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Trial record **2 of 2** for: CAIN457A2202

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Efficacy, Safety and Tolerability of AIN457 in Moderate to Severe Active Crohn's Disease

This study has been terminated.

(The study was terminated prematurely after futility criterion was met at planned interim analysis of 41 patients.)

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT00584740

First received: December 21, 2007
Last updated: March 24, 2015
Last verified: March 2015
History of Changes

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Results First Received: January 28, 2015

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:	Crohn's Disease
Interventions:	Drug: AIN457 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
AIN457	AIN457 10 mg/kg was given as an intravenous infusion at day 1 and day 22.
Placebo	Matching placebo to AIN457 was given as an infusion at day 1 and day 22.

Participant Flow: Overall Study

	AIN457	**Placebo**
STARTED	**39**	**20**

COMPLETED	**27**	**14**
NOT COMPLETED	**12**	**6**
Adverse Event	**1**	**1**
Lack of Efficacy	**8**	**2**
Withdrawal by Subject	**3**	**2**
Lost to Follow-up	**0**	**1**

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
AIN457	AIN457 10 mg/kg was given as an intravenous infusion at day 1 and day 22.
Placebo	Matching placebo to AIN457 was given as an infusion at day 1 and day 22.
Total	Total of all reporting groups

Baseline Measures

	AIN457	Placebo	Total
Number of Participants [units: participants]	**39**	**20**	**59**
Age [units: Years] Mean (Standard Deviation)	**37.3 (11.96)**	**38.3 (14.29)**	**37.6 (12.68)**
Gender [units: Participants]			
Female	**15**	**9**	**24**
Male	**24**	**11**	**35**

Outcome Measures

Hide All Outcome Measures

1. Primary: Mean Change From Baseline in Crohns Disease Activity Index (CDAI) Score [Time Frame: 6 weeks]

Measure Type	Primary
Measure Title	Mean Change From Baseline in Crohns Disease Activity Index (CDAI) Score
Measure Description	The Crohns Disease Activity Index or CDAI is a research tool used to quantify the symptoms of patients with Crohns disease. Participants were asked to record on a paper diary the frequency of stools, abdominal pain and general well-being on a daily basis. In addition to the diary data, the investigator assessed the following for the calculation of CDAI score: arthritis/arthralgia, iritis/uveitis, erythema nodosum/pyoderma gangrenousum/aphthous stomatitis, anal fissure/fistula/abscess, other fistula; fever; use of antidiarrheal; abdominal mass; hematocrit; body weight. The CDAI score is the sum of the products of each item multiplied by its weighting factor. CDAI ranges from 0 to >=600, where remission of Crohn's disease is defined as CDAI < 150, and severe disease is defined as CDAI > 450. A negative

	change in mean score indicates improvement.
Time Frame	6 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.
Safety Analysis Set: the safety set included all participants.

Reporting Groups

	Description
AIN457	AIN457 10 mg/kg was given as an intravenous infusion at day 1 and day 22.
Placebo	Matching placebo to AIN457 was given as an infusion at day 1 and day 22.

Measured Values

	AIN457	**Placebo**
Number of Participants Analyzed [units: participants]	**39**	**20**
Mean Change From Baseline in Crohns Disease Activity Index (CDAI) Score [units: score on a scale] Mean (Standard Deviation)	**-29.2 (14.0)**	**-63.1 (13.9)**

No statistical analysis provided for Mean Change From Baseline in Crohns Disease Activity Index (CDAI) Score

2. Secondary: Percentage of Participants Achieving Remission and/or Response [Time Frame: 6 weeks]

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving Remission and/or Response
Measure Description	Remission or response was defined as CDAI < 150 points or CDAI reduction from baseline of at least 70 points.
Time Frame	6 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.
Safety Analysis Set: the safety set included all participants.

Reporting Groups

	Description
AIN457	AIN457 10 mg/kg was given as an intravenous infusion at day 1 and day 22.
Placebo	Matching placebo to AIN457 was given as an infusion at day 1 and day 22.

Measured Values

	AIN457	**Placebo**
Number of Participants Analyzed [units: participants]	**39**	**20**
Percentage of Participants Achieving Remission and/or Response	**26**	**65**

[units: Percentage of participants]		

No statistical analysis provided for Percentage of Participants Achieving Remission and/or Response

3. Secondary: Percentage of Participants Achieving Remission [Time Frame: 6 weeks]

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving Remission
Measure Description	Remission was defined as CDAI < 150 points.
Time Frame	6 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.
Safety Analysis Set: the safety set included all participants.

Reporting Groups

	Description
AIN457	AIN457 10 mg/kg was given as an intravenous infusion at day 1 and day 22.
Placebo	Matching placebo to AIN457 was given as an infusion at day 1 and day 22.

Measured Values

	AIN457	**Placebo**
Number of Participants Analyzed [units: participants]	**39**	**20**
Percentage of Participants Achieving Remission [units: Percentage of participants]	**10**	**15**

No statistical analysis provided for Percentage of Participants Achieving Remission

4. Secondary: Percentage of Participants Achieving Response [Time Frame: 6 weeks]

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving Response
Measure Description	Response was defined as CDAI reduction of at least 70 points from baseline.
Time Frame	6 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.
Safety Analysis Set: the safety set included all participants.

Reporting Groups

	Description

AIN457	AIN457 10 mg/kg was given as an intravenous infusion at day 1 and day 22.
Placebo	Matching placebo to AIN457 was given as an infusion at day 1 and day 22.

Measured Values

	AIN457	Placebo
Number of Participants Analyzed [units: participants]	**39**	**10**
Percentage of Participants Achieving Response [units: Percentage of participants]	**26**	**65**

No statistical analysis provided for Percentage of Participants Achieving Response

5. Secondary: Mean Change From Baseline in CDAI Score [Time Frame: baseline, 2 weeks, 4 weeks]

Measure Type	Secondary
Measure Title	Mean Change From Baseline in CDAI Score
Measure Description	The Crohns Disease Activity Index or CDAI is a research tool used to quantify the symptoms of patients with Crohns disease. Participants were asked to record on a paper diary the frequency of stools, abdominal pain and general well-being on a daily basis. In addition to the diary data, the investigator assessed the following for the calculation of CDAI score: arthritis/arthralgia, iritis/uveitis, erythema nodosum/pyoderma gangrenousum/aphthous stomatitis, anal fissure/fistula/abscess, other fistula; fever; use of antidiarrheal; abdominal mass; hematocrit; body weight. The CDAI score is the sum of the products of each item multiplied by its weighting factor. CDAI ranges from 0 to >=600, where remission of Crohn's disease is defined as CDAI < 150, and severe disease is defined as CDAI > 450. A negative change in mean score indicates improvement.
Time Frame	baseline, 2 weeks, 4 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.
Safety Analysis Set: the safety set included all participants.

Reporting Groups

	Description
AIN457	AIN457 10 mg/kg was given as an intravenous infusion at day 1 and day 22.
Placebo	Matching placebo to AIN457 was given as an infusion at day 1 and day 22.

Measured Values

	AIN457	Placebo
Number of Participants Analyzed [units: participants]	**39**	**20**
Mean Change From Baseline in CDAI Score [units: score on a scale] Mean (Standard Deviation)		
Week 2	**-15.28 (14.010)**	**-52.85 (13.900)**
Week 4	**-23.52 (14.010)**	**-58.48 (13.900)**

No statistical analysis provided for Mean Change From Baseline in CDAI Score

6. Secondary: Area Under CDAI Curve [Time Frame: 10 weeks]

Measure Type	Secondary
Measure Title	Area Under CDAI Curve
Measure Description	The Crohns Disease Activity Index or CDAI is a research tool used to quantify the symptoms of patients with Crohns disease. Participants were asked to record on a paper diary the frequency of stools, abdominal pain and general well-being on a daily basis. In addition to the diary data, the investigator assessed the following for the calculation of CDAI score: arthritis/arthralgia, iritis/uveitis, erythema nodosum/pyoderma gangrenousum/aphthous stomatitis, anal fissure/fistula/abscess, other fistula; fever; use of antidiarrheal; abdominal mass; hematocrit; body weight. The CDAI score is the sum of the products of each item multiplied by its weighting factor. CDAI ranges from 0 to >=600, where remission of Crohn's disease is defined as CDAI < 150, and severe disease is defined as CDAI > 450. An area under the CDAI response curve analysis was performed with a starting point from week 4.
Time Frame	10 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.
Safety Analysis Set: the safety set included all participants.

Reporting Groups

	Description
AIN457	AIN457 10 mg/kg was given as an intravenous infusion at day 1 and day 22.
Placebo	Matching placebo to AIN457 was given as an infusion at day 1 and day 22.

Measured Values

	AIN457	Placebo
Number of Participants Analyzed [units: participants]	**39**	**20**
Area Under CDAI Curve [units: Units on a scale*day] Least Squares Mean (Standard Error)	**11766.26 (594.54)**	**9723.45 (784.46)**

No statistical analysis provided for Area Under CDAI Curve

7. Secondary: Percentage of Participants Maintaining Remission [Time Frame: 10 weeks]

Measure Type	Secondary
Measure Title	Percentage of Participants Maintaining Remission
Measure Description	Remission was defined as CDAI < 150 points.
Time Frame	10 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 analysis population included participants of the safety set who achieved remission.

Reporting Groups

	Description
AIN457	AIN457 10 mg/kg was given as an intravenous infusion at day 1 and day 22.
Placebo	Matching placebo to AIN457 was given as an infusion at day 1 and day 22.

Measured Values

	AIN457	Placebo
Number of Participants Analyzed [units: participants]	**4**	**3**
Percentage of Participants Maintaining Remission [units: Percentage of participants]	**100**	**67**

No statistical analysis provided for Percentage of Participants Maintaining Remission

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
AIN457 Twice 10mg/kg	AIN457 10 mg/kg was given as an intravenous infusion at day 1 and day 22.
Placebo	Matching placebo to AIN457 was given as an infusion at day 1 and day 22.

Serious Adverse Events

	AIN457 Twice 10mg/kg	Placebo
Total, serious adverse events		
# participants affected / at risk	**7/39 (17.95%)**	**3/20 (15.00%)**
Blood and lymphatic system disorders		
Leukopenia † 1		
# participants affected / at risk	**1/39 (2.56%)**	**0/20 (0.00%)**
Gastrointestinal disorders		
Aphthous stomatitis † 1		
# participants affected / at risk	**1/39 (2.56%)**	**0/20 (0.00%)**
Crohn's disease † 1		
# participants affected / at risk	**5/39 (12.82%)**	**3/20 (15.00%)**
Oesophagitis † 1		
# participants affected / at risk	**1/39 (2.56%)**	**0/20 (0.00%)**
General disorders		
Disease progression † 1		
# participants affected / at risk	**1/39 (2.56%)**	**0/20 (0.00%)**
Investigations		

C-reactive protein increased † 1		
# participants affected / at risk	**1/39 (2.56%)**	**0/20 (0.00%)**

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

Other Adverse Events

Hide Other Adverse Events

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

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
AIN457 Twice 10mg/kg	AIN457 10 mg/kg was given as an intravenous infusion at day 1 and day 22.
Placebo	Matching placebo to AIN457 was given as an infusion at day 1 and day 22.

Other Adverse Events

	AIN457 Twice 10mg/kg	**Placebo**
Total, other (not including serious) adverse events		
# participants affected / at risk	**22/39 (56.41%)**	**9/20 (45.00%)**
Cardiac disorders		
Cardiac flutter † 1		
# participants affected / at risk	**0/39 (0.00%)**	**1/20 (5.00%)**
Ventricular extrasystoles † 1		
# participants affected / at risk	**0/39 (0.00%)**	**1/20 (5.00%)**
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	**5/39 (12.82%)**	**2/20 (10.00%)**
Crohn's disease † 1		
# participants affected / at risk	**3/39 (7.69%)**	**0/20 (0.00%)**
Diarrhoea † 1		
# participants affected / at risk	**2/39 (5.13%)**	**1/20 (5.00%)**
Dyspepsia † 1		
# participants affected / at risk	**0/39 (0.00%)**	**1/20 (5.00%)**
Frequent bowel movements † 1		
# participants affected / at risk	**0/39 (0.00%)**	**1/20 (5.00%)**
Gastrooesophageal reflux disease † 1		
# participants affected / at risk	**0/39 (0.00%)**	**1/20 (5.00%)**
Nausea † 1		
# participants affected / at risk	**2/39 (5.13%)**	**3/20 (15.00%)**
Vomiting † 1		

# participants affected / at risk	5/39 (12.82%)	1/20 (5.00%)
General disorders		
Fatigue † 1		
# participants affected / at risk	2/39 (5.13%)	2/20 (10.00%)
Pain † 1		
# participants affected / at risk	0/39 (0.00%)	1/20 (5.00%)
Pyrexia † 1		
# participants affected / at risk	2/39 (5.13%)	1/20 (5.00%)
Infections and infestations		
Candidiasis † 1		
# participants affected / at risk	2/39 (5.13%)	0/20 (0.00%)
Nasopharyngitis † 1		
# participants affected / at risk	2/39 (5.13%)	0/20 (0.00%)
Upper respiratory tract infection † 1		
# participants affected / at risk	3/39 (7.69%)	0/20 (0.00%)
Investigations		
Blood pressure diastolic decreased † 1		
# participants affected / at risk	2/39 (5.13%)	0/20 (0.00%)
Blood pressure increased † 1		
# participants affected / at risk	0/39 (0.00%)	1/20 (5.00%)
C-reactive protein increased † 1		
# participants affected / at risk	0/39 (0.00%)	1/20 (5.00%)
Electrocardiogram QT prolonged † 1		
# participants affected / at risk	2/39 (5.13%)	0/20 (0.00%)
Red blood cell sedimentation rate increased † 1		
# participants affected / at risk	0/39 (0.00%)	1/20 (5.00%)
Metabolism and nutrition disorders		
Dehydration † 1		
# participants affected / at risk	2/39 (5.13%)	0/20 (0.00%)
Hypokalaemia † 1		
# participants affected / at risk	2/39 (5.13%)	0/20 (0.00%)
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	4/39 (10.26%)	0/20 (0.00%)
Myalgia † 1		
# participants affected / at risk	2/39 (5.13%)	0/20 (0.00%)
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	1/39 (2.56%)	1/20 (5.00%)
Headache † 1		
# participants affected / at risk	3/39 (7.69%)	3/20 (15.00%)
Lethargy † 1		
# participants affected / at risk	0/39 (0.00%)	1/20 (5.00%)
Psychiatric disorders		

Anxiety † 1		
# participants affected / at risk	**0/39 (0.00%)**	**1/20 (5.00%)**
Insomnia † 1		
# participants affected / at risk	**0/39 (0.00%)**	**2/20 (10.00%)**
Reproductive system and breast disorders		
Prostatitis † 1		
# participants affected / at risk	**0/39 (0.00%)**	**1/20 (5.00%)**
Skin and subcutaneous tissue disorders		
Erythema † 1		
# participants affected / at risk	**0/39 (0.00%)**	**1/20 (5.00%)**
Hyperhidrosis † 1		
# participants affected / at risk	**1/39 (2.56%)**	**1/20 (5.00%)**
Rash † 1		
# participants affected / at risk	**1/39 (2.56%)**	**1/20 (5.00%)**
Vascular disorders		
Hot flush † 1		
# participants affected / at risk	**0/39 (0.00%)**	**1/20 (5.00%)**
Hypertension † 1		
# participants affected / at risk	**0/39 (0.00%)**	**1/20 (5.00%)**

† 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 or disclosure of trial results in their entirety.

Results Point of Contact:

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

No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
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Other Study ID Numbers:	**CAIN457A2202**
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Health Authority:	United States: Food and Drug Administration Canada: Health Canada