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Trial record **2 of 2** for: CACZ885H2361

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Safety and Efficacy of Canakinumab Prefilled Syringes in Frequently Flaring Acute Gouty Arthritis Patients

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01356602

First received: May 16, 2011
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History of Changes

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Results First Received: September 6, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Acute Gouty Arthritis
Interventions:	Drug: Canakinumab pre-filled syringe Drug: Canakinumab lyophilized powder Drug: Triamcinolone Acetonide Drug: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

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

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Number of subjects randomized was 397. Only 389 subjects (including one subject with 3 placebo injections) received study drug (Safety set). Subjects who received more than one active dose were counted in each treatment group, leading to a safety set of 399 subjects. Subjects who did not receive study drug were excluded from analysis.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.

Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Participant Flow: Overall Study

	Canakinumab, Pre-filled Syringes (PFS)	Canakinumab, Lyophilizate (LYO)	Triamcinolone Acetonide
STARTED	133	132	132
Safety Set	133 [1]	133 [2]	133 [2]
Full Analysis Set	131	129	129
COMPLETED	124	117	108
NOT COMPLETED	9	15	24
Protocol Deviation	0	1	1
Administrative Problems	1	4	5
Lost to Follow-up	4	5	6
Withdrawal by Subject	4	3	7
Lack of Efficacy	0	1	4
Adverse Event	0	1	1

[1] In this arm, 1 patient had only 3 placebo injections and 3 patients also took other active drug.
[2] In this arm, 3 patients also took other active 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, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.
Total	Total of all reporting groups

Baseline Measures

	Canakinumab, Pre-filled Syringes (PFS)	Canakinumab, Lyophilizate (LYO)	Triamcinolone Acetonide	Total
Number of Participants [units: participants]	133	133	133	399
Age [units: Years] Mean (Standard	53.4 (11.21)	53 (11.84)	53.7 (11.33)	53.5 (11.44)

Deviation)				
Gender [units: Participants]				
Female	**15**	**9**	**11**	**35**
Male	**118**	**124**	**122**	**364**

Outcome Measures

Hide All Outcome Measures

1. Primary: Pain Intensity on a 0-100 mm Visual Analog Scale (VAS) Between the Canakinumab 150 mg PFS and Triamcinolone Acetonide 40 mg Groups [Time Frame: 72 hours post dose]

Measure Type	Primary
Measure Title	Pain Intensity on a 0-100 mm Visual Analog Scale (VAS) Between the Canakinumab 150 mg PFS and Triamcinolone Acetonide 40 mg Groups
Measure Description	The Visual Analog Scale (VAS) is an instrument used to measure a person's subjective quantitative evaluation of an item such as pain intensity. The VAS contains a continuous line between two end points whereby the respondent places a mark on the line to indicate his or her response. In this study, patients scored their pain intensity in the most affected joint of the gout flare on a 0 100 mm VAS. The scale ranged from 0 (no pain) to 100 (unbearable pain). The scores were measured to the nearest millimeter from the left. Missing pain intensity data at 72 hours was imputed using the Last-Observation-Carried-Forward (LOCF) method.
Time Frame	72 hours post dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set: The Full Analysis Set (FAS) consisted of all patients as randomized that had at least one dose of study drug. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Measured Values

	Canakinumab, Pre-filled Syringes (PFS)	**Canakinumab, Lyophilizate (LYO)**	**Triamcinolone Acetonide**
Number of Participants Analyzed [units: participants]	**130**	**0**	**126**
Pain Intensity on a 0-100 mm Visual Analog Scale (VAS) Between the Canakinumab 150 mg PFS and Triamcinolone Acetonide 40 mg Groups [units: Millimeters] Least Squares Mean (Standard Error)	**17.1 (2.04)**		**32 (2.08)**

No statistical analysis provided for Pain Intensity on a 0-100 mm Visual Analog Scale (VAS) Between the Canakinumab 150 mg PFS and Triamcinolone Acetonide 40 mg Groups

2. Secondary: Pain Intensity on a 0 - 100 mm VAS Between the Canakinumab 150 mg PFS and Canakinumab 150 mg LYO Groups [Time Frame: 72 hours post dose]

Measure Type	Secondary
Measure Title	Pain Intensity on a 0 - 100 mm VAS Between the Canakinumab 150 mg PFS and Canakinumab 150 mg LYO Groups
Measure Description	The Visual Analog Scale (VAS) is an instrument used to measure a person's subjective quantitative evaluation of an item such as pain intensity. The VAS contains a continuous line between two end points whereby the respondent places a mark on the line to indicate his or her response. In this study, patients scored their pain intensity in the most affected joint of the gout flare on a 0 100 mm VAS. The scale ranged from 0 (no pain) to 100 (unbearable pain). The scores were measured to the nearest millimeter from the left. Missing pain intensity data at 72 hours was imputed using the Last-Observation-Carried-Forward (LOCF) method.
Time Frame	72 hours post dose
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set: The Full Analysis Set (FAS) consisted of all patients as randomized that had at least one dose of study drug. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Measured Values

	Canakinumab, Pre-filled Syringes (PFS)	**Canakinumab, Lyophilizate (LYO)**	**Triamcinolone Acetonide**
Number of Participants Analyzed [units: participants]	**130**	**129**	**0**
Pain Intensity on a 0 - 100 mm VAS Between the Canakinumab 150 mg PFS and Canakinumab 150 mg LYO Groups [units: Millimeters] Least Squares Mean (Standard Error)	**17.1 (2.04)**	**19.7 (2.05)**	

No statistical analysis provided for Pain Intensity on a 0 - 100 mm VAS Between the Canakinumab 150 mg PFS and Canakinumab 150 mg LYO Groups

3. Secondary: Patient's Assessment of Pain Intensity on a 0-100mm VAS [Time Frame: 14 days]

Measure Type	Secondary

Measure Title	Patient's Assessment of Pain Intensity on a 0-100mm VAS
Measure Description	The Visual Analog Scale (VAS) is an instrument used to measure a person's subjective quantitative evaluation of an item such as pain intensity. The VAS contains a continuous line between two end points whereby the respondent places a mark on the line to indicate his or her response. In this study, patients scored their pain intensity in the most affected joint of the gout flare on a 0 100 mm VAS. The scale ranged from 0 (no pain) to 100 (unbearable pain). The scores were measured to the nearest millimeter from the left. The LOCF method was used to impute post-dose pain intensity VAS measurements up to 14 days.
Time Frame	14 days
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set: The Full Analysis Set (FAS) consisted of all patients as randomized that had at least one dose of study drug. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Measured Values

	Canakinumab, Pre-filled Syringes (PFS)	**Canakinumab, Lyophilizate (LYO)**	**Triamcinolone Acetonide**
Number of Participants Analyzed [units: participants]	**130**	**129**	**126**
Patient's Assessment of Pain Intensity on a 0-100mm VAS [units: Millimeters] Least Squares Mean (Standard Error)	**7.9 (1.69)**	**8.2 (1.7)**	**14.8 (1.72)**

No statistical analysis provided for Patient's Assessment of Pain Intensity on a 0-100mm VAS

4. Secondary: Patient's Assessment of Pain Intensity on a 5-point Likert Scale [Time Frame: 72 hours]

Measure Type	Secondary
Measure Title	Patient's Assessment of Pain Intensity on a 5-point Likert Scale
Measure Description	A Likert scale is a type of scale with a range of responses corresponding to an item such as pain. The respondent selects the best response that indicates the respondent's subjective evaluation of the item. Patients scored their pain intensity in the most affected joint of the gout flare on a 5-point Likert scale (none, mild, moderate, severe, extreme). The scores were measured to the nearest millimeter from the left. The LOCF method was used to impute post-dose pain intensity Likert measurements up to 14 days.
Time Frame	72 hours
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set: The Full Analysis Set (FAS) consisted of all patients as randomized that had at least one dose of study drug. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Measured Values

	Canakinumab, Pre-filled Syringes (PFS)	**Canakinumab, Lyophilizate (LYO)**	**Triamcinolone Acetonide**
Number of Participants Analyzed [units: participants]	**131**	**129**	**128**
Patient's Assessment of Pain Intensity on a 5-point Likert Scale [units: Percentage of Patients]			
None	**35.9**	**32.6**	**23.4**
Mild	**45.8**	**44.2**	**36.7**
Moderate	**15.3**	**21.7**	**21.9**
Severe	**2.3**	**1.6**	**14.1**
Extreme	**0.8**	**0**	**3.9**

No statistical analysis provided for Patient's Assessment of Pain Intensity on a 5-point Likert Scale

5. Secondary: Number of Patients With at Least One New Gouty Arthritis Flare After Baseline [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Number of Patients With at Least One New Gouty Arthritis Flare After Baseline
Measure Description	Patients met the definition of a new flare if they had: a flare in a joint, which was not a previously affected joint (at baseline or during the study), or a flare in a joint previously affected (at baseline or during the study) after the previous flare in that joint had resolved completely according to the patient’s perception. Patients did NOT meet the criterion of having a new gout flare if they had increasing/renewed gout pain in an affected joint before the flare had resolved completely.
Time Frame	12 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.
Full Analysis Set: The Full Analysis Set (FAS) consisted of all patients as randomized that had at least one dose of study drug. Following the

intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Measured Values

	Canakinumab, Pre-filled Syringes (PFS)	Canakinumab, Lyophilizate (LYO)	Triamcinolone Acetonide
Number of Participants Analyzed [units: participants]	**131**	**129**	**129**
Number of Patients With at Least One New Gouty Arthritis Flare After Baseline [units: Particpants]	**12**	**12**	**52**

No statistical analysis provided for Number of Patients With at Least One New Gouty Arthritis Flare After Baseline

6. Secondary: Time to the First New Gouty Arthritis Flare [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Time to the First New Gouty Arthritis Flare
Measure Description	Patients met the definition of a new flare if they had: a flare in a joint, which was not a previously affected joint (at baseline or during the study), or a flare in a joint previously affected (at baseline or during the study) after the previous flare in that joint had resolved completely according to the patient's perception. Patients did NOT meet the criterion of having a new gout flare if they had increasing/renewed gout pain in an affected joint before the flare had resolved completely. Less than 50% of patients had new flares. Therefore, the median time to new flare could not be calculated.
Time Frame	12 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.

Full Analysis Set: The Full Analysis Set (FAS) consisted of all patients as randomized that had at least one dose of study drug. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare.

	The patients were given 3 injections: two placebo and one active drug.

Measured Values

	Canakinumab, Pre-filled Syringes (PFS)	Canakinumab, Lyophilizate (LYO)	Triamcinolone Acetonide
Number of Participants Analyzed [units: participants]	**131**	**129**	**129**
Time to the First New Gouty Arthritis Flare [units: Days] Median (95% Confidence Interval)	**NA** [1]	**NA** [1]	**NA** [1]

[1] Less than 50% of patients had new flares. Therefore, the median time to new flare could not be calculated.

No statistical analysis provided for Time to the First New Gouty Arthritis Flare

7. Secondary: Time to 50% Reduction in Baseline Pain on a 0 - 100 VAS [Time Frame: 14 days]

Measure Type	Secondary
Measure Title	Time to 50% Reduction in Baseline Pain on a 0 - 100 VAS
Measure Description	The Visual Analog Scale (VAS) is an instrument used to measure a person's subjective quantitative evaluation of an item such as pain intensity. The VAS contains a continuous line between two end points whereby the respondent places a mark on the line to indicate his or her response. In this study, patients scored their pain intensity in the most affected joint of the gout flare on a 0 100 mm VAS. The scale ranged from 0 (no pain) to 100 (unbearable pain). The scores were measured to the nearest millimeter from the left. Kaplan Meier estimate of time to 50% reduction in baseline pain, along with associated 95% confidence interval, were reported.
Time Frame	14 days
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set: The Full Analysis Set (FAS) consisted of all patients as randomized that had at least one dose of study drug. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Measured Values

	Canakinumab, Pre-filled Syringes (PFS)	Canakinumab, Lyophilizate (LYO)	Triamcinolone Acetonide
Number of Participants Analyzed [units: participants]	**130**	**129**	**129**
Time to 50% Reduction in Baseline Pain on a 0 -			

100 VAS [units: Hours] Median (95% Confidence Interval)	**24 (22 to 25)**	**25 (24 to 48)**	**48 (25 to 54)**

No statistical analysis provided for Time to 50% Reduction in Baseline Pain on a 0 - 100 VAS

8. Secondary: Time to Resolution of Gouty Arthritis Flare as Reported by Patient [Time Frame: 14 days]

Measure Type	Secondary
Measure Title	Time to Resolution of Gouty Arthritis Flare as Reported by Patient
Measure Description	Patients completed diary entries at 6, 12, 24, 48 and 72 hours post dose and then daily up to 7 days post-dose and/or daily until resolution of the flare. Kaplan Meier estimate of time to resolution of gouty flare as reported by patient, along with associated 95% confiedence interval, were reported.
Time Frame	14 days
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set: The Full Analysis Set (FAS) consisted of all patients as randomized that had at least one dose of study drug. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Measured Values

	Canakinumab, Pre-filled Syringes (PFS)	**Canakinumab, Lyophilizate (LYO)**	**Triamcinolone Acetonide**
Number of Participants Analyzed [units: participants]	**131**	**128**	**129**
Time to Resolution of Gouty Arthritis Flare as Reported by Patient [units: Hours] Median (95% Confidence Interval)	**142 (96 to 168)**	**120 (96 to 145)**	**170 (144 to 216)**

No statistical analysis provided for Time to Resolution of Gouty Arthritis Flare as Reported by Patient

9. Secondary: Patient's Global Assessment of Response to Treatment on a 5-point Likert Scale [Time Frame: 72 hours]

Measure Type	Secondary
Measure Title	Patient's Global Assessment of Response to Treatment on a 5-point Likert Scale

Measure Description	A Likert scale is a type of scale with a range of responses corresponding to an item such as pain. The respondent selects the best response that indicates the respondent's subjective evaluation of the item. Patients scored their response to treatment on a 5-point Likert scale (excellent, good, acceptable, slight, poor). This outcome measure shows the number of patients indicating each score on the scale.
Time Frame	72 hours
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set: The Full Analysis Set (FAS) consisted of all patients as randomized that had at least one dose of study drug. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Measured Values

	Canakinumab, Pre-filled Syringes (PFS)	**Canakinumab, Lyophilizate (LYO)**	**Triamcinolone Acetonide**
Number of Participants Analyzed [units: participants]	**131**	**129**	**129**
Patient's Global Assessment of Response to Treatment on a 5-point Likert Scale [units: Percentage of Participants]			
Excellent	**36.0**	**34.8**	**20.4**
Good	**43.2**	**36.5**	**31.9**
Acceptable	**10.4**	**20.0**	**21.2**
Slight	**6.4**	**7.8**	**14.2**
Poor	**4.0**	**0.9**	**12.4**

No statistical analysis provided for Patient's Global Assessment of Response to Treatment on a 5-point Likert Scale

10. Secondary: Physician's Global Assessment of Response to Treatment on a 5 Point Likert Scale [Time Frame: 72 hours]

Measure Type	Secondary
Measure Title	Physician's Global Assessment of Response to Treatment on a 5 Point Likert Scale
Measure Description	A Likert scale is a type of scale with a range of responses corresponding to an item such as pain. The respondent selects the best response that indicates the respondent's subjective evaluation of the item. Study physicians scored their assessment of the patients' response to treatment on a 5-point Likert scale (very good, good, fair, poor, very poor).
Time Frame	72 hours

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set: The Full Analysis Set (FAS) consisted of all patients as randomized that had at least one dose of study drug. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Measured Values

	Canakinumab, Pre-filled Syringes (PFS)	**Canakinumab, Lyophilizate (LYO)**	**Triamcinolone Acetonide**
Number of Participants Analyzed [units: participants]	**131**	**129**	**129**
Physician's Global Assessment of Response to Treatment on a 5 Point Likert Scale [units: Percentage of Participants]			
Very good	**46.2**	**33.6**	**21.5**
Good	**35.4**	**48.8**	**33.9**
Fair	**15.4**	**16.0**	**23.1**
Poor	**1.5**	**1.6**	**14.0**
Very poor	**1.5**	**0.0**	**7.4**

No statistical analysis provided for Physician's Global Assessment of Response to Treatment on a 5 Point Likert Scale

11. Secondary: Physician's Assessment of Tenderness [Time Frame: 72 hours]

Measure Type	Secondary
Measure Title	Physician's Assessment of Tenderness
Measure Description	The study physician assessed the most affected joint for tenderness. Tenderness was measured on a 0 - 3 point scale as follows: 0 = no pain, 1 = patient states that “there is pain”, 2 = patient states “there is pain and winces” and 3 = patient states “there is pain, winces and withdraws” on palpation or passive movement of the affected study joint.
Time Frame	72 hours
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set: The Full Analysis Set (FAS) consisted of all patients as randomized that had at least one dose of study drug. Following the

intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Measured Values

	Canakinumab, Pre-filled Syringes (PFS)	Canakinumab, Lyophilizate (LYO)	Triamcinolone Acetonide
Number of Participants Analyzed [units: participants]	**131**	**129**	**129**
Physician's Assessment of Tenderness [units: Percentage of Participants]			
No pain	**50.0**	**40.0**	**29.8**
There is pain	**43.1**	**52.8**	**47.1**
There is pain and winces	**5.4**	**6.4**	**14.0**
There is pain, winces and withdraws	**1.5**	**0.8**	**9.1**

No statistical analysis provided for Physician's Assessment of Tenderness

12. Secondary: Physician's Assessment of Swelling [Time Frame: 72 hours]

Measure Type	Secondary
Measure Title	Physician's Assessment of Swelling
Measure Description	The study physician assessed the most affected joint for swelling. Swelling was measured on a 0 - 3 point scale as follows: 0 = no swelling, 1 = palpable, 2= visible and 3 = bulging beyond the joint margins.
Time Frame	72 hours
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set: The Full Analysis Set (FAS) consisted of all patients as randomized that had at least one dose of study drug. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.

Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Measured Values

	Canakinumab, Pre-filled Syringes (PFS)	Canakinumab, Lyophilizate (LYO)	Triamcinolone Acetonide
Number of Participants Analyzed [units: participants]	**131**	**129**	**129**
Physician's Assessment of Swelling [units: Percentage of Partipants]			
No swelling	**60.8**	**55.2**	**51.2**
Palpable	**26.9**	**25.6**	**15.7**
Visible	**10.8**	**17.6**	**24.8**
Bulging beyond the joint margins	**1.5**	**1.6**	**8.3**

No statistical analysis provided for Physician's Assessment of Swelling

13. Secondary: Physician's Assessment of Erythema [Time Frame: 72 hours]

Measure Type	Secondary
Measure Title	Physician's Assessment of Erythema
Measure Description	The study physician assessed the most affected joint for erythema. Erythema was assessed as present, absent or not assessable.
Time Frame	72 hours
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set: The Full Analysis Set (FAS) consisted of all patients as randomized that had at least one dose of study drug. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Measured Values

	Canakinumab, Pre-filled Syringes	Canakinumab, Lyophilizate	Triamcinolone

	(PFS)	(LYO)	Acetonide
Number of Participants Analyzed [units: participants]	**131**	**129**	**129**
Physician's Assessment of Erythema [units: Percentage of Participants]			
Absent	**88.3**	**82.9**	**68.6**
Present	**11.7**	**17.1**	**31.4**

No statistical analysis provided for Physician's Assessment of Erythema

14. Secondary: Physician's Assessment of Range of Motion of the Most Affected Joint [Time Frame: 72 hours]

Measure Type	Secondary
Measure Title	Physician's Assessment of Range of Motion of the Most Affected Joint
Measure Description	The study physician assessed the patient's range of motion of the most affected joint on a 5 point Likert scale (normal, mildly restricted, moderately restricted, severely restricted and immobilized).
Time Frame	72 hours
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set: The Full Analysis Set (FAS) consisted of all patients as randomized that had at least one dose of study drug. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Measured Values

	Canakinumab, Pre-filled Syringes (PFS)	Canakinumab, Lyophilizate (LYO)	Triamcinolone Acetonide
Number of Participants Analyzed [units: participants]	**131**	**129**	**129**
Physician's Assessment of Range of Motion of the Most Affected Joint [units: Percentage of Participants]			
Normal	**50.0**	**44.8**	**35.5**
Mildly restricted	**37.7**	**40.8**	**37.2**
Moderately restricted	**11.5**	**12.0**	**14.0**

Severely restricted	**0.8**	**2.4**	**12.4**
Immobilized	**0.0**	**0.0**	**0.8**

No statistical analysis provided for Physician's Assessment of Range of Motion of the Most Affected Joint

15. Secondary: Proportion of Patients With Rescue Medication Intake [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Proportion of Patients With Rescue Medication Intake
Measure Description	Patients used a diary to record the time of intake of rescue medication and the amount taken.
Time Frame	12 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.
Full Analysis Set: The Full Analysis Set (FAS) consisted of all patients as randomized that had at least one dose of study drug. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Measured Values

	Canakinumab, Pre-filled Syringes (PFS)	**Canakinumab, Lyophilizate (LYO)**	**Triamcinolone Acetonide**
Number of Participants Analyzed [units: participants]	**131**	**129**	**129**
Proportion of Patients With Rescue Medication Intake [units: Percentage of Particpants]	**29.0**	**31.8**	**45.7**

No statistical analysis provided for Proportion of Patients With Rescue Medication Intake

16. Secondary: Time to First Rescue Medication Intake [Time Frame: 14 days]

Measure Type	Secondary
Measure Title	Time to First Rescue Medication Intake
Measure Description	Patients used a diary to record the time of intake of rescue medication and the amount taken.
Time Frame	14 days

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set: The Full Analysis Set (FAS) consisted of all patients as randomized that had at least one dose of study drug. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Measured Values

	Canakinumab, Pre-filled Syringes (PFS)	**Canakinumab, Lyophilizate (LYO)**	**Triamcinolone Acetonide**
Number of Participants Analyzed [units: participants]	**38**	**40**	**59**
Time to First Rescue Medication Intake [units: Hours] Median (Full Range)	**11 (4 to 279)**	**7.5 (3 to 142)**	**11 (1 to 186)**

No statistical analysis provided for Time to First Rescue Medication Intake

17. Secondary: Amount of Rescue Medication Taken (mg) [Time Frame: 14 days]

Measure Type	Secondary
Measure Title	Amount of Rescue Medication Taken (mg)
Measure Description	Patients used a diary to record the time of intake of rescue medication and the amount taken.
Time Frame	14 days
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set: The Full Analysis Set (FAS) consisted of all patients as randomized that had at least one dose of study drug. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.

Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Measured Values

	Canakinumab, Pre-filled Syringes (PFS)	Canakinumab, Lyophilizate (LYO)	Triamcinolone Acetonide
Number of Participants Analyzed [units: participants]	**131**	**129**	**129**
Amount of Rescue Medication Taken (mg) [units: milligrams (mg)] Mean (Standard Deviation)			
Acetaminophen	**609.2 (1800.06)**	**1108.3 (2821.54)**	**2323.1 (5580.82)**
Codeine	**12.7 (55.30)**	**23.9 (124.56)**	**60.8 (191.2)**
Prednisolone / Prednisone	**5.8 (23.13)**	**6.7 (25.09)**	**24.7 (53.20)**

No statistical analysis provided for Amount of Rescue Medication Taken (mg)

18. Secondary: C-reactive Protein Level [Time Frame: 72 hours]

Measure Type	Secondary
Measure Title	C-reactive Protein Level
Measure Description	A central laboratory was used for analysis of all blood samples collected.
Time Frame	72 hours
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set: The Full Analysis Set (FAS) consisted of all patients as randomized that had at least one dose of study drug. Following the intent-to-treat principle, patients were analyzed according to the treatment they were assigned to at randomization.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Measured Values

	Canakinumab, Pre-filled Syringes (PFS)	Canakinumab, Lyophilizate (LYO)	Triamcinolone Acetonide

Number of Participants Analyzed [units: participants]	**123**	**119**	**118**
C-reactive Protein Level [units: mg / L] Least Squares Mean (95% Confidence Interval)	**3.65 (3.11 to 4.29)**	**3.37 (2.86 to 3.96)**	**5.2 (4.41 to 6.13)**

No statistical analysis provided for C-reactive Protein Level

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	12 weeks
Additional Description	Only 389 subjects (including one subject with 3 placebo injections) received study drug (Safety set). Subjects who received more than one active dose were counted in each treatment group, leading to an artificial safety set of 399 subjects.

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Serious Adverse Events

	Canakinumab, Pre-filled Syringes (PFS)	**Canakinumab, Lyophilizate (LYO)**	**Triamcinolone Acetonide**
Total, serious adverse events			
# participants affected / at risk	**6/133 (4.51%)**	**6/133 (4.51%)**	**5/133 (3.76%)**
Cardiac disorders			
Angina unstable † 1			
# participants affected / at risk	**0/133 (0.00%)**	**1/133 (0.75%)**	**0/133 (0.00%)**
Cardiac failure † 1			
# participants affected / at risk	**0/133 (0.00%)**	**1/133 (0.75%)**	**0/133 (0.00%)**
Coronary artery disease † 1			
# participants affected / at risk	**0/133 (0.00%)**	**1/133 (0.75%)**	**0/133 (0.00%)**
Myocardial infarction † 1			
# participants affected / at risk	**0/133 (0.00%)**	**0/133 (0.00%)**	**1/133 (0.75%)**
Gastrointestinal disorders			
Constipation † 1			
# participants affected / at risk	**0/133 (0.00%)**	**0/133 (0.00%)**	**1/133 (0.75%)**
General disorders			
Chest pain † 1			
# participants affected / at risk	**0/133 (0.00%)**	**0/133 (0.00%)**	**1/133 (0.75%)**

Drug ineffective † 1			
# participants affected / at risk	**0/133 (0.00%)**	**0/133 (0.00%)**	**1/133 (0.75%)**
Infections and infestations			
Respiratory tract infection viral † 1			
# participants affected / at risk	**0/133 (0.00%)**	**1/133 (0.75%)**	**0/133 (0.00%)**
Staphylococcal bacteraemia † 1			
# participants affected / at risk	**0/133 (0.00%)**	**1/133 (0.75%)**	**0/133 (0.00%)**
Viral infection † 1			
# participants affected / at risk	**1/133 (0.75%)**	**0/133 (0.00%)**	**0/133 (0.00%)**
Wound infection staphylococcal † 1			
# participants affected / at risk	**1/133 (0.75%)**	**0/133 (0.00%)**	**0/133 (0.00%)**
Injury, poisoning and procedural complications			
Muscle rupture † 1			
# participants affected / at risk	**1/133 (0.75%)**	**0/133 (0.00%)**	**0/133 (0.00%)**
Nervous system disorders			
Migraine † 1			
# participants affected / at risk	**1/133 (0.75%)**	**0/133 (0.00%)**	**0/133 (0.00%)**
Psychiatric disorders			
Delirium † 1			
# participants affected / at risk	**1/133 (0.75%)**	**0/133 (0.00%)**	**0/133 (0.00%)**
Depression † 1			
# participants affected / at risk	**0/133 (0.00%)**	**0/133 (0.00%)**	**1/133 (0.75%)**
Renal and urinary disorders			
Calculus ureteric † 1			
# participants affected / at risk	**1/133 (0.75%)**	**0/133 (0.00%)**	**0/133 (0.00%)**
Obstructive uropathy † 1			
# participants affected / at risk	**1/133 (0.75%)**	**0/133 (0.00%)**	**0/133 (0.00%)**
Respiratory, thoracic and mediastinal disorders			
Asthma † 1			
# participants affected / at risk	**0/133 (0.00%)**	**1/133 (0.75%)**	**0/133 (0.00%)**
Vascular disorders			
Aortitis † 1			
# participants affected / at risk	**0/133 (0.00%)**	**1/133 (0.75%)**	**0/133 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	12 weeks
Additional Description	Only 389 subjects (including one subject with 3 placebo injections) received study drug (Safety set). Subjects who received more than one active dose were counted in each treatment group, leading to an artificial safety set of 399

	subjects.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Canakinumab, Pre-filled Syringes (PFS)	Patients on this arm received 150 mg subcutaneously (s.c.) at randomization and upon new flare. The doses were provided as pre-filled syringes. The patients were given 3 injections: two placebo and one active drug.
Canakinumab, Lyophilizate (LYO)	The patients on this arm received 150 mg s.c. at randomization and upon new flare. The doses were provided as lyophilized power and had to be reconstituted with water for injection before application. The patients were given 3 injections: two placebo and one active drug.
Triamcinolone Acetonide	The patients on this arm received 40 mg intramuscular (i.m.) at randomization and upon new flare. The patients were given 3 injections: two placebo and one active drug.

Other Adverse Events

	Canakinumab, Pre-filled Syringes (PFS)	Canakinumab, Lyophilizate (LYO)	Triamcinolone Acetonide
Total, other (not including serious) adverse events			
# participants affected / at risk	**0/133 (0.00%)**	**0/133 (0.00%)**	**0/133 (0.00%)**

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:** Principal Investigators are NOT employed by the organization sponsoring the study. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of pooled data (i.e.,data from all sites) in clinical trial.

Results Point of Contact:

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

No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT01356602 History of Changes
Other Study ID Numbers:	**CACZ885H2361** 2010-024173-39 (EudraCT Number)
Study First Received:	May 16, 2011
Results First Received:	September 6, 2013
Last Updated:	December 10, 2013
Health Authority:	United States: Food and Drug Administration Belgium: Federal Agency for Medicinal Products and Health Products Canada: Health Canada Germany: Federal Institute for Drugs and Medical Devices Hungary: Institutional Ethics Committee Lithuania: State Medicine Control Agency - Ministry of Health