † 1				
# participants affected / at risk	**5/71 (7.04%)**	**6/64 (9.38%)**	**3/69 (4.35%)**	**5/70 (7.14%)**
Dyspepsia † 1				
# participants affected / at risk	**1/71 (1.41%)**	**1/64 (1.56%)**	**4/69 (5.80%)**	**0/70 (0.00%)**
Nausea † 1				
# participants affected / at risk	**4/71 (5.63%)**	**5/64 (7.81%)**	**1/69 (1.45%)**	**4/70 (5.71%)**
General disorders				
Fatigue † 1				
# participants affected / at risk	**3/71 (4.23%)**	**3/64 (4.69%)**	**3/69 (4.35%)**	**5/70 (7.14%)**
Oedema peripheral † 1				
# participants affected / at risk	**3/71 (4.23%)**	**4/64 (6.25%)**	**4/69 (5.80%)**	**6/70 (8.57%)**
Infections and infestations				
Bronchitis † 1				
# participants affected / at risk	**6/71 (8.45%)**	**6/64 (9.38%)**	**4/69 (5.80%)**	**3/70 (4.29%)**
Gastroenteritis † 1				
# participants affected / at risk	**6/71 (8.45%)**	**2/64 (3.13%)**	**0/69 (0.00%)**	**4/70 (5.71%)**
Influenza † 1				
# participants affected / at risk	**1/71 (1.41%)**	**2/64 (3.13%)**	**4/69 (5.80%)**	**3/70 (4.29%)**
Nasopharyngitis † 1				
# participants affected / at risk	**14/71 (19.72%)**	**12/64 (18.75%)**	**12/69 (17.39%)**	**10/70 (14.29%)**
Sinusitis † 1				
# participants affected / at risk	**5/71 (7.04%)**	**0/64 (0.00%)**	**1/69 (1.45%)**	**1/70 (1.43%)**
Upper respiratory tract infection † 1				
# participants affected / at risk	**6/71 (8.45%)**	**8/64 (12.50%)**	**5/69 (7.25%)**	**8/70 (11.43%)**
Urinary tract infection † 1				
# participants affected / at risk	**7/71 (9.86%)**	**5/64 (7.81%)**	**3/69 (4.35%)**	**4/70 (5.71%)**
Musculoskeletal and connective tissue disorders				
Arthralgia † 1				

# participants affected / at risk	**6/71 (8.45%)**	**3/64 (4.69%)**	**5/69 (7.25%)**	**6/70 (8.57%)**
Back pain † 1				
# participants affected / at risk	**2/71 (2.82%)**	**4/64 (6.25%)**	**3/69 (4.35%)**	**4/70 (5.71%)**
Myalgia † 1				
# participants affected / at risk	**2/71 (2.82%)**	**2/64 (3.13%)**	**4/69 (5.80%)**	**1/70 (1.43%)**
Osteoarthritis † 1				
# participants affected / at risk	**4/71 (5.63%)**	**4/64 (6.25%)**	**1/69 (1.45%)**	**0/70 (0.00%)**
Rheumatoid arthritis † 1				
# participants affected / at risk	**3/71 (4.23%)**	**8/64 (12.50%)**	**6/69 (8.70%)**	**7/70 (10.00%)**
Tendonitis † 1				
# participants affected / at risk	**0/71 (0.00%)**	**3/64 (4.69%)**	**1/69 (1.45%)**	**4/70 (5.71%)**
Nervous system disorders				
Dizziness † 1				
# participants affected / at risk	**2/71 (2.82%)**	**2/64 (3.13%)**	**1/69 (1.45%)**	**4/70 (5.71%)**
Headache † 1				
# participants affected / at risk	**8/71 (11.27%)**	**4/64 (6.25%)**	**4/69 (5.80%)**	**4/70 (5.71%)**
Respiratory, thoracic and mediastinal disorders				
Cough † 1				
# participants affected / at risk	**3/71 (4.23%)**	**5/64 (7.81%)**	**5/69 (7.25%)**	**5/70 (7.14%)**
Skin and subcutaneous tissue disorders				
Rash † 1				
# participants affected / at risk	**0/71 (0.00%)**	**1/64 (1.56%)**	**4/69 (5.80%)**	**1/70 (1.43%)**
Vascular disorders				
Hypertension † 1				
# participants affected / at risk	**3/71 (4.23%)**	**6/64 (9.38%)**	**3/69 (4.35%)**	**2/70 (2.86%)**

† 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 the pooled data (i.e., data from all sites) in the clinical trial.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300

No publications provided by Novartis

Publications automatically indexed to this study:

Alten R, Gomez-Reino J, Durez P, Beaulieu A, Sebba A, Krammer G, Preiss R, Arulmani U, Widmer A, Gitton X, Kellner H. Efficacy and safety of the human anti-IL-1β monoclonal antibody canakinumab in rheumatoid arthritis: results of a 12-week, Phase II, dose-finding study. BMC Musculoskelet Disord. 2011 Jul 7;12:153. doi: 10.1186/1471-2474-12-153.

Responsible Party:	Novartis
ClinicalTrials.gov Identifier:	NCT00424346 History of Changes
Obsolete Identifiers:	NCT00471198, NCT00784628
Other Study ID Numbers:	**CACZ885A2201** **CACZ885A2201**E1 **CACZ885A2201**E2
Study First Received:	January 17, 2007
Results First Received:	April 2, 2013
Last Updated:	January 14, 2014
Health Authority:	United States: Food and Drug Administration Austria: Federal Ministry for Health and Women Belgium: Federal Agency for Medicines and Health Products, FAMHP Canada: Health Canada Germany: Federal Institute for Drugs and Medical Devices Spain: Spanish Agency of Medicines