Evaluating Efficacy of Canakinumab (ACZ885) in Prevention of Acute Flares in Chronic Gout Patients Initiating Allopurinol Therapy

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00819585

First received: January 8, 2009
Last updated: April 12, 2011
Last verified: April 2011
History of Changes

Results First Received: February 28, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Prevention
Condition:	Gout
Interventions:	Drug: Canakinumab 25 mg Drug: Canakinumab 50 mg Drug: Canakinumab 100 mg Drug: Canakinumab 200 mg Drug: Canakinumab 300 mg Drug: Canakinumab repeated every 4 week (q4wk) Drug: Colchicine Drug: Allopurinol Drug: Placebo Matching Canakinumab Drug: Placebo Matching Colchicine

Participant Flow

Hide Participant Flow

Recruitment Details

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

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Canakinumab 25 mg	Canakinumab 25 mg subcutaneously (s.c.) once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 50 mg	Canakinumab 50 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16

	weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
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Canakinumab 300 mg	Canakinumab 300 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab q4wk	Canakinumab 50 mg s.c. at Days 1, and 29 followed by canakinumab 25 mg s.c. on Days 57, and 85 plus daily placebo capsules for 16 weeks, repeated every 4 week (q4wk). Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Colchicine 0.5 mg	Colchicine 0.5 mg capsule orally once daily throughout the whole treatment phase of 16 weeks plus placebo matching canakinumab s.c. at Days 1, 29, 57, and 85. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.

Participant Flow: Overall Study

	Canakinumab 25 mg	Canakinumab 50 mg	Canakinumab 100 mg	Canakinumab 200 mg	Canakinumab 300 mg	Canakinumab q4wk	Colchicine 0.5 mg
STARTED	55 [1]	54	54	54	53	54	108
Safety Population	55	54	54	54	53	53 [2]	108
COMPLETED	49	48	48	49	50	52	95
NOT COMPLETED	6	6	6	5	3	2	13
Adverse Event	2	1	1	4	1	0	2
Abnormal laboratory value(s)	2	0	0	0	0	0	0
Unsatisfactory therapeutic effect	0	1	0	0	0	0	1
Subject no longer requires study drug	0	0	0	0	1	0	0
Subject withdrew consent	0	3	2	1	0	0	3
Lost to Follow-up	2	1	2	0	1	1	1
Administrative problems	0	0	0	0	0	0	2
Death	0	0	0	0	0	0	1
Protocol Violation	0	0	1	0	0	1	3

[1] "Started" indicates randomized as well as full analysis set.
[2] A pt. who was randomized to repeated dose regimen, found as HIV +ve, didn't take any study drug.

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 25 mg	Canakinumab 25 mg subcutaneously (s.c.) once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
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Total	Total of all reporting groups

Baseline Measures

	Canakinumab 25 mg	Canakinumab 50 mg	Canakinumab 100 mg	Canakinumab 200 mg	Canakinumab 300 mg	Canakinumab q4wk	Colchicine 0.5 mg	Total
Number of Participants [units: participants]	55	54	54	54	53	53	108	431
Age [1] [units: Years] Mean (Standard Deviation)	50.7 (9.72)	54.4 (12.18)	51.3 (12.41)	52.6 (10.78)	52.4 (11.30)	52.8 (10.38)	52.4 (10.69)	52.4 (11.02)
Gender [units: participants]								
Female	0	3	6	4	2	4	7	26
Male	55	51	48	50	51	49	101	405

[1] Baseline measures are based on safety population.

Outcome Measures

Hide All Outcome Measures

1. Primary: The Mean Number of Gout Flares for Each Treatment Arm [Time Frame: 16 weeks after randomization]

Measure Type	Primary
Measure Title	The Mean Number of Gout Flares for Each Treatment Arm
Measure Description	The primary efficacy variable was number of gout flares per participant per arm. Mean number of gout flares per treatment arm was derived from this primary variable. A gout flare was defined as an increase in participant-reported gout pain in the most affected joint during a gout attack. The target dose was defined as the minimum single dose that leads to at least the same expected efficacy as the expected efficacy of the comparator colchicine with respect to the mean number of gout flares. Four dose-response models (linear, linear in log-dose, logistic and emax) were chosen.
Time Frame	16 weeks after randomization
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 Full Analysis Set (FAS) consisted of all patients as randomized that had at least one post-baseline assessment of the primary efficacy variable. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab 25 mg	Canakinumab 25 mg subcutaneously (s.c.) once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 50 mg	Canakinumab 50 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
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Canakinumab 300 mg	Canakinumab 300 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab q4wk	Canakinumab 50 mg s.c. at Days 1, and 29 followed by canakinumab 25 mg s.c. on Days 57, and 85 plus daily placebo capsules for 16 weeks, repeated every 4 week (q4wk). Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Colchicine 0.5 mg	Colchicine 0.5 mg capsule orally once daily throughout the whole treatment phase of 16 weeks plus placebo matching canakinumab s.c. at Days 1, 29, 57, and 85. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.

Measured Values

	Canakinumab 25 mg	**Canakinumab 50 mg**	**Canakinumab 100 mg**	**Canakinumab 200 mg**	**Canakinumab 300 mg**	**Canakinumab q4wk**	**Colchicine 0.5 mg**
Number of Participants Analyzed [units: participants]	**55**	**54**	**54**	**54**	**53**	**54**	**108**

The Mean Number of Gout Flares for Each Treatment Arm [units: gout flares] Mean (Standard Deviation)	**0.5 (1.03)**	**0.4 (1.82)**	**0.2 (0.53)**	**0.4 (1.35)**	**0.2 (0.53)**	**0.7 (2.24)**	**0.7 (1.00)**

No statistical analysis provided for The Mean Number of Gout Flares for Each Treatment Arm

2. Secondary: The Mean Number of Gout Flares for the Repeat Dose Regimen of Canakinumab as Compared to the Single Doses of Canakinumab [Time Frame: up to 16 weeks after randomization]

Measure Type	Secondary
Measure Title	The Mean Number of Gout Flares for the Repeat Dose Regimen of Canakinumab as Compared to the Single Doses of Canakinumab
Measure Description	No text entered.
Time Frame	up to 16 weeks after randomization
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 Full Analysis Set (FAS) consisted of all patients as randomized that had at least one post-baseline assessment of the primary efficacy variable. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab 25 mg	Canakinumab 25 mg subcutaneously (s.c.) once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
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Canakinumab q4wk	Canakinumab 50 mg s.c. at Days 1, and 29 followed by canakinumab 25 mg s.c. on Days 57, and 85 plus daily placebo capsules for 16 weeks, repeated every 4 week (q4wk). Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.

Measured Values

	Canakinumab 25 mg	**Canakinumab 50 mg**	**Canakinumab 100 mg**	**Canakinumab 200 mg**	**Canakinumab 300 mg**	**Canakinumab q4wk**

Number of Participants Analyzed [units: participants]	**55**	**54**	**54**	**54**	**53**	**54**
The Mean Number of Gout Flares for the Repeat Dose Regimen of Canakinumab as Compared to the Single Doses of Canakinumab [units: gout flares per patient] Least Squares Mean (Standard Error)	**0.48 (0.204)**	**0.43 (0.207)**	**0.22 (0.209)**	**0.38 (0.205)**	**0.21 (0.209)**	**0.68 (0.209)**

No statistical analysis provided for The Mean Number of Gout Flares for the Repeat Dose Regimen of Canakinumab as Compared to the Single Doses of Canakinumab

3. Secondary: The Percentage of Participants With Gout Flares for Each Canakinumab Treatment Arm as Compared to Colchicine [Time Frame: 16 weeks after randomization]

Measure Type	Secondary
Measure Title	The Percentage of Participants With Gout Flares for Each Canakinumab Treatment Arm as Compared to Colchicine
Measure Description	The percentage of participants experiencing at least one gout flare within 16 weeks after randomization. A gout flare was defined as an increase in patient-reported gout pain in the most affected joint during a gout attack. The start of a gout flare was defined as that day when the patient reported increased pain in the most affected joint for the first time in the patient diary. The end of a gout flare was defined as the patient's confirmation in the diary that the patient felt he/she had recovered from the gout flare or the acute gout pain had disappeared (whichever was first).
Time Frame	16 weeks after randomization
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 Full Analysis Set (FAS) consisted of all patients as randomized that had at least one post-baseline assessment of the primary efficacy variable. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab 25 mg	Canakinumab 25 mg subcutaneously (s.c.) once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 50 mg	Canakinumab 50 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
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Canakinumab 300 mg	Canakinumab 300 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab q4wk	Canakinumab 50 mg s.c. at Days 1, and 29 followed by canakinumab 25 mg s.c. on Days 57, and 85 plus daily placebo capsules for 16 weeks, repeated every 4 week (q4wk). Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1).

	Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Colchicine 0.5 mg	Colchicine 0.5 mg capsule orally once daily throughout the whole treatment phase of 16 weeks plus placebo matching canakinumab s.c. at Days 1, 29, 57, and 85. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.

Measured Values

	Canakinumab 25 mg	Canakinumab 50 mg	Canakinumab 100 mg	Canakinumab 200 mg	Canakinumab 300 mg	Canakinumab q4wk	Colchicine 0.5 mg
Number of Participants Analyzed [units: participants]	55	54	54	54	53	54	108
The Percentage of Participants With Gout Flares for Each Canakinumab Treatment Arm as Compared to Colchicine [units: Percentage of participants]	27.3	16.7	14.8	18.5	15.1	16.7	44.4

No statistical analysis provided for The Percentage of Participants With Gout Flares for Each Canakinumab Treatment Arm as Compared to Colchicine

4. Secondary: The Percentage of Participants With Gout Flare at Different Time Points for Each Canakinumab Treatment Arm as Compared to Colchicine [Time Frame: 2 days, 4 days, 6 days, 2 weeks, 4 weeks, 6 weeks, 10 weeks and 16 weeks]

Measure Type	Secondary
Measure Title	The Percentage of Participants With Gout Flare at Different Time Points for Each Canakinumab Treatment Arm as Compared to Colchicine
Measure Description	A gout flare was defined as an increase in participant-reported gout pain in the most affected joint during a gout attack. The start of a gout flare was defined as that day when the patient reported increased pain in the most affected joint for the first time in the patient diary. The end of a gout flare was defined as the patient's confirmation in the diary that the patient felt he/she had recovered from the gout flare or the acute gout pain had disappeared (whichever was first).
Time Frame	2 days, 4 days, 6 days, 2 weeks, 4 weeks, 6 weeks, 10 weeks and 16 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.
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Canakinumab 25 mg	Canakinumab 25 mg subcutaneously (s.c.) once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
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Measured Values

	Canakinumab 25 mg	**Canakinumab 50 mg**	**Canakinumab 100 mg**	**Canakinumab 200 mg**	**Canakinumab 300 mg**	**Canakinumab q4wk**	**Colchicine 0.5 mg**
Number of Participants Analyzed [units: participants]	**55**	**54**	**54**	**54**	**53**	**54**	**108**
The Percentage of Participants With Gout Flare at Different Time Points for Each Canakinumab Treatment Arm as Compared to Colchicine [units: Percentage of participants] Number (95% Confidence Interval)							
2-days post-dose	**5.5 (1.79 to 15.96)**	**3.7 (0.94 to 14.01)**	**3.7 (0.94 to 14.01)**	**3.7 (0.94 to 14.01)**	**0.0 (0.0 to 0.0)**	**3.8 (0.96 to 14.26)**	**5.6 (2.53 to 11.95**
4-days post-dose	**10.9 (5.05 to 22.68)**	**3.7 (0.94 to 14.01)**	**3.7 (0.94 to 14.01)**	**3.7 (0.94 to 14.01)**	**5.7 (1.86 to 16.53)**	**3.8 (0.96 to 14.26)**	**10.2 (5.77 to 17.64**
6-days post-dose	**12.7 (6.28 to 24.85)**	**5.6 (1.83 to 16.24)**	**3.7 (0.94 to 14.01)**	**7.4 (2.85 to 18.54)**	**5.7 (1.86 to 16.53)**	**3.8 (0.96 to 23.56)**	**11.1 (6.47 to 18.74**
2-weeks post-dose	**14.5 (7.55 to 26.99)**	**7.4 (2.85 to 18.54)**	**7.4 (2.85 to 18.54)**	**11.1 (5.15 to 23.07)**	**7.5 (2.90 to 18.87)**	**11.3 (5.25 to 23.48)**	**16.7 (10.85 to 25.1**
4-weeks post-dose	**14.5 (7.55 to 26.99)**	**9.3 (3.96 to 20.83)**	**7.4 (2.85 to 18.54)**	**13.0 (6.40 to 25.28)**	**11.4 (5.27 to 23.56)**	**15.1 (7.85 to 27.92)**	**25.1 (17.93 to 34.3**
6-weeks post-dose	**16.5 (8.96 to 29.39)**	**11.1 (5.15 to 23.07)**	**9.3 (3.98 to 20.91)**	**13.0 (6.40 to 25.28)**	**11.4 (5.27 to 23.56)**	**27.92 (7.85 to 27.92)**	**32.6 (24.58 to 42.3**
10-weeks post-dose	**22.5 (13.43 to 36.26)**	**13.1 (6.46 to 25.52)**	**11.2 (5.19 to 23.22)**	**16.8 (9.11 to 29.79)**	**11.4 (5.27 to 23.56)**	**17.0 (9.22 to 30.09)**	**37.5 (29.06 to 47.4**

16-weeks post-dose	**28.7** **(18.34 to 43.10)**	**17.3** **(9.37 to 30.66)**	**15.1** **(7.82 to 27.87)**	**18.8** **(10.59 to 32.19)**	**15.3** **(7.96 to 28.29)**	**17.0** **(9.22 to 30.09)**	**45.8** **(36.76 to 55.8**

No statistical analysis provided for The Percentage of Participants With Gout Flare at Different Time Points for Each Canakinumab Treatment Arm as Compared to Colchicine

5. Secondary: Patient’s Global Pain Intensity on a 0-100 mm Visual Analog Scale (VAS) up to Day 7 During All Gout Flares for Each Canakinumab Treatment Arm as Compared to Colchicine [Time Frame: up to 16 weeks after randomization]

Measure Type	Secondary
Measure Title	Patient’s Global Pain Intensity on a 0-100 mm Visual Analog Scale (VAS) up to Day 7 During All Gout Flares for Each Canakinumab Treatment Arm as Compared to Colchicine
Measure Description	The pain intensity on a 0-100 mm VAS scale, ranging from no pain (0) to unbearable pain (100) in the affected joint (Scores on the 100-mm linear scale were measured to the nearest millimeter from the left) • on the day of onset of the gout flare and • in the morning of the 6 following days
Time Frame	up to 16 weeks after randomization
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 Full Analysis Set (FAS) consisted of all patients as randomized that had at least one post-baseline assessment of the primary efficacy variable. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab 25 mg	Canakinumab 25 mg subcutaneously (s.c.) once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 50 mg	Canakinumab 50 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 100 mg	Canakinumab 100 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 200 mg	Canakinumab 200 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 300 mg	Canakinumab 300 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab q4wk	Canakinumab 50 mg s.c. at Days 1, and 29 followed by canakinumab 25 mg s.c. on Days 57, and 85 plus daily placebo capsules for 16 weeks, repeated every 4 week (q4wk). Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Colchicine 0.5 mg	Colchicine 0.5 mg capsule orally once daily throughout the whole treatment phase of 16 weeks plus placebo matching canakinumab s.c. at Days 1, 29, 57, and 85. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol

	was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.

Measured Values

	Canakinumab 25 mg	Canakinumab 50 mg	Canakinumab 100 mg	Canakinumab 200 mg	Canakinumab 300 mg	Canakinumab q4wk	Colchicine 0.5 mg
Number of Participants Analyzed [units: participants]	55	54	54	54	53	54	108
Patient's Global Pain Intensity on a 0-100 mm Visual Analog Scale (VAS) up to Day 7 During All Gout Flares for Each Canakinumab Treatment Arm as Compared to Colchicine [units: Units on a scale] Mean (Standard Deviation)							
Day 1 : (n = 15, 9, 8, 9, 8, 9, 48)	41.1 (31.01)	44.6 (15.82)	56.3 (26.72)	53.0 (27.99)	52.2 (19.40)	66.1 (15.07)	53.1 (24.18)
Day 2: (n = 12, 7, 6, 5, 5, 7, 44)	44.8 (30.06)	40.1 (26.73)	46.2 (35.11)	19.8 (32.05)	43.1 (17.62)	59.3 (23.53)	42.8 (24.37)
Day 3: (n = 10, 4, 4, 4, 4, 5, 38)	31.5 (20.82)	49.5 (18.48)	49.5 (25.29)	56.7 (40.91)	26.3 (14.64)	58.0 (27.59)	38.1 (23.37)
Day 4: (n = 7, 3, 2, 3, 3, 6, 31)	31.8 (16.77)	46.3 (10.60)	16.5 (23.33)	63.5 (33.0)	11.0 (11.0)	49.4 (27.73)	30.5 (26.68)
Day 5: (n = 7, 2, 1, 3, 2, 4, 22)	19.3 (14.79)	48.0 (5.66)	0.0 (0.0)	54.8 (43.38)	13.0 (0.0)	41.4 (33.63)	31.8 (29.91)
Day 6: (n = 6, 1, 1, 2, 1, 3, 18)	19.6 (14.14)	44.0 (0.0)	0.0 (0.0)	57.5 (60.10)	12.0 (0.0)	43.5 (24.38)	33.7 (26.66)
Day 7: (n = 6, 0, 1, 2, 1, 2, 16)	20.9 (16.91)	NA [1]	0.0 (0.0)	35.0 (49.50)	0.0 (0.0)	52.0 (11.31)	33.0 (22.16)

[1] No data is available

No statistical analysis provided for Patient's Global Pain Intensity on a 0-100 mm Visual Analog Scale (VAS) up to Day 7 During All Gout Flares for Each Canakinumab Treatment Arm as Compared to Colchicine

6. Secondary: Patient's Global Pain Intensity on 5-point Likert Scale up to Day 7 During All Gout Flares for Each Canakinumab Treatment Arm as Compared to Colchicine [Time Frame: up to 16 weeks after randomization]

Measure Type	Secondary
Measure Title	Patient's Global Pain Intensity on 5-point Likert Scale up to Day 7 During All Gout Flares for Each Canakinumab Treatment Arm as Compared to Colchicine
Measure Description	Participants were handed out a diary at baseline (Visit 2), Day 15 (Visit 3), Day 29 (Visit 4), Day 57 (Visit 5), Day 85 (Visit 6), Day 113 (Visit 7), and Day 141 (Visit 8) to record information on a daily basis during a gout flare. The patients were to score their current amount of acute gout pain in the joint on a 5-point Likert scale 1=None, 2=Mild, 3=Moderate, 4=Severe, 5=Extreme. • on the day of onset of the gout flare and • in the morning of the 6 following days
Time Frame	up to 16 weeks after randomization
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 Full Analysis Set (FAS) consisted of all patients as randomized that had at least one post-baseline assessment of the primary efficacy variable. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab 25 mg	Canakinumab 25 mg subcutaneously (s.c.) once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 50 mg	Canakinumab 50 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 100 mg	Canakinumab 100 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 200 mg	Canakinumab 200 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 300 mg	Canakinumab 300 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab q4wk	Canakinumab 50 mg s.c. at Days 1, and 29 followed by canakinumab 25 mg s.c. on Days 57, and 85 plus daily placebo capsules for 16 weeks, repeated every 4 week (q4wk). Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Colchicine 0.5 mg	Colchicine 0.5 mg capsule orally once daily throughout the whole treatment phase of 16 weeks plus placebo matching canakinumab s.c. at Days 1, 29, 57, and 85. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.

Measured Values

	Canakinumab 25 mg	Canakinumab 50 mg	Canakinumab 100 mg	Canakinumab 200 mg	Canakinumab 300 mg	Canakinumab q4wk	Colchicine 0.5 mg
Number of Participants Analyzed [units: participants]	55	54	54	54	53	54	108
Patient's Global Pain Intensity on 5-point Likert Scale up to Day 7 During All Gout Flares for Each Canakinumab Treatment Arm as Compared to Colchicine [units: Units on a scale] Mean (Standard Deviation)							
Day 1: (n= 15, 8, 8, 9, 8, 9, 48)	2.8 (0.88)	3.1 (0.65)	3.5 (1.20)	3.2 (0.92)	3.1 (0.35)	3.8 (0.60)	3.2 (0.77)
Day 2: (n = 12, 6, 6, 5, 5, 7, 44)	2.9 (0.92)	2.6 (1.02)	3.3 (1.51)	2.2 (1.10)	2.9 (0.74)	3.5 (1.05)	3.0 (0.86)
Day 3: (n = 10, 4, 4, 4, 4, 6, 38)	2.4 (0.73)	3.1 (0.63)	2.3 (0.96)	3.0 (1.15)	2.3 (0.50)	3.4 (1.07)	2.7 (0.76)
Day 4: (n = 7, 3, 2, 3, 3, 7, 31)	2.6 (0.57)	2.7 (0.58)	1.5 (0.71)	3.0 (1.00)	1.7 (0.58)	3.2 (1.08)	2.4 (0.90)
Day 5: (n = 7, 2, 1, 3, 2, 4,	2.2 (0.69)	2.5 (0.71)	1.0 (0)	3.2 (1.76)	1.5 (0.71)	2.7 (1.28)	2.6

22)							(0.95)
Day 6: (n = 6, 1, 1, 2, 2, 3, 18)	2.4 (0.49)	3.0 (0.0)	1.0 (0.0)	3.5 (2.12)	1.5 (0.71)	2.9 (0.84)	2.5 (1.05)
Day 7: (n = 6, 0, 1, 2, 1, 2, 16)	2.4 (0.49)	0.0 (0.0)	1.0 (0.0)	2.5 (2.12)	1.0 (0.0)	3.3 (0.47)	2.4 (0.81)

No statistical analysis provided for Patient's Global Pain Intensity on 5-point Likert Scale up to Day 7 During All Gout Flares for Each Canakinumab Treatment Arm as Compared to Colchicine

7. Secondary: Physician’s Global Assessment of Response to Therapy on a 5-point Likert Scale for Each Canakinumab Treatment Arm as Compared to Colchicine [Time Frame: At Day 15, Day 29, Day 57, Day 85, Day 113 and Day 141]

Measure Type	Secondary
Measure Title	Physician’s Global Assessment of Response to Therapy on a 5-point Likert Scale for Each Canakinumab Treatment Arm as Compared to Colchicine
Measure Description	To evaluate the efficacy of canakinumab as compared to colchicine with regards to the Physician’s global assessment of response to therapy on a 5-point Likert scale up to 16 weeks after randomization. The study physician made a global assessment of the patient’s response to treatment using a 5-point Likert scale: Very good, Good, Fair, Poor, Very poor. Physician’s global assessment was performed at the visits like Day 15 (Visit 3), Day 29 (Visit 4), Day 57 (Visit 5), Day 85 (Visit 6), Day 113 (Visit 7), and Day 141 (Visit 8). The category ‘Not assessed’ combines the missing and 'not done'.
Time Frame	At Day 15, Day 29, Day 57, Day 85, Day 113 and Day 141
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 Full Analysis Set (FAS) consisted of all patients as randomized that had at least one post-baseline assessment of the primary efficacy variable. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab 25 mg	Canakinumab 25 mg subcutaneously (s.c.) once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 50 mg	Canakinumab 50 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 100 mg	Canakinumab 100 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 200 mg	Canakinumab 200 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 300 mg	Canakinumab 300 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab q4wk	Canakinumab 50 mg s.c. at Days 1, and 29 followed by canakinumab 25 mg s.c. on Days 57, and 85 plus daily placebo capsules for 16 weeks, repeated every 4 week (q4wk). Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.

Colchicine 0.5 mg	Colchicine 0.5 mg capsule orally once daily throughout the whole treatment phase of 16 weeks plus placebo matching canakinumab s.c. at Days 1, 29, 57, and 85. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.

Measured Values

	Canakinumab 25 mg	Canakinumab 50 mg	Canakinumab 100 mg	Canakinumab 200 mg	Canakinumab 300 mg	Canakinumab q4wk	Colchicine 0.5 mg
Number of Participants Analyzed [units: participants]	55	54	54	54	53	54	108
Physician's Global Assessment of Response to Therapy on a 5-point Likert Scale for Each Canakinumab Treatment Arm as Compared to Colchicine [units: Participants]							
Day 15: Very good	19	23	24	23	27	25	40
- Good	28	24	23	26	21	20	42
- Fair	5	4	3	4	0	3	16
- Poor	0	0	2	0	3	4	6
- Very poor	0	1	0	0	0	0	2
- Not assessed	3	1	1	1	1	2	2
Day 29: Very good	26	24	25	24	27	27	39
- Good	23	22	22	26	23	22	42
- Fair	2	4	5	3	2	2	19
- Poor	0	0	1	0	0	2	2
- Very poor	0	1	0	0	0	0	1
- Not assessed	0	3	0	0	0	1	3
Day 57: Very good	25	27	28	27	30	28	46
- Good	21	20	16	21	18	20	43
- Fair	5	3	6	4	4	3	9
- Poor	0	0	2	0	0	2	3
- Very poor	0	1	0	0	0	0	1
- Not assessed	0	2	1	0	0	1	4
Day 85: Very good	27	31	32	32	31	29	43
- Good	20	17	15	16	17	17	41
- Fair	3	2	5	4	2	3	12
- Poor	0	0	1	0	1	2	2
- Very poor	0	0	0	0	0	1	0
- Not assessed	1	2	0	0	1	1	5
Day 113 : Very good	24	29	30	26	29	32	50
- Good	18	18	18	20	20	15	36
- Fair	5	3	2	3	1	3	7
- Poor	2	0	1	1	1	2	2
- Very poor	0	0	0	0	0	0	1

- Not Assessed	0	2	0	0	0	2	8
Day 141 : Very good	26	25	24	31	32	32	41
- Good	16	20	19	12	14	14	36
- Fair	6	2	3	6	2	3	16
- Poor	1	1	3	0	0	2	2
- Very poor	0	0	0	1	1	1	0
- Not Assessed	0	3	1	0	1	1	5

No statistical analysis provided for Physician's Global Assessment of Response to Therapy on a 5-point Likert Scale for Each Canakinumab Treatment Arm as Compared to Colchicine

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	End of the study (EOS)
Additional Description	Safety Population

Reporting Groups

	Description
Canakinumab 25mg	Canakinumab 25 mg subcutaneously (s.c.) once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 50mg	Canakinumab 50 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 100mg	Canakinumab 100 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 200mg	Canakinumab 200 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 300mg	Canakinumab 300 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg-300 mg) for 24 weeks.
Canakinumab q4wk	Canakinumab 50 mg s.c. at Days 1, and 29 followed by canakinumab 25 mg s.c. on Days 57, and 85 plus daily placebo capsules for 16 weeks, repeated every 4 week (q4wk). Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Colchicine 0.5 mg	Colchicine 0.5 mg capsule orally once daily throughout the whole treatment phase of 16 weeks plus placebo matching canakinumab s.c. at Days 1, 29, 57, and 85. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.

Serious Adverse Events

	Canakinumab 25mg	Canakinumab 50mg	Canakinumab 100mg	Canakinumab 200mg	Canakinumab 300mg	Canakinumab q4wk	Colchicine 0.5 mg
Total, serious adverse events							

# participants affected / at risk	2/55 (3.64%)	2/54 (3.70%)	3/54 (5.56%)	3/54 (5.56%)	3/53 (5.66%)	1/53 (1.89%)	6/108 (5.56%)
Cardiac disorders							
Acute myocardial infarction † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	1/54 (1.85%)	0/53 (0.00%)	0/53 (0.00%)	0/108 (0.00%)
Angina pectoris † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/53 (0.00%)	0/53 (0.00%)	1/108 (0.93%)
Myocardial infarction † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/53 (0.00%)	0/53 (0.00%)	1/108 (0.93%)
Gastrointestinal disorders							
Abdominal pain † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/53 (0.00%)	0/53 (0.00%)	1/108 (0.93%)
Colitis ulcerative † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	1/53 (1.89%)	0/53 (0.00%)	0/108 (0.00%)
Gastritis † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	1/54 (1.85%)	0/53 (0.00%)	0/53 (0.00%)	0/108 (0.00%)
Haemorrhoidal haemorrhage † 1							
# participants affected / at risk	0/55 (0.00%)	1/54 (1.85%)	0/54 (0.00%)	0/54 (0.00%)	0/53 (0.00%)	0/53 (0.00%)	0/108 (0.00%)
Umbilical hernia † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/53 (0.00%)	0/53 (0.00%)	1/108 (0.93%)
Hepatobiliary disorders							
Cholelithiasis † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/53 (0.00%)	0/53 (0.00%)	1/108 (0.93%)
Infections and infestations							
Ear infection † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/53 (0.00%)	1/53 (1.89%)	0/108 (0.00%)
Erysipelas † 1							
# participants affected / at risk	1/55 (1.82%)	0/54 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/53 (0.00%)	0/53 (0.00%)	0/108 (0.00%)
Gangrene † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	1/54 (1.85%)	0/53 (0.00%)	0/53 (0.00%)	0/108 (0.00%)
Pneumonia † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/53 (0.00%)	1/53 (1.89%)	0/108 (0.00%)
Sepsis † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	1/54 (1.85%)	0/53 (0.00%)	0/53 (0.00%)	0/108 (0.00%)
Tonsillitis † 1							

# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	1/54 (1.85%)	0/53 (0.00%)	0/53 (0.00%)	0/108 (0.00%)
Injury, poisoning and procedural complications							
Femur fracture † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/53 (0.00%)	0/53 (0.00%)	1/108 (0.93%)
Hand fracture † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/53 (0.00%)	0/53 (0.00%)	1/108 (0.93%)
Ligament rupture † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	1/53 (1.89%)	0/53 (0.00%)	0/108 (0.00%)
Radius fracture † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/53 (0.00%)	0/53 (0.00%)	1/108 (0.93%)
Tibia fracture † 1							
# participants affected / at risk	1/55 (1.82%)	0/54 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/53 (0.00%)	0/53 (0.00%)	0/108 (0.00%)
Ulna fracture † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/53 (0.00%)	0/53 (0.00%)	1/108 (0.93%)
Musculoskeletal and connective tissue disorders							
Osteoarthritis † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	1/54 (1.85%)	0/54 (0.00%)	0/53 (0.00%)	0/53 (0.00%)	0/108 (0.00%)
Tendonitis † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/53 (0.00%)	0/53 (0.00%)	1/108 (0.93%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Prostate cancer † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	1/53 (1.89%)	0/53 (0.00%)	0/108 (0.00%)
Renal cancer † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/53 (0.00%)	0/53 (0.00%)	1/108 (0.93%)
Nervous system disorders							
Stupor † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	1/54 (1.85%)	0/54 (0.00%)	0/53 (0.00%)	0/53 (0.00%)	0/108 (0.00%)
Renal and urinary disorders							
Haematuria † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	1/54 (1.85%)	1/54 (1.85%)	0/53 (0.00%)	0/53 (0.00%)	0/108 (0.00%)
Nephrolithiasis † 1							
# participants affected / at risk	0/55 (0.00%)	1/54 (1.85%)	0/54 (0.00%)	0/54 (0.00%)	0/53 (0.00%)	0/53 (0.00%)	0/108 (0.00%)
Nephrotic syndrome † 1							

# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	1/54 (1.85%)	0/53 (0.00%)	0/53 (0.00%)	0/108 (0.00%)
Renal failure † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	1/54 (1.85%)	0/53 (0.00%)	0/53 (0.00%)	0/108 (0.00%)

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	End of the study (EOS)
Additional Description	Safety Population

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Canakinumab 25mg	Canakinumab 25 mg subcutaneously (s.c.) once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 50mg	Canakinumab 50 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 100mg	Canakinumab 100 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 200mg	Canakinumab 200 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Canakinumab 300mg	Canakinumab 300 mg s.c. once at Day 1, placebo s.c. at Days 29, 57, and 85 plus daily placebo capsules for 16 weeks. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg-300 mg) for 24 weeks.
Canakinumab q4wk	Canakinumab 50 mg s.c. at Days 1, and 29 followed by canakinumab 25 mg s.c. on Days 57, and 85 plus daily placebo capsules for 16 weeks, repeated every 4 week (q4wk). Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.
Colchicine 0.5 mg	Colchicine 0.5 mg capsule orally once daily throughout the whole treatment phase of 16 weeks plus placebo matching canakinumab s.c. at Days 1, 29, 57, and 85. Allopurinol treatment was initiated at the latest at baseline (Visit 2) according to the patient's renal function / estimated creatinine clearance at screening (Visit 1). Allopurinol was administered orally to all randomized patients once daily (100 mg- 300 mg) for 24 weeks.

Other Adverse Events

	Canakinumab 25mg	Canakinumab 50mg	Canakinumab 100mg	Canakinumab 200mg	Canakinumab 300mg	Canakinumab q4wk	Colchicine 0.5 mg
Total, other (not including serious) adverse events							

# participants affected / at risk	21/55 (38.18%)	15/54 (27.78%)	13/54 (24.07%)	13/54 (24.07%)	14/53 (26.42%)	14/53 (26.42%)	21/108 (19.44%)
Gastrointestinal disorders							
Diarrhoea † 1							
# participants affected / at risk	3/55 (5.45%)	1/54 (1.85%)	2/54 (3.70%)	3/54 (5.56%)	1/53 (1.89%)	0/53 (0.00%)	2/108 (1.85%)
Nausea † 1							
# participants affected / at risk	2/55 (3.64%)	1/54 (1.85%)	3/54 (5.56%)	0/54 (0.00%)	0/53 (0.00%)	1/53 (1.89%)	1/108 (0.93%)
Infections and infestations							
Nasopharyngitis † 1							
# participants affected / at risk	5/55 (9.09%)	2/54 (3.70%)	2/54 (3.70%)	0/54 (0.00%)	0/53 (0.00%)	3/53 (5.66%)	1/108 (0.93%)
Upper respiratory tract infection † 1							
# participants affected / at risk	2/55 (3.64%)	1/54 (1.85%)	2/54 (3.70%)	3/54 (5.56%)	1/53 (1.89%)	3/53 (5.66%)	4/108 (3.70%)
Investigations							
Alanine aminotransferase increased † 1							
# participants affected / at risk	3/55 (5.45%)	1/54 (1.85%)	0/54 (0.00%)	1/54 (1.85%)	0/53 (0.00%)	0/53 (0.00%)	1/108 (0.93%)
Aspartate aminotransferase increased † 1							
# participants affected / at risk	3/55 (5.45%)	1/54 (1.85%)	0/54 (0.00%)	1/54 (1.85%)	0/53 (0.00%)	0/53 (0.00%)	1/108 (0.93%)
Musculoskeletal and connective tissue disorders							
Arthralgia † 1							
# participants affected / at risk	4/55 (7.27%)	5/54 (9.26%)	4/54 (7.41%)	2/54 (3.70%)	3/53 (5.66%)	2/53 (3.77%)	3/108 (2.78%)
Back pain † 1							
# participants affected / at risk	3/55 (5.45%)	3/54 (5.56%)	1/54 (1.85%)	3/54 (5.56%)	0/53 (0.00%)	0/53 (0.00%)	4/108 (3.70%)
Nervous system disorders							
Headache † 1							
# participants affected / at risk	4/55 (7.27%)	3/54 (5.56%)	1/54 (1.85%)	2/54 (3.70%)	6/53 (11.32%)	3/53 (5.66%)	6/108 (5.56%)
Respiratory, thoracic and mediastinal disorders							

Sinus congestion † 1							
# participants affected / at risk	0/55 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	0/54 (0.00%)	3/53 (5.66%)	0/53 (0.00%)	1/108 (0.93%)
Skin and subcutaneous tissue disorders							
Rash † 1							
# participants affected / at risk	1/55 (1.82%)	1/54 (1.85%)	0/54 (0.00%)	0/54 (0.00%)	0/53 (0.00%)	3/53 (5.66%)	1/108 (0.93%)
Vascular disorders							
Hypertension † 1							
# participants affected / at risk	6/55 (10.91%)	2/54 (3.70%)	2/54 (3.70%)	5/54 (9.26%)	4/53 (7.55%)	2/53 (3.77%)	1/108 (0.93%)

† 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

Responsible Party:	External Affairs, Novartis Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00819585 History of Changes
Other Study ID Numbers:	**CACZ885H2251** EudraCT : 2008-005876-28
Study First Received:	January 8, 2009
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Health Authority:	Argentina: Ministry of Health Belgium: Federal Agency for Medicinal Products and Health Products Colombia: National Institutes of Health Czech Republic: State Institute for Drug Control Finland: Finnish Medicines Agency Germany: Federal Institute for Drugs and Medical Devices Guatemala: Ministry of Health Hungary: National Institute of Pharmacy Portugal: National Pharmacy and Medicines Institute Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Russia: Pharmacological Committee, Ministry of Health Singapore: Health Sciences Authority Slovakia: State Institute for Drug Control South Africa: Medicines Control Council Spain: Spanish Agency of Medicines Taiwan: Department of Health Turkey: Ministry of Health United Kingdom: Medicines and Healthcare Products Regulatory Agency United States: Food and Drug Administration