Immunogenicity and Safety of Subcutaneously-administered Avonex (Interferon Beta-1a) in Multiple Sclerosis (MS) Patients

This study has been terminated.

(Terminated early by Sponsor for business reasons unrelated to safety.)

Sponsor:
Biogen Idec

Information provided by (Responsible Party):
Biogen Idec

ClinicalTrials.gov Identifier:
NCT00784836

First received: October 29, 2008
Last updated: April 7, 2014
Last verified: April 2014
History of Changes

Results First Received: February 17, 2010

Study Type:	Interventional
Study Design:	Endpoint Classification: Safety Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Multiple Sclerosis
Intervention:	Drug: BG9418 (interferon beta 1-a)

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
The study expected an enrollment of 150 participants, but terminated after 3 were enrolled.

Reporting Groups

	Description
Avonex	Avonex 30 mcg given subcutaneously, once weekly, for 18 months.

Participant Flow: Overall Study

	Avonex
STARTED	3
COMPLETED	0 [1]
NOT COMPLETED	3
Early Study Termination	3

[1] The study was terminated early by the Sponsor for business reason not related to safety.

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
Avonex	Avonex 30 mcg given subcutaneously, once weekly, for 18 months.

Baseline Measures

	Avonex
Number of Participants [units: participants]	3
Age, Customized [units: participants]	
<=18 years	0
Between 18 and 60 years	3
> 60 years	0
Gender [units: Participants]	
Female	2
Male	1

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants Who Developed Neutralizing Antibodies (NAbs) to Interferon-beta (IFN-beta) [Time Frame: assessed every 3 months up to 18 months]

Measure Type	Primary
Measure Title	Number of Participants Who Developed Neutralizing Antibodies (NAbs) to Interferon-beta (IFN-beta)
Measure Description	The presence of antibodies to IFN-beta in human serum, determined using a tiered approach involving a screening Enzyme-Linked ImmunoSorbent Assay (ELISA) to detect binding antibodies (BAbs). Positive samples characterized and titrated in a cell-based neutralizing antibody (NAb) assay.
Time Frame	assessed every 3 months up to 18 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.

The study was terminated early before any of the 3 enrolled subjects completed the study; therefore, no statistical analysis was performed.

Reporting Groups

	Description
Avonex	Avonex 30 mcg given subcutaneously, once weekly, for 18 months.

Measured Values

	Avonex
Number of Participants Analyzed [units: participants]	0
Number of Participants Who Developed Neutralizing Antibodies (NAbs) to Interferon-beta (IFN-beta)	

No statistical analysis provided for Number of Participants Who Developed Neutralizing Antibodies (NAbs) to Interferon-beta (IFN-beta)

2. Secondary: Number of Participants With Adverse Events (AEs) and Serious Adverse Events (SAEs) [Time Frame: Planned for up to 18 months plus 30 days; actual study duration was 111 days.]

Measure Type	Secondary
Measure Title	Number of Participants With Adverse Events (AEs) and Serious Adverse Events (SAEs)
Measure Description	AE: any untoward medical occurrence in a participant that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of an investigational product, whether or not related to the investigational product. SAE: any untoward medical occurrence that at any dose: results in death; in the view of the investigator, places the participant at immediate risk of death (a life-threatening event); requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability/incapacity; or results in a congenital anomaly/birth defect. An SAE may also be any other medically important event that, in the opinion of the investigator, may jeopardize the participant or may require intervention to prevent one of the other outcomes listed in the definition above.
Time Frame	Planned for up to 18 months plus 30 days; actual study duration was 111 days.
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
Avonex	Avonex 30 mcg given subcutaneously, once weekly, for 18 months.

Measured Values

	Avonex
Number of Participants Analyzed [units: participants]	3
Number of Participants With Adverse Events (AEs) and Serious Adverse Events (SAEs) [units: participants]	
AEs	3

SAEs	0

No statistical analysis provided for Number of Participants With Adverse Events (AEs) and Serious Adverse Events (SAEs)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Planned for up to 18 months plus 30 days; actual study duration was 111 days.
Additional Description	No text entered.

Reporting Groups

	Description
Avonex	Avonex 30 mcg given subcutaneously, once weekly, for 18 months.

Serious Adverse Events

	Avonex
Total, serious adverse events	
# participants affected / at risk	0/3 (0.00%)

Other Adverse Events

Hide Other Adverse Events

Time Frame	Planned for up to 18 months plus 30 days; actual study duration was 111 days.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	0%

Reporting Groups

	Description
Avonex	Avonex 30 mcg given subcutaneously, once weekly, for 18 months.

Other Adverse Events

	Avonex
Total, other (not including serious) adverse events	
# participants affected / at risk	3/3 (100.00%)
General disorders	
Injection site reaction * 1	
# participants affected / at risk	1/3 (33.33%)
Influenza like illness * 1	
# participants affected / at risk	2/3 (66.67%)

Investigations	
Hepatic enzyme increased * 1	
# participants affected / at risk	1/3 (33.33%)

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 11.0

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
Early termination with partial data from 3 subjects, therefore, no statistical analysis performed.

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: Our agreement is subject to confidentiality but generally the PI can publish, for noncommercial purposes only, results and methods of the trial, but no other Sponsor Confidential Information. PI must give Sponsor no less than 60 days to review any manuscript for a proposed publication and must delay publication for up to an additional 90 days thereafter if Sponsor needs to file any patent application to protect any of Sponsor's intellectual property contained in the proposed publication.

Results Point of Contact:

Name/Title: Biogen Idec Medical Director
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No publications provided

Responsible Party:	Biogen Idec
ClinicalTrials.gov Identifier:	NCT00784836 History of Changes
Other Study ID Numbers:	108MS303
Study First Received:	October 29, 2008
Results First Received:	February 17, 2010
Last Updated:	April 7, 2014
Health Authority:	United States: Institutional Review Board