

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

**First published:** 14/07/2015

**Last updated:** 05/04/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/39640>

### 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

Study contact

[clinical-trials-contact@bayer.com](mailto: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

### **Name of medicine**

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 BETACONNECT™ autoinjector according to the attending physician's decision.

#### Inclusion criterion/criteria

- Patients aged  $\geq 18$  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 BETACONNECT™ 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 questionnaire Adherence 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 BETACONNECT<sup>TM</sup>. 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

## Data management

### 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