BETAEVAL GLOBAL- The new BETACONNECT auto-injector: Adherence and EVALuation of MS patients treated with Betaferon®

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To better understand the utilities of the new BETACONNECT device and characterize its contribution to adherence, we plan to prospectively follow-up MS patients using the device for 24 weeks.

Ethical review	Not approved
Status	Will not start
Health condition type	Demyelinating disorders
Study type	Interventional

Summary

ID

NL-OMON42023

Source
ToetsingOnline

Brief title
BETAEVAL GLOBAL

Condition

- Demyelinating disorders

Synonym
multiple sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Bayer

Source(s) of monetary or material Support: Bayer

Intervention

Keyword: Adherence, Auto-injector, MS patients

Outcome measures

Primary outcome

Primary outcome is the adherence to therapy at the final visit among patients who are using the BETACONNECTTM autoinjector.

Secondary outcome

Satisfaction with and evaluation of the BETACONNECT auto-injector. Satisfaction with and evaluation of the BETACONNECT auto-injector will be recorded with the patient questionnaire

Injection site pain and prophylactic analgesic use. Injection site pain and prophylactic analgesic use will be recorded with the patient questionnaire.

Health related quality of life. Health related quality of life will be measured with the self-administered Functional Assessment of Multiple Sclerosis (FAMS) questionnaire.

Anxiety Anxiety will be measured with the self-administered Hospital anxiety and depression scale (HADS).

Depression. Depression will be mesured with the self-administered Center of Epidemiologic Studies Depression Scale (CES-D).

Fatigue. Fatigue will be measured with the self-administered Fatigue Scale for Motor and Cognitive Functions (FSMC).

Cognition. Cognition will be measured by the HCP with the Symbol Digits Modalities Test (SDMT).

Local skin reactions. Local skin reactions will be recorded by HCP evaluation (local inspection).

Injection-related specifics. Injection-related specifics such as injection date, time, and speed will be recorded by the BETACONNECT device.

Study description

Background summary

Considering the significance of an early and consequent Multiple Sclerose (MS) treatment as well as the challenge to achieve high adherence to treatment, evaluating benefits of any new measure to improve adherence is important. The data storage capabilities of the BETACONNECT device, including automated recording of injections will facilitate the collection of reliable data on patient's injection behavior and adherence, which should be unaffected by recall bias and reporting bias.

Study objective

To better understand the utilities of the new BETACONNECT device and characterize its contribution to adherence, we plan to prospectively follow-up MS patients using the device for 24 weeks.

Study design

This is a prospective, international, non-interventional, multi-center, observational cohort study that will be conducted in neurological centers and

neurology departments in different European countries and New Zealand specialized in the treatment of MS patients

Intervention

not applicable

Study burden and risks

There are no additional risks for the patient in this study (it concerns use of Betaferon® and the BETACONNECT-autoinjector in daily practice setting).

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

Patients with the diagnosis of relapsing multiple sclerosis (RRMS) or a clinically isolated syndrome (CIS)
Patients must be on treatment with Betaferon or the decision to treat a patient with Betaferon has been made by the attending physician
Patient and the attending physicians must have agreed on the usage of the BETACONNECT auto-injector device.
Written informed consent must be obtained.

Exclusion criteria

Patients receiving any other disease modifiying drug.
Contraindications of Betaferon as described in the Summary of Product Chatacteristics.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	19
Type:	Anticipated

Medical products/devices used

Generic name:	BETACONNECT autoinjector
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	02-09-2015
Application type:	First submission
Review commission:	METC Atrium-Orbis-Zuyd

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
ClinicalTrials.gov	NCT02247310
CCMO	NL52505.096.15