A Dose-Frequency Blinded, Multicenter, Extension Study to Determine the Long-Term Safety and Efficacy of PEGylated Interferon Beta-1a (BIIB017) in Subjects With Relapsing Multiple Sclerosis

Published: 09-12-2011
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Primary: To evaluate the long-term safety and tolerability of BIIB017 in subjects originally treated in Study 105MS301 who continue BIIB017 treatment.Secondary: To describe long-term MS outcomes in subjects originally treated in Study 105MS301 who...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Demyelinating disorders
Study type	Interventional

Summary

ID

NL-OMON39656

Source
ToetsingOnline

Brief title
ATTAIN / 105MS302

Condition

- Demyelinating disorders

Synonym
Relapsing Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Biogen Idec LTD
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: Extension, Interferon, MS, PEGylated

Outcome measures

Primary outcome

Primary endpoints: The incidence of adverse events (AEs), serious AEs (SAEs),

and discontinuations of study treatment due to an AE, as well as the incidence

of laboratory abnormalities.

Secondary outcome

Secondary endpoints: Secondary endpoints include MS relapse outcomes, MRI

outcomes, disability outcomes, Quality of Life (QoL), and other outcomes

assessed over the 2-year period of the study.

Study description

Background summary

The purpose of this Extension Study is to determine the long-term safety, tolerability, and MS outcomes of BIIB017 in subjects completing Study 105MS301 (ADVANCE). Subjects will administer 125 mcg BIIB017 subcutaneously (SC) at 2 dose frequencies: every 2 weeks or every 4 weeks. In this extension study, subjects will continue to administer BIIB017 at the same dose regimen they were following during their participation in the second treatment year of Study 105MS301.
Once results from Study 105MS301 are available, the dose frequencies studied in this extension study may be modified.

Study objective

Primary: To evaluate the long-term safety and tolerability of BIIB017 in subjects originally treated in Study 105MS301 who continue BIIB017 treatment.

Secondary: To describe long-term MS outcomes in subjects originally treated in Study 105MS301 who continue BIIB017 treatment.

Study design

Multicenter, parallel-group, dose-frequency blinded study

Intervention

Group 1: subjects will receive 125 mcg BIIB017 SC every 2 weeks for 96 weeks
Group 2: subjects will receive 125 mcg BIIB017 SC every 4 weeks for 96 weeks

Study burden and risks

Summary of procedures:

4x Physical Examination
7x Blood pressure and pulse
3x MRI
5x EDSS
4x Symbol Digit Modalities Test
4x Quality of Life Questionnaires
6x BDI-II questionnaire

Patients will keep a patient diary up to date.

No serious side effects of the study drug were reported in the healthy volunteer studies (see Addendum III).

The side effects seen in clinical studies of BIIB017 in patients with MS are as follows:

Very common (at least 1 in 10 people reported these symptoms if they had taken BIIB017 for 1 year). This means that you may have at least a 10% chance of having any of these symptoms if you take BIIB017.

* Injection site redness (erythema)
* Headache
* Flu-like illness
* Fever (pyrexia)
* Feeling weak (asthenia)

* Injection site itching
* Muscle pain (myalgia)
* Joint pain (arthralgia)
* Chills
* Back pain
* Injection site pain

Common (fewer than 1 in 10 people, but more than 1 in 100 people reported these symptoms if they had taken BIIB017 for 1 year). This means that you may have less than a 10% chance of having any of these symptoms if you take BIIB017.

* Increased body temperature (hyperthermia)
* Increased liver enzymes
* Vomiting
* Nausea
* Injection site warmth
* Injection site hematoma
* Injection site rash
* Pain
* Sleepiness (somnolence)
* Urinary tract infection
* Oral herpes
* Itching (pruritus)
* Injection site swelling (edema)
* Feeling unwell (malaise)
* Swollen lymph nodes (lymphadenopathy)

Serious side effects. The following serious side effects have been reported in the ongoing studies of BIIB017 in patients with MS:

* Liver failure
* Increased level of liver tests (bilirubin, alanine aminotransferase, asparate aminotransferase)
* Blood clot in the leg veins
* Malnutrition
* Pneumonia
* Partial paralysis
* Low platelet level (thrombocytopenia)
* Seizure
* Swelling of the skin
* Miscarriage
* Injection site redness
* Injection site pain
* Constipation
* Stomach swelling (abdominal distension)
* Blood infection (sepsis)
* Cancer of the lip and/or mouth

* Fever with decreased neutrophils (febrile neutropenia)
* Skin inflammation with death of the tissue (gangrenous cellulitis)
* Increased body temperature
* Infected bed sore (infected skin ulcer)
* Urinary tract infection
* Viral infection of the ear (herpes zoster oticus)
* Bipolar disorder

Other possible side effects:
-Liver injuries: Liver injury, including abnormal liver tests, hepatitis and inflammation of the liver (autoimmune hepatitis) and rare cases of severe liver failure have been reported with interferon beta (a drug that is similar to BIIB017). Abnormal liver tests and liver injury have been observed with the use of BIIB017.
-Depression and suicide
-Allergic reactions
-Injection site reactions
-Decreased blood cells
-Seizure
-Heart disease

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Subjects who participated in Study 105MS301, who completed the study treatment and visit schedule through Week 96.

Exclusion criteria

1. Subjects exceeding more than 6 weeks since completion of the Week 96 visit of Study 105MS301.
2. Subjects with any significant change in medical history, including laboratory tests, or a current clinically significant condition that in the opinion of the Investigator would have excluded the subject from participation in Study 105MS301. The Investigator must re-review the subject*s medical fitness for participation and consider any factors that would preclude treatment including:
* Presence of any clinically significant (as determined by the Investigator) cardiac, endocrinologic, hematologic, hepatic, immunologic, metabolic, urologic, pulmonary, neurologic, dermatologic, psychiatric, renal, or other major disease that would preclude participation in a clinical study.
* Presence of malignant disease, including solid tumors and hematologic malignancies (with the exception of basal cell and squamous cell carcinomas of the skin that have been completely excised and are considered cured).
* Clinically significant laboratory abnormalities (hematology and blood chemistry) on the most recently available test of Study 105MS301, as determined by the Investigator. Laboratory findings mandating discontinuation of study treatment as defined in protocol 105MS301 are exclusionary.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-07-2012
Enrollment:	11
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	PEGylated interferon beta-1a
Generic name:	-

Ethics review

Approved WMO Date:	09-12-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	11-04-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-06-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-01-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

	Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-02-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-03-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-11-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-11-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	11-02-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-02-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-05-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-06-2014

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-07-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-08-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	30-12-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-01-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-04-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2010-024477-39-NL
ClinicalTrials.gov	NCT01332019
CCMO	NL37071.068.11