BENEFIT 11 a long-term, follow-up study (16401) of the BENEFIT (304747), BENEFIT Follow-up (305207) Studies and BENEFIT Extension (311129) Study to further evaluate the progress of patients with first demyelinating event suggestive of multiple sclerosis

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Demyelinating disorders
Study type	Observational invasive

Summary

ID

NL-OMON38856

Source
ToetsingOnline

Brief title
BENEFIT 11

Condition

- Demyelinating disorders

Synonym
MS - progress observation MS

Research involving
Human

Sponsors and support

Primary sponsor: Bayer
Source(s) of monetary or material Support: Bayer

Intervention

Keyword: Follow-up, Long term, Multiple Sclerosis

Outcome measures

Primary outcome

The primary objectives are to describe the disease course (conversion to clinically-definite multiple sclerosis [CDMS]), change in disability, cognitive function, resource use, and employment status, in relation to treatment with Interferon beta-1b.

Secondary outcome

The secondary objectives are to assess MRI and OCT parameters, treatment history, quality of life (QoL) parameters and depression, the choice of MS-specific medication, and to investigate tolerability of Interferon beta-1b in the full former clinically-isolated syndrome (CIS) cohort as well as in subgroups of patients.

Study description

Background summary

The objective of this study is to obtain clinical long-term data, magnetic

resonance imaging (MRI), and optic coherence tomography (OCT) information after early or delayed interferon-beta-1b treatment in patients with a first demyelinating event suggestive of multiple sclerosis (MS) enrolled in the Betaferon®/Betaseron® in Newly Emerging Multiple Sclerosis for Initial Treatment (BENEFIT) study (304747) for an average of 11 years after their first clinical event. An integrated statistical analysis will include data from the BENEFIT (304747), the BENEFIT follow-up (305207), and the BENEFIT extension (311129) studies, and this BENEFIT 11 study (16401).

Study objective

The primary objectives are to describe the disease course (conversion to clinically-definite multiple sclerosis [CDMS]), change in disability, cognitive function, resource use, and employment status, in relation to treatment with Interferon beta-1b.
The secondary objectives are to assess MRI and OCT parameters, treatment history, quality of life (QoL) parameters and depression, the choice of MS-specific medication, and to investigate tolerability of Interferon beta-1b in the full former clinically-isolated syndrome (CIS) cohort as well as in subgroups of patients.

Study design

Multicenter, international, cross-sectional, interventional, observational follow-up study in MS patients
This observational study may include all patients who were randomized into and treated at least once in the BENEFIT Study 304747, inclusive of patients who prematurely discontinued study participation in that study, and Studies 305207 or 311129, and patients who did not transfer from Study 304747 to Study 305207 as well as patients who did not participate in Study 311129.
In this study, one (and up to four, if required, for MRI and OCT assessments) clinical visits are planned. In addition to the clinical assessment, a telephone based assessment has been added to allow for more complete inclusion of all patients. The telephone-based, validated assessment will capture a small number of key outcome variables exclusively for patients who are unable to visit the site in-person, and will be performed by the investigator*s staff.

Study burden and risks

Regular face-to-face site visit
Variables of primary interest:
* Relapses
* Conversion to CDMS, to MS by McDonald criteria (2001, 2010), and / or to secondary progressive multiple sclerosis (disease course)
* Expanded Disability Status Scale (EDSS) including DSS 3 and 6 information, Multiple Sclerosis Functional Composite (MSFC) (disability and disability

progression) and Multiple Sclerosis Severity Score (MSSS)
* Paced Auditory Serial Addition Test and Symbol Digit Modalities Test (cognitive function)
* Resource use and vocational status

Variables of secondary interest:
* Diagnosis and disease course
* MRI parameters
* OCT parameters
* Visual acuity and ophthalmological findings
* Center of Epidemiological Studies Depression Scale (CES-D) (Depression)
* Fatigue Scale for Sensory and Motor Fatigue (Fatigue)
* Choice of and adherence to MS-specific medication
* Functional Assessment of Multiple Sclerosis (FAMS), and European Quality of Life * 5 Dimensions (EQ-5D) (QoL)
* Deoxyribonucleic acid [DNA], ribonucleic acid [RNA], biomarkers
* Vitamin D

Telephone assessment for patients unable to visit site with selected outcomes
* Relapses
* Telephone EDSS [Error! Reference source not found.]
* Conversion to CDMS (disease course)
* Resource use and vocational status
* Choice of and adherence to MS-specific medication
* CES-D (Depression)
* FAMS, EQ-5D (QoL)

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. Male and female patients with CIS or MS who have been treated at least once in BENEFIT Study 304747.
2. Patients who do not qualify for one or more interventional assessments (eg, MRI due to severe claustrophobia) are invited to participate in the other assessments of this study.
3. Written informed consent

Exclusion criteria

1. Patients who meet any of the following criteria at the time of screening will be excluded from the study:
* Patients who, according to the investigator*s judgment, have medical, psychiatric, or other conditions that compromise the patient*s ability to understand the purpose of the study
2. Patients who meet any of the following criteria at the time of screening will be excluded from interventional MRI assessment. However, they should be encouraged to still participate in the study:
* Pregnant or nursing (including pumping for storage and feeding)
* Contraindications to MRI examination (eg, inability to hold breath, severe arrhythmias, very low cardiac output, severe claustrophobia, or patients with implanted defibrillators or other metallic devices not approved for MRI)
3. Patients who meet any of the following criteria at the time of screening will be excluded from contrast media administration. However, they may undergo MRI assessment:
* Contraindication to the use of Gadobutrol-containing contrast agents (including patients who are suspected for or known to have nephrogenic systemic fibrosis).
History of severe (as judged by the investigator, taking into account the intensity of the event) allergic or anaphylactoid reaction to any allergen, including drugs and contrast agents

* Received any contrast agent within 72 hours prior to the study magnetic resonance angiography (MRA), or scheduled to receive any contrast agent within 72 hours after the study MRA. This also applies to any computed tomography angiogram (CTA) scheduled during the course of the study.
* Renal insufficiency, defined by baseline glomerular filtration rate, estimated value
* 30 mL/min/1.73 m2 derived from a serum creatinine result within 2 weeks prior to gadobutrol injection needed. Any patient on hemodialysis or peritoneal dialysis is excluded from contrast media administration. If there are multiple creatinine values, the values obtained prior to and closest to the time of the MRA should be used. The core lab value should not be used if not available prior to the MRA/CTA.
* Acute renal insufficiency of any intensity, either due to hepato-renal syndrome or occurring in the perioperative liver transplantation period
* Known history of severe cardiovascular disease (eg, acute myocardial infarction [< 14 days], unstable angina, congestive heart failure New York Heart Association Class IV) or known prolonged QT syndrome
* Suspected clinical instability or unpredictability of the clinical course during the study (eg, due to previous surgery or acute stroke)

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	1
Type:	Anticipated

Ethics review

Approved WMO

Date:	22-07-2013

Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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
CCMO	NL44539.096.13