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Trial record **1 of 1** for: CACZ885A2212

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Efficacy and Safety of a Single Dose of Canakinumab (ACZ885) in Hospitalized Patients With Acute Gout

This study has been completed.

Sponsor:
Novartis

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT00663169

First received: April 18, 2008
Last updated: December 4, 2012
Last verified: December 2012
History of Changes

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Results First Received: August 30, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Arthritis, Gouty
Interventions:	Biological: canakinumab Drug: dexamethasone Other: placebo matching canakinumab Other: placebo matching dexamethasone

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	Canakinumab 10 mg/kg intravenous infusion and placebo matching dexamethasone intravenous infusion on Day 1.
Dexamethasone	Dexamethasone 12 mg intravenous infusion and placebo matching canakinumab on Day 1.

Participant Flow: Overall Study

	Canakinumab	Dexamethasone
STARTED	**3**	**3**

COMPLETED	**3**	**3**
NOT COMPLETED	**0**	**0**

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	Canakinumab 10 mg/kg intravenous infusion and placebo matching dexamethasone intravenous infusion on Day 1.
Dexamethasone	Dexamethasone 12 mg intravenous infusion and placebo matching canakinumab on Day 1.
Total	Total of all reporting groups

Baseline Measures

	Canakinumab	**Dexamethasone**	**Total**
Number of Participants [units: participants]	**3**	**3**	**6**
Age [units: years] Mean (Standard Deviation)	**46.7 (10.97)**	**46.0 (3.46)**	**46.3 (7.28)**
Gender [units: participants]			
Female	**0**	**1**	**1**
Male	**3**	**2**	**5**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants With Improvement in Gout at 72 Hours Post-dose Using a Likert Scale [Time Frame: 72 hours]

Measure Type	Primary
Measure Title	Percentage of Participants With Improvement in Gout at 72 Hours Post-dose Using a Likert Scale
Measure Description	72 hours following treatment, patients were asked the question: “How would you rate the improvement in your gout since receiving the study medication?” Patients rated their improvement on the Likert 5-point scale: 1=Excellent, 2=Good, 3=Acceptable,4=Slight and 5=Poor. Improvement was assessed by determining patients who scored a “good” or “excellent” response.
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.
Pharmacodynamic set included all randomized subjects with evaluable (or complete) pharmacodynamic parameter data.

Reporting Groups

	Description
Canakinumab	Canakinumab 10 mg/kg intravenous infusion and placebo matching dexamethasone intravenous infusion on Day 1.
Dexamethasone	Dexamethasone 12 mg intravenous infusion and placebo matching canakinumab on Day 1.

Measured Values

	Canakinumab	Dexamethasone
Number of Participants Analyzed [units: participants]	**3**	**3**
Percentage of Participants With Improvement in Gout at 72 Hours Post-dose Using a Likert Scale [units: Percentage of participants]	**100**	**100**

No statistical analysis provided for Percentage of Participants With Improvement in Gout at 72 Hours Post-dose Using a Likert Scale

2. Secondary: Non-inferiority of a Single Dose of Canakinumab Compared to Dexamethasone During Treatment Period [Time Frame: 72 hours]

Measure Type	Secondary
Measure Title	Non-inferiority of a Single Dose of Canakinumab Compared to Dexamethasone During Treatment Period
Measure Description	No text entered.
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.
Since the study only recruited 6 subjects this analysis was not done.

Reporting Groups

	Description
Canakinumab	Canakinumab 10 mg/kg intravenous infusion and placebo matching dexamethasone intravenous infusion on Day 1.
Dexamethasone	Dexamethasone 12 mg intravenous infusion and placebo matching canakinumab on Day 1.

Measured Values

	Canakinumab	Dexamethasone
Number of Participants Analyzed [units: participants]	**0**	**0**
Non-inferiority of a Single Dose of Canakinumab Compared to Dexamethasone During Treatment Period		

No statistical analysis provided for Non-inferiority of a Single Dose of Canakinumab Compared to Dexamethasone During Treatment Period

3. Secondary: Time to Recurrence of the Symptoms of Acute Gout (if Applicable) During Treatment Period [Time Frame: 4 months]

Measure Type	Secondary

Measure Title	Time to Recurrence of the Symptoms of Acute Gout (if Applicable) During Treatment Period
Measure Description	Time to recurrence is defined as from the point of improvement (good to excellent on Likert scale) to recurrence.
Time Frame	4 months
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.
Since the study recruited only 6 subjects this analysis was not done.

Reporting Groups

	Description
Canakinumab	Canakinumab 10 mg/kg intravenous infusion and placebo matching dexamethasone intravenous infusion on Day 1.
Dexamethasone	Dexamethasone 12 mg intravenous infusion and placebo matching canakinumab on Day 1.

Measured Values

	Canakinumab	**Dexamethasone**
Number of Participants Analyzed [units: participants]	**0**	**0**
Time to Recurrence of the Symptoms of Acute Gout (if Applicable) During Treatment Period		

No statistical analysis provided for Time to Recurrence of the Symptoms of Acute Gout (if Applicable) During Treatment Period

4. Secondary: Time to Walk Independently (if Applicable) During Treatment Period [Time Frame: 4 months]

Measure Type	Secondary
Measure Title	Time to Walk Independently (if Applicable) During Treatment Period
Measure Description	No text entered.
Time Frame	4 months
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.
Since the study recruited only 6 subjects this analysis was not done.

Reporting Groups

	Description
Canakinumab	Canakinumab 10 mg/kg intravenous infusion and placebo matching dexamethasone intravenous infusion on Day 1.
Dexamethasone	Dexamethasone 12 mg intravenous infusion and placebo matching canakinumab on Day 1.

Measured Values

	Canakinumab	**Dexamethasone**
Number of Participants Analyzed [units: participants]	**0**	**0**
Time to Walk Independently (if Applicable) During Treatment Period		

No statistical analysis provided for Time to Walk Independently (if Applicable) During Treatment Period

5. Secondary: Number of Participants With Discontinuation of Treatment Due to Adverse Events, Deaths or Serious Adverse Events During the Study [Time Frame: 4 months]

Measure Type	Secondary
Measure Title	Number of Participants With Discontinuation of Treatment Due to Adverse Events, Deaths or Serious Adverse Events During the Study
Measure Description	Additional safety information can be found in the Adverse Event section.
Time Frame	4 months
Safety Issue	Yes

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	Canakinumab 10 mg/kg intravenous infusion and placebo matching dexamethasone intravenous infusion on Day 1.
Dexamethasone	Dexamethasone 12 mg intravenous infusion and placebo matching canakinumab on Day 1.

Measured Values

	Canakinumab	**Dexamethasone**
Number of Participants Analyzed [units: participants]	**3**	**3**
Number of Participants With Discontinuation of Treatment Due to Adverse Events, Deaths or Serious Adverse Events During the Study [units: Participants]		
Discontinuation from treatment	**0**	**0**
Death	**0**	**0**
Serious Adverse Event	**0**	**1**

No statistical analysis provided for Number of Participants With Discontinuation of Treatment Due to Adverse Events, Deaths or Serious Adverse Events During the Study

6. Secondary: Change in C-reactive Protein (CRP) From Baseline at Month 4 [Time Frame: Baseline, Month 4]

Measure Type	Secondary
Measure Title	Change in C-reactive Protein (CRP) From Baseline at Month 4
Measure Description	Blood was collected at Baseline and Month 4 for CRP to identify the presence of inflammation, to determine its severity, and to monitor response to treatment. A negative change from baseline indicates improvement.
Time Frame	Baseline, Month 4
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.
Pharmacodynamic set included all randomized patients with evaluable (or complete) pharmacodynamic parameter data.

Reporting Groups

	Description
Canakinumab	Canakinumab 10 mg/kg intravenous infusion and placebo matching dexamethasone intravenous infusion on Day 1.
Dexamethasone	Dexamethasone 12 mg intravenous infusion and placebo matching canakinumab on Day 1.

Measured Values

	Canakinumab	**Dexamethasone**
Number of Participants Analyzed [units: participants]	**3**	**3**
Change in C-reactive Protein (CRP) From Baseline at Month 4 [units: mg/L] Mean (Standard Deviation)	**-22.23 (16.822)**	**-30.30 (51.963)**

No statistical analysis provided for Change in C-reactive Protein (CRP) From Baseline at Month 4

7. Secondary: Change in Serum Amyloid A Protein (SAA) From Baseline at Month 4 [Time Frame: Baseline, Month 4]

Measure Type	Secondary
Measure Title	Change in Serum Amyloid A Protein (SAA) From Baseline at Month 4
Measure Description	Blood was collected at Baseline and Month 4 for SAA to identify the presence of inflammation, to determine its severity, and to monitor response to treatment. A negative change from baseline indicates improvement.
Time Frame	Baseline, Month 4
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.
Pharmacodynamic set included all randomized patients with evaluable (or complete) pharmacodynamic parameter data.

Reporting Groups

	Description
Canakinumab	Canakinumab 10 mg/kg intravenous infusion and placebo matching dexamethasone intravenous infusion on Day 1.
Dexamethasone	Dexamethasone 12 mg intravenous infusion and placebo matching canakinumab on Day 1.

Measured Values

	Canakinumab	**Dexamethasone**
Number of Participants Analyzed [units: participants]	**3**	**3**
Change in Serum Amyloid A Protein (SAA) From Baseline at Month 4 [units: mg/L] Mean (Standard Deviation)	**-579.980 (563.7449)**	**-260.327 (463.8600)**

No statistical analysis provided for Change in Serum Amyloid A Protein (SAA) From Baseline at Month 4

8. Secondary: ACZ885 (Canakinumab) Pharmacokinetics (PK) Serum Concentration During the Treatment Period [Time Frame: Baseline, Days 0.25, 1, 3, 6, 20, 34, 55 and 119]

Measure Type	Secondary
Measure Title	ACZ885 (Canakinumab) Pharmacokinetics (PK) Serum Concentration During the Treatment Period
Measure Description	Blood was collected for ACZ885 (canakinumab) levels at baseline and Days 0.25, 1, 3, 6, 20, 34, 55 and 119. Serum was analyzed by means of a competitive Enzyme linked immunosorbant assay (ELISA).
Time Frame	Baseline, Days 0.25, 1, 3, 6, 20, 34, 55 and 119
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.
Pharmacodynamic set included all randomized subjects with evaluable (or complete) pharmacodynamic parameter data.

Reporting Groups

	Description
Canakinumab	Canakinumab 10 mg/kg intravenous infusion and placebo matching dexamethasone intravenous infusion on Day 1.

Measured Values

	Canakinumab
Number of Participants Analyzed [units: participants]	**3**
ACZ885 (Canakinumab) Pharmacokinetics (PK) Serum Concentration During the Treatment Period [units: µg/mL] Mean (Standard Deviation)	
Baseline	**0.0 (0.00)**
Day 0.25	**221.5 (143.58)**
Day 1 (n=2)	**276.5 (26.163)**
Day 3 (n=1)	**92.3** [1]
Day 6	**136.6 (41,532)**
Day 20	**72.37 (11.154)**
Day 34	**52.87 (13.194)**
Day 55	**31.67 (8.4884)**
Day 119	**7.643 (4.6151)**

[1] Standard deviation not calculated- data available for only 1 participant.

No statistical analysis provided for ACZ885 (Canakinumab) Pharmacokinetics (PK) Serum Concentration During the Treatment Period

9. Secondary: Change From Baseline in Pain Using a Visual Analog Scale at Month 4 [Time Frame: Baseline, Month 4]

Measure Type	Secondary
Measure Title	Change From Baseline in Pain Using a Visual Analog Scale at Month 4

Measure Description	Patients rated their pain on a 100 millimeter (mm) visual analog scale, ranging from no pain (0) to unbearable pain (100). A negative change from baseline indicates improvement.
Time Frame	Baseline, Month 4
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.
Pharmacodynamic set included all randomized subjects with evaluable (or complete) pharmacodynamic parameter data.

Reporting Groups

	Description
Canakinumab	Canakinumab 10 mg/kg intravenous infusion and placebo matching dexamethasone intravenous infusion on Day 1.
Dexamethasone	Dexamethasone 12 mg intravenous infusion and placebo matching canakinumab on Day 1.

Measured Values

	Canakinumab	**Dexamethasone**
Number of Participants Analyzed [units: participants]	**3**	**3**
Change From Baseline in Pain Using a Visual Analog Scale at Month 4 [units: Score on a scale] Mean (Standard Deviation)	**-62.0 (3.61)**	**-65.7 (17.62)**

No statistical analysis provided for Change From Baseline in Pain Using a Visual Analog Scale at Month 4

10. Secondary: Number of Patients Who Took Rescue Medication [Time Frame: 4 months]

Measure Type	Secondary
Measure Title	Number of Patients Who Took Rescue Medication
Measure Description	Patients who did not improve by 72 hours post-dose (i.e. patients who show a pain Visual Analog (VAS) decrease of less than 50 % from baseline (Day 1, pre-dose) would have been treated with rescue medication of methylprednisolone 80 mg intravenous or intramuscular once at the discretion of the clinical investigator.
Time Frame	4 months
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.
All participants.

Reporting Groups

	Description
Canakinumab	Canakinumab 10 mg/kg intravenous infusion and placebo matching dexamethasone intravenous infusion on Day 1.
Dexamethasone	Dexamethasone 12 mg intravenous infusion and placebo matching canakinumab on Day 1.

Measured Values

	Canakinumab	**Dexamethasone**

Number of Participants Analyzed [units: participants]	**3**	**3**
Number of Patients Who Took Rescue Medication [units: Participants]	**0**	**0**

No statistical analysis provided for Number of Patients Who Took Rescue Medication

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Canakinumab	Canakinumab 10 mg/kg intravenous infusion and placebo matching dexamethasone intravenous infusion on Day 1.
Dexamethasone	Dexamethasone 12 mg intravenous infusion and placebo matching canakinumab on Day 1.

Serious Adverse Events

	Canakinumab	Dexamethasone
Total, serious adverse events		
# participants affected / at risk	**0/3 (0.00%)**	**1/3 (33.33%)**
Metabolism and nutrition disorders		
Gout † 1		
# participants affected / at risk	**0/3 (0.00%)**	**1/3 (33.33%)**

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

Other Adverse Events

Hide Other Adverse Events

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

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Canakinumab	Canakinumab 10 mg/kg intravenous infusion and placebo matching dexamethasone intravenous infusion on Day 1.
Dexamethasone	Dexamethasone 12 mg intravenous infusion and placebo matching canakinumab on Day 1.

Other Adverse Events

	Canakinumab	Dexamethasone
Total, other (not including serious) adverse events		

# participants affected / at risk	**2/3 (66.67%)**	**3/3 (100.00%)**
Eye disorders		
Ocular hyperaemia † 1		
# participants affected / at risk	**0/3 (0.00%)**	**1/3 (33.33%)**
Gastrointestinal disorders		
Constipation † 1		
# participants affected / at risk	**0/3 (0.00%)**	**1/3 (33.33%)**
Injury, poisoning and procedural complications		
Joint injury † 1		
# participants affected / at risk	**0/3 (0.00%)**	**1/3 (33.33%)**
Investigations		
Alanine aminotransferase increased † 1		
# participants affected / at risk	**0/3 (0.00%)**	**1/3 (33.33%)**
Aspartate aminotransferase increased † 1		
# participants affected / at risk	**0/3 (0.00%)**	**1/3 (33.33%)**
Blood urine present † 1		
# participants affected / at risk	**1/3 (33.33%)**	**0/3 (0.00%)**
Metabolism and nutrition disorders		
Gout † 1		
# participants affected / at risk	**0/3 (0.00%)**	**3/3 (100.00%)**
Hyperuricaemia † 1		
# participants affected / at risk	**1/3 (33.33%)**	**0/3 (0.00%)**
Musculoskeletal and connective tissue disorders		
Arthritis † 1		
# participants affected / at risk	**0/3 (0.00%)**	**1/3 (33.33%)**

† 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:	Novartis
ClinicalTrials.gov Identifier:	NCT00663169 History of Changes
Other Study ID Numbers:	**CACZ885A2212**
Study First Received:	April 18, 2008
Results First Received:	August 30, 2012
Last Updated:	December 4, 2012
Health Authority:	United States: Food and Drug Administration Switzerland: Swissmedic United Kingdom: Medicines and Healthcare Products Regulatory Agency