BETAPREDICT - MS patients treated with BETAferon®: PREDICTors of treatment adherence

First published: 14/07/2015

Last updated: 05/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS10249

Study ID

39640

DARWIN EU® study

No

Study countries

Germany

Study description

This study aims to evaluate potential predictors of adherence by investigating a representative cohort of MS patients in Germany treated with Betaferon

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 35 centres are involved in the study

Contact details

Study institution contact

Bayer Clinical Trials Contact Bayer AG clinical-trials-contact@bayer.com

Study contact

clinical-trials-contact@bayer.com

Primary lead investigator

Bayer Clinical Trials Contact Bayer AG

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 15/07/2015

Actual: 15/07/2015

Study start date
Planned: 15/08/2015

Actual: 08/09/2015

Date of final study report
Planned: 01/11/2020

Actual: 09/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer

Study protocol

18016_Protocol.pdf (570.34 KB)

18016_Study Protocol_Redacted_V1.0_2015-02-12.pdf (540.42 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Identification of predictors for adherence

Data collection methods:

Primary data collection

Main study objective:

This study aims to evaluate potential predictors of adherence by investigating a representative cohort of MS patients in Germany treated with Betaferon

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

BETAFERON

Study drug International non-proprietary name (INN) or common name

INTERFERON BETA-1A

INTERFERON BETA-1B

Anatomical Therapeutic Chemical (ATC) code

(L03AB08) interferon beta-1b

interferon beta-1b

Medical condition to be studied

Multiple sclerosis

Population studied

Short description of the study population

The study population will consist of male & female patients with relapsing remitting multiple sclerosis (RRMS) or patients with a clinically isolated syndrome (CIS) who are treated with Betaferon® or will be treated with Betaferon® and are willing to use the BETACONNECTTM autoinjector according to the attending physician’s decision.

Inclusion criterion/criteria
- Patients aged ≥ 18 years with the diagnosis of relapsing remitting multiple sclerosis or a clinically isolated syndrome.
- Patients must be on treatment with Betaferon® or the decision to treat patients with Betaferon® has been made by the attending physician.
- Patients must be using or willing to use the BETACONNECTTM autoinjector for Betaferon® application.
- Written informed consent must be obtained.

Exclusion criterion/criteria
- Patients receiving any other disease modifying drug.
- Contraindications of Betaferon® described in the Summary of Product Characteristics.
- Patients participating in any other clinical or non-interventional study, evaluating MS therapy.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Immunocompromised

Estimated number of subjects

250

Study design details

Outcomes

Compliance to therapy (%)Persistence of therapy (Yes or No)Overall adherence to therapy (Yes or No), Satisfaction with the BETACONNECT autoinjector, recorded by the patient questionnaireAdherence to Betaferon treatment is associated with: depression, health related quality of life, coping mechanisms, self-management mechanisms, social support, fatigue, and cognition. (Yes or No)Adherence to Betaferon treatment is associated with number of relapses (Yes or No)

Data analysis plan

All variables will be analyzed descriptively with appropriate statistical methods: categorical variables by frequency tables and continuous variables by sample statistics (i.e. mean, standard deviation, minimum, median, quartiles and maximum). Continuous variables will be described by absolute value and as change from baseline per analysis time point. All analyses will be performed for the total study population or when defined otherwise within a valid subpopulation. Patients receiving at least one dose of Betaferon will be included in the analysis. Whenever reasonable, data will be stratified by subgroups.For the analyses of our primary outcome compliance we will use descriptive statistics to characterize compliance. This will include a stratified analysis according to the patients' pre-study experience with the BETACONNECTTM.We will then investigate the association between baseline covariates and compliance in percentage using Analysis of Variance and linear regression.

Documents

Study results

18016_EU PAS Abstract_Redacted_V1.0_2020-12-09.pdf (1.81 MB)

Study report

18016_Study_Report_Redacted_V1.0_2020-12-09.pdf (6.77 MB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No