ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Trial record **1 of 2** for: CAIN457B2201

Previous Study | Return to List | Next Study

POC-MD MRI-based Trial in Relapsing-remitting Multiple Scler

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01051817

First received: January 19, 2010
Last updated: February 12, 2015
Last verified: February 2015
History of Changes

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

Results First Received: February 12, 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
Conditions:	Relapsing-remitting Multiple Sclerosis RRMS
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	IV dose 10 mg/kg week 0, 2, 4, 8, 12, 16, and 20.
Placebo	Placebo IV week 0, 2, 4, 8, 12, 16, and 20.

Participant Flow: Overall Study

	AIN457	Placebo
STARTED	**38**	**35**
COMPLETED	**35**	**26**
NOT COMPLETED	**3**	**9**
Adverse Event	**0**	**2**
Abnormal Test Proceedure reults	**0**	**1**
Withdrawal by Subject	**3**	**5**
Protocol Violation	**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	IV dose 10 mg/kg week 0, 2, 4, 8, 12, 16, and 20.
Placebo	Placebo IV week 0, 2, 4, 8, 12, 16, and 20.
Total	Total of all reporting groups

Baseline Measures

	AIN457	Placebo	Total
Number of Participants [units: participants]	**38**	**35**	**73**
Age [units: years] Mean (Standard Deviation)	**36.1 (9.8)**	**32.7 (9.9)**	**34.5 (9.95)**
Gender [units: Participants]			
Female	**21**	**29**	**50**
Male	**17**	**6**	**23**
Ethnicity (NIH/OMB) [units: Participants]			
Hispanic or Latino	**3**	**1**	**4**
Not Hispanic or Latino	**35**	**34**	**69**
Unknown or Not Reported	**0**	**0**	**0**

Race (NIH/OMB) [units: Participants]			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	36	33	69
More than one race	0	0	0
Unknown or Not Reported	2	2	4

Outcome Measures

Hide All Outcome Measures

1. Primary: Summary of Raw Number of Cumulative Combined Unique Active Lesions in Patients With Relapsing Remitting Multiple Sclerosis by Visit and Treatment [Time Frame: weeks 4,8,12,16,20,24,28]

Measure Type	Primary
Measure Title	Summary of Raw Number of Cumulative Combined Unique Active Lesions in Patients With Relapsing Remitting Multiple Sclerosis by Visit and Treatment
Measure Description	Combined unique active lesions (CUAL) observed on brain MRI scans performed every 4th week from week 4 to week 24 in patients with relapsing-remitting multiple sclerosis (RRMS). CUAL is defined as: new gadolinium (Gd)-enhancing lesions on T1-weighted, or new or enlarging lesions on T2-weighted MRI scans, without double counting.
Time Frame	weeks 4,8,12,16,20,24,28
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

Reporting Groups

	Description
AIN457B	10 mg/Kg IV week 0, 2, 4, 8, 12, 16, and 20
Placebo	Placebo IV week 0, 2, 4, 8, 12, 16, and 20.

Measured Values

	AIN457B	Placebo
Number of Participants Analyzed **[units: participants]**	**38**	**35**
Summary of Raw Number of Cumulative Combined Unique Active Lesions in Patients With Relapsing Remitting Multiple Sclerosis by Visit and Treatment **[units: Combined Unique Active Lesions]** **Mean (Full Range)**		
Week 4 (n=37,34)	**2.4 (0 to 33)**	**3.2 (0 to 16)**
Week 8 (n=36, 31)	**3.9 (0 to 47)**	**5.4 (0 to 27)**
Week 12 (n=35,31)	**5.4 (0 to 80)**	**8.6 (0 to 34)**
Week 16 (n=32,29)	**6.0 (0 to 104)**	**11.5 (0 to 50)**
Week 20 (n=34,27)	**7.7 (0 to 118)**	**13.0 (0 to 51)**

Week 24 (n=32,24)	**7.7 (0 to 122)**	**15.1 (0 to 64)**
Week 28 (n=32,29)	**9.4 (0 to 142)**	**19.9 (0 to 110)**

No statistical analysis provided for Summary of Raw Number of Cumulative Combined Unique Active Lesions in Patients With Relapsing Remitting Multiple Sclerosis by Visit and Treatment

2. Secondary: Raw Number of Cumulative New Gd-T1 Lesions [Time Frame: MRI brain scans performed every 4 weeks at week 4, 8, 12, 16, 20, 24 and 28 (EOS).]

Measure Type	Secondary
Measure Title	Raw Number of Cumulative New Gd-T1 Lesions
Measure Description	The summary of raw number of cumulative new Gadolinium-enhanced T1 lesions observed on brain MRI scans performed every 4th week from WK 4 to WK 28. The end-point is week 24.
Time Frame	MRI brain scans performed every 4 weeks at week 4, 8, 12, 16, 20, 24 and 28 (EOS).
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

Reporting Groups

	Description

AIN457B	10 mg/Kg IV week 0, 2, 4, 8, 12, 16, and 20
Placebo	Placebo IV week 0, 2, 4, 8, 12, 16, and 20.

Measured Values

	AIN457B	Placebo
Number of Participants Analyzed [units: participants]	**38**	**35**
Raw Number of Cumulative New Gd-T1 Lesions [units: cumulative new Gd-T1 lesions] Mean (Full Range)		
Week 4 (n=37,34)	**1.4 (0 to 31)**	**1.7 (0 to 12)**
Week 8 (n= 36,31)	**2.6 (0 to 44)**	**3.0 (0 to 16)**
Week 12 (n=35,31)	**4.3 (0 to 76)**	**5.5 (0 to 26)**
Week 16 (n= 32,29)	**4.0 (0 to 99)**	**7.8 (0 to 36)**
Week 20 (n=34,27)	**5.6 (0 to 112)**	**9.2 (0 to 40)**
Week 24 (n=32,24)	**5.4 (0 to 116)**	**11.1 (0 to 55)**
Week 28 (n=32,29)	**6.5 (0 to 135)**	**14.4 (0 to 99)**

No statistical analysis provided for Raw Number of Cumulative New Gd-T1 Lesions

3. Secondary: Raw Number of Cumulative New Gd-T2 Lesions [Time Frame: MRI brain scans performed every 4 weeks at week 4, 8, 12, 16, 20, 24 and 28 (EOS).]

Measure Type	Secondary
Measure Title	Raw Number of Cumulative New Gd-T2 Lesions
Measure Description	The summary of raw number of cumulative new Gadolinium-enhanced T2 lesions observed on brain MRI scans performed every 4th week from WK 4 to WK 28. The endpoint is week 24.
Time Frame	MRI brain scans performed every 4 weeks at week 4, 8, 12, 16, 20, 24 and 28 (EOS).
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

Reporting Groups

	Description
AIN457B	10 mg/Kg IV week 0, 2, 4, 8, 12, 16, and 20
Placebo	Placebo IV week 0, 2, 4, 8, 12, 16, and 20.

Measured Values

	AIN457B	**Placebo**
Number of Participants Analyzed [units: participants]	**38**	**35**
Raw Number of Cumulative New Gd-T2 Lesions [units: Cumulative new Gd-T2 lesions] Mean (Full Range)		
Week 4 (n= 37,34)	**2.3 (0 to 30)**	**3.1 (0 to 16)**
Week 8 (n=36,31)	**3.6 (0 to 43)**	**5.4 (0 to 28)**
Week 12 (n=35,31)	**5.0**	**8.3**

	(0 to 72)	(0 to 34)
Week 16 (n=32,29)	5.6 (0 to 91)	11.0 (0 to 50)
Week 20 (n= 34,27)	7.2 (0 to 106)	12.3 (0 to 51)
Week 24 (n=32,24)	7.2 (0 to 110)	14.6 (0 to 64)
Week 28 (n=32,29)	8.8 (0 to 126)	19.1 (0 to 110)

No statistical analysis provided for Raw Number of Cumulative New Gd-T2 Lesions

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
PLACEBO	PLACEBO
AIN457 10mg/kg	AIN457 10mg/kg

Serious Adverse Events

	PLACEBO	AIN457 10mg/kg
Total, serious adverse events		
# participants affected / at risk	**0/35 (0.00%)**	**0/38 (0.00%)**

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
PLACEBO	PLACEBO
AIN457 10mg/kg	AIN457 10mg/kg

Other Adverse Events

	PLACEBO	AIN457 10mg/kg
Total, other (not including serious) adverse events		
# participants affected / at risk	**7/35 (20.00%)**	**13/38 (34.21%)**
Blood and lymphatic system disorders		
Leukopenia †1		
# participants affected / at risk	**2/35 (5.71%)**	**0/38 (0.00%)**
Gastrointestinal disorders		
Dyspepsia †1		
# participants affected / at risk	**0/35 (0.00%)**	**2/38 (5.26%)**
Infections and infestations		
Oral herpes †1		

# participants affected / at risk	**0/35 (0.00%)**	**2/38 (5.26%)**
Pharyngitis †1		
# participants affected / at risk	**0/35 (0.00%)**	**2/38 (5.26%)**
Respiratory tract infection viral †1		
# participants affected / at risk	**2/35 (5.71%)**	**2/38 (5.26%)**
Viral infection †1		
# participants affected / at risk	**0/35 (0.00%)**	**2/38 (5.26%)**
Injury, poisoning and procedural complications		
Contusion †1		
# participants affected / at risk	**0/35 (0.00%)**	**2/38 (5.26%)**
Musculoskeletal and connective tissue disorders		
Back pain †1		
# participants affected / at risk	**2/35 (5.71%)**	**1/38 (2.63%)**
Nervous system disorders		
Headache †1		
# participants affected / at risk	**3/35 (8.57%)**	**1/38 (2.63%)**
Paraesthesia †1		
# participants affected / at risk	**0/35 (0.00%)**	**2/38 (5.26%)**
Psychiatric disorders		
Anxiety †1		
# participants affected / at risk	**0/35 (0.00%)**	**2/38 (5.26%)**

† 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 (ie, 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 (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT01051817 History of Changes
Other Study ID Numbers:	**CAIN457B2201** 2009-011626-34
Study First Received:	January 19, 2010
Results First Received:	February 12, 2015
Last Updated:	February 12, 2015
Health Authority:	United States: Food and Drug Administration