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Trial record **1 of 1** for: CACZ885A2207

Previous Study | Return to List | Next Study

Safety and Efficacy of ACZ885 in Adult Patients With Established Rheumatoid Arthritis

This study has been completed.

Sponsor:
Novartis

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT00504595

First received: July 19, 2007
Last updated: August 2, 2012
Last verified: August 2012
History of Changes

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

Results First Received: January 20, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Rheumatoid Arthritis
Interventions:	Drug: ACZ885 (investigational) 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
No text entered.

Reporting Groups

	Description
ACZ885 (Canakinumab) : RA Patients	Patients with Rheumatoid Arthritis RA taking 600 mg of ACZ885 (Canakinumab) Intravenous (IV) on Day 1, Day 15, and Day 43.
ACZ885 (Canakinumab) : Healthy Volunteers	Healthy Volunteers taking 600 mg of ACZ885 (Canakinumab) Intravenous (IV) on Day 1
Placebo Comparator: RA Patients	Rheumatoid Arthritis patients who received placebo Intravenous (IV) on Day 1, Day 15 and Day 43.
Placebo Comparator: Healthy Volunteers	Healthy Volunteers who received placebo Intravenous (IV) at Day 1.

Participant Flow: Overall Study

	ACZ885 (Canakinumab) : RA Patients	ACZ885 (Canakinumab) : Healthy Volunteers	Placebo Comparator: RA Patients	Placebo Comparator: Healthy Volunteers
STARTED	50	10	10	10
COMPLETED	49	10	8	10
NOT COMPLETED	1	0	2	0
Lack of Efficacy	1	0	0	0
Not specified	0	0	2	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
ACZ885 (Canakinumab) : RA Patients	Patients with Rheumatoid Arthritis RA taking 600 mg of ACZ885 (Canakinumab) Intravenous (IV) on Day 1, Day 15, and Day 43.
ACZ885 (Canakinumab) : Healthy Volunteers	Healthy Volunteers taking 600 mg of ACZ885 (Canakinumab) Intravenous (IV) on Day 1
Placebo Comparator: RA Patients	Rheumatoid Arthritis patients who received placebo Intravenous (IV) on Day 1, Day 15 and Day 43.
Placebo Comparator: Healthy Volunteers	Healthy Volunteers who received placebo Intravenous (IV) at Day 1.
Total	Total of all reporting groups

Baseline Measures

	ACZ885 (Canakinumab) : RA Patients	ACZ885 (Canakinumab) : Healthy Volunteers	Placebo Comparator: RA Patients	Placebo Comparator: Healthy Volunteers	Total
Number of Participants [units: participants]	50	10	10	10	80
Age [units: Years] Mean (Standard Deviation)	54.4 (13.42)	28.8 (7.42)	46.2 (12.83)	28.0 (5.52)	46.9 (16.22)
Gender [units: participants]					
Female	42	4	9	2	57
Male	8	6	1	8	23

Outcome Measures

Hide All Outcome Measures

1. Primary: Response to Treatment (ACR20) in Adult Patients With Established Rheumatoid Arthritis (RA) [Time Frame: 6 weeks and 12 weeks]

Measure Type	Primary
Measure Title	Response to Treatment (ACR20) in Adult Patients With Established Rheumatoid Arthritis (RA)
Measure Description	At each post-dose visit, an ACR20 responder was defined as someone who achieved at least 20% improvement in the tender and the swollen 28-joint count, and 20% improvement in at least 3 of the following 5 measures:: • Patient's pain assessment (Visual Analogue Scale (VAS) 100 mm) • Patient's global assessment of disease activity (VAS 100 mm) • Physician's global assessment of disease activity (VAS 100 mm) • Patient self-assessed disability (Health Assessment Questionnaire (HAQ) score) • Acute phase reactant (high sensitivity C-reactive Protein (hsCRP))
Time Frame	6 weeks and 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.
The Safety Analysis Set consisted of all subjects who received at least one dose of study medication. The analysis used last observation carried forward (LOCF) imputation for missing values.

Reporting Groups

	Description
ACZ885 (Canakinumab) : RA Patients	Patients with Rheumatoid Arthritis RA taking 600 mg of ACZ885 (Canakinumab) Intravenous (IV) on Day 1, Day 15, and Day 43.
Placebo Comparator: RA Patients	Rheumatoid Arthritis patients who received placebo Intravenous (IV) on Day 1, Day 15 and Day 43.

Measured Values

	ACZ885 (Canakinumab) : RA Patients	**Placebo Comparator: RA Patients**
Number of Participants Analyzed [units: participants]	**50**	**10**
Response to Treatment (ACR20) in Adult Patients With Established Rheumatoid Arthritis (RA) [units: Participants]		
ACR20 response rate at 6 weeks	**17**	**2**
ACR20 response rate at 12 weeks	**27**	**2**

No statistical analysis provided for Response to Treatment (ACR20) in Adult Patients With Established Rheumatoid Arthritis (RA)

2. Secondary: Efficacy of ACZ885 by Assessing the Response to Treatment Using the Simple Disease Index (SDAI) [Time Frame: 6 weeks and 12 weeks]

Measure Type	Secondary
Measure Title	Efficacy of ACZ885 by Assessing the Response to Treatment Using the Simple Disease Index (SDAI)
Measure Description	SDAI is derived by the number of swollen joints and tender joints using the 28-joint count (tender28 and swollen28).

	SDAI measures the high sensitivity C-reactive protein (hsCRP) level, patient's global disease activity (PGDA) and evaluator's global disease activity (EGDA). PGDA and EGDA are measured on a 100 mm Visual Analogue Scale (VAS), ranging from no arthritis activity to maximal arthritis activity. SDAI = tender28 + swollen28 + CRP + (PGDA/10) + (EGDA/10). Lower scores indicate less disease activity.
Time Frame	6 weeks and 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.
The Safety Analysis Set consisted of all subjects who received at least one dose of study medication. The analysis used last observation carried forward (LOCF) imputation for missing values.

Reporting Groups

	Description
ACZ885 (Canakinumab): RA Patients	Patients with Rheumatoid Arthritis (RA) taking 600 mg of ACZ885 (Canakinumab) Intravenous (IV) on Day 1, Day 15, and Day 43.
Placebo Comparator: RA Patients	Patients with Rheumatoid Arthritis (RA) who received placebo Intravenous (IV) on Day 1, Day 15 and Day 43.

Measured Values

	ACZ885 (Canakinumab): RA Patients	**Placebo Comparator: RA Patients**
Number of Participants Analyzed [units: participants]	**50**	**10**
Efficacy of ACZ885 by Assessing the Response to Treatment Using the Simple Disease Index (SDAI) [units: Scores on a scale] Mean (Standard Deviation)		
6 Weeks	**32.623 (13.6218)**	**33.841 (15.0053)**
12 Weeks	**29.163 (13.0927)**	**32.412 (12.2633)**

No statistical analysis provided for Efficacy of ACZ885 by Assessing the Response to Treatment Using the Simple Disease Index (SDAI)

3. Secondary: Efficacy of ACZ885 (Canakinumab) by Assessing the Response to Treatment Using the Disease Activity Score (DAS28) [Time Frame: 6 weeks and 12 weeks]

Measure Type	Secondary
Measure Title	Efficacy of ACZ885 (Canakinumab) by Assessing the Response to Treatment Using the Disease Activity Score (DAS28)
Measure Description	DAS28 is derived by the number of swollen joints and tender joints using the 28-joint count (tender28 and swollen28). DAS28 measures the C-reactive protein (CRP) (in mg/L) and the patient's general health (GH). GH is measured on a 100 mm Visual Analogue Scale (VAS), ranging from no arthritis activity to maximal arthritis activity. DAS28 = 0.56*√(tender28) + 0.28*√(swollen28) + 0.36*log_e(CRP+1) + 0.014*PGDA + 0.96. Lower scores indicate less disease activity.
Time Frame	6 weeks and 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.

The Safety Analysis Set consisted of all subjects who received at least one dose of study medication. The analysis used last observation carried forward (LOCF) imputation for missing values.

Reporting Groups

	Description
ACZ885 (Canakinumab) : RA Patients	Patients with Rheumatoid Arthritis RA taking 600 mg of ACZ885 (Canakinumab) Intravenous (IV) on Day 1, Day 15, and Day 43.
Placebo Comparator: RA Patients	Rheumatoid Arthritis patients who received placebo Intravenous (IV) on Day 1, Day 15 and Day 43.

Measured Values

	ACZ885 (Canakinumab) : RA Patients	Placebo Comparator: RA Patients
Number of Participants Analyzed [units: participants]	**50**	**10**
Efficacy of ACZ885 (Canakinumab) by Assessing the Response to Treatment Using the Disease Activity Score (DAS28) [units: Scores on a scale] Mean (Standard Deviation)		
6 Weeks	**5.088 (1.1148)**	**5.397 (1.0591)**
12 Weeks	**4.853 (1.1879)**	**5.400 (0.9321)**

No statistical analysis provided for Efficacy of ACZ885 (Canakinumab) by Assessing the Response to Treatment Using the Disease Activity Score (DAS28)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	18 Weeks (12 Week treatment period + 6 Week Follow-up period)
Additional Description	No text entered.

Reporting Groups

	Description
ACZ885 (Canakinumab): Healthy Volunteers	Healthy Volunteers taking 600 mg of ACZ885 (Canakinumab) Intravenous (IV) on Day 1.
Placebo Comparator: Healthy Volunteers	Healthy Volunteers who received placebo Intravenous (IV) at Day 1.
ACZ885 (Canakinumab): RA Patients	Patients with Rheumatoid Arthritis RA taking 600 mg of ACZ885 (Canakinumab) Intravenous (IV) on Day 1, Day 15, and Day 43.
Placebo Comparator: RA Patients	Rheumatoid Arthritis patients who received placebo Intravenous (IV) on Day 1, Day 15 and Day 43.

Serious Adverse Events

	ACZ885 (Canakinumab): Healthy Volunteers	Placebo Comparator: Healthy Volunteers	ACZ885 (Canakinumab): RA Patients	Placebo Comparator: RA Patients
Total, serious adverse events				
# participants affected / at risk	**0/10 (0.00%)**	**0/10 (0.00%)**	**2/50 (4.00%)**	**0/10 (0.00%)**
Ear and labyrinth disorders				
Deafness Neurosensory † 1				

# participants affected / at risk	0/10 (0.00%)	0/10 (0.00%)	1/50 (2.00%)	0/10 (0.00%)
Infections and infestations				
Ear Infection † 1				
# participants affected / at risk	0/10 (0.00%)	0/10 (0.00%)	1/50 (2.00%)	0/10 (0.00%)
Sinusitis † 1				
# participants affected / at risk	0/10 (0.00%)	0/10 (0.00%)	1/50 (2.00%)	0/10 (0.00%)
Musculoskeletal and connective tissue disorders				
Musculoskeletal Chest Pain † 1				
# participants affected / at risk	0/10 (0.00%)	0/10 (0.00%)	1/50 (2.00%)	0/10 (0.00%)

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	18 Weeks (12 Week treatment period + 6 Week Follow-up period)
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
ACZ885 (Canakinumab): Healthy Volunteers	Healthy Volunteers taking 600 mg of ACZ885 (Canakinumab) Intravenous (IV) on Day 1.
Placebo Comparator: Healthy Volunteers	Healthy Volunteers who received placebo Intravenous (IV) at Day 1.
ACZ885 (Canakinumab): RA Patients	Patients with Rheumatoid Arthritis RA taking 600 mg of ACZ885 (Canakinumab) Intravenous (IV) on Day 1, Day 15, and Day 43.
Placebo Comparator: RA Patients	Rheumatoid Arthritis patients who received placebo Intravenous (IV) on Day 1, Day 15 and Day 43.

Other Adverse Events

	ACZ885 (Canakinumab): Healthy Volunteers	Placebo Comparator: Healthy Volunteers	ACZ885 (Canakinumab): RA Patients	Placebo Comparator: RA Patients
Total, other (not including serious) adverse events				
# participants affected / at risk	6/10 (60.00%)	4/10 (40.00%)	12/50 (24.00%)	8/10 (80.00%)
Ear and labyrinth disorders				
Vertigo † 1				
# participants affected / at risk	0/10 (0.00%)	0/10 (0.00%)	3/50 (6.00%)	0/10 (0.00%)
Gastrointestinal disorders				

Abdominal Pain † 1				
# participants affected / at risk	**0/10 (0.00%)**	**0/10 (0.00%)**	**3/50 (6.00%)**	**0/10 (0.00%)**
Enterocolitis † 1				
# participants affected / at risk	**0/10 (0.00%)**	**0/10 (0.00%)**	**0/50 (0.00%)**	**1/10 (10.00%)**
Nausea † 1				
# participants affected / at risk	**0/10 (0.00%)**	**0/10 (0.00%)**	**1/50 (2.00%)**	**2/10 (20.00%)**
Toothache † 1				
# participants affected / at risk	**0/10 (0.00%)**	**1/10 (10.00%)**	**0/50 (0.00%)**	**1/10 (10.00%)**
Vomiting † 1				
# participants affected / at risk	**0/10 (0.00%)**	**0/10 (0.00%)**	**0/50 (0.00%)**	**1/10 (10.00%)**
General disorders				
Influenza Like Illness † 1				
# participants affected / at risk	**1/10 (10.00%)**	**0/10 (0.00%)**	**0/50 (0.00%)**	**0/10 (0.00%)**
Oedema Peripheral † 1				
# participants affected / at risk	**1/10 (10.00%)**	**0/10 (0.00%)**	**1/50 (2.00%)**	**0/10 (0.00%)**
Infections and infestations				
Acute Tonsillitis † 1				
# participants affected / at risk	**0/10 (0.00%)**	**0/10 (0.00%)**	**0/50 (0.00%)**	**1/10 (10.00%)**
Pyelonephritis Acute † 1				
# participants affected / at risk	**0/10 (0.00%)**	**0/10 (0.00%)**	**0/50 (0.00%)**	**1/10 (10.00%)**
Respiratory Tract Infection Viral † 1				
# participants affected / at risk	**0/10 (0.00%)**	**0/10 (0.00%)**	**3/50 (6.00%)**	**2/10 (20.00%)**
Upper Respiratory Tract Infection † 1				
# participants affected / at risk	**1/10 (10.00%)**	**0/10 (0.00%)**	**0/50 (0.00%)**	**1/10 (10.00%)**
Viral Infection † 1				
# participants affected / at risk	**0/10 (0.00%)**	**0/10 (0.00%)**	**0/50 (0.00%)**	**1/10 (10.00%)**
Investigations				
Hepatic Enzyme Increased † 1				
# participants affected / at risk	**0/10 (0.00%)**	**0/10 (0.00%)**	**0/50 (0.00%)**	**1/10 (10.00%)**
Metabolism and nutrition disorders				
Iron Deficiency † 1				
# participants affected / at risk	**1/10 (10.00%)**	**0/10 (0.00%)**	**0/50 (0.00%)**	**0/10 (0.00%)**

Musculoskeletal and connective tissue disorders				
Back Pain † 1				
# participants affected / at risk	**0/10 (0.00%)**	**1/10 (10.00%)**	**1/50 (2.00%)**	**0/10 (0.00%)**
Rheumatoid Arthritis † 1				
# participants affected / at risk	**0/10 (0.00%)**	**0/10 (0.00%)**	**2/50 (4.00%)**	**3/10 (30.00%)**
Nervous system disorders				
Headache † 1				
# participants affected / at risk	**2/10 (20.00%)**	**1/10 (10.00%)**	**3/50 (6.00%)**	**1/10 (10.00%)**
Respiratory, thoracic and mediastinal disorders				
Cough † 1				
# participants affected / at risk	**0/10 (0.00%)**	**1/10 (10.00%)**	**1/50 (2.00%)**	**0/10 (0.00%)**
Skin and subcutaneous tissue disorders				
Rash † 1				
# participants affected / at risk	**0/10 (0.00%)**	**0/10 (0.00%)**	**0/50 (0.00%)**	**1/10 (10.00%)**
Vascular disorders				
Hypertension † 1				
# participants affected / at risk	**0/10 (0.00%)**	**0/10 (0.00%)**	**2/50 (4.00%)**	**1/10 (10.00%)**
Phlebitis † 1				
# participants affected / at risk	**1/10 (10.00%)**	**0/10 (0.00%)**	**1/50 (2.00%)**	**0/10 (0.00%)**

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

Limitations and Caveats

Hide Limitations and Caveats

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

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can

☐ embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of 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:	NCT00504595 History of Changes
Other Study ID Numbers:	**CACZ885A2207**
Study First Received:	July 19, 2007
Results First Received:	January 20, 2011
Last Updated:	August 2, 2012
Health Authority:	Spain: Spanish Agency of Medicines