Subcutaneous Interferon beta therapy in multiple sclerosis patients and characterization of injection site reactions and flu-like symptoms under daily practice setting (PERFECT)

First published: 22/11/2017

Last updated: 02/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/36739

EU PAS number

EUPAS21013

Study ID

36739

DARWIN EU® study

No

Study countries

Germany

Study description

The purpose of this study is to investigate the safety of subcutaneous (SC) interferon beta therapies with regard to frequency of injection site reactions (ISR) and flu-like symptoms (FLS) as reported by the relapsing-remitting multiple sclerosis (RRMS) participants.

Study status

Finalised

Research institutions and networks

Institutions

Biogen

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 54 centres are involved in the study

Contact details

Study institution contact

Study Director Biogen

Study contact

CTRR@biogen.com

Primary lead investigator

Study Director Biogen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/12/2017

Actual: 31/12/2017

Study start date

Planned: 31/12/2017

Actual: 16/11/2017

Data analysis start date

Planned: 30/08/2019

Date of final study report

Planned: 31/12/2019

Actual: 16/06/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Biogen

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

GER-PEG-16-10988

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The purpose of this study to investigate the safety of subcutaneous (SC) interferon beta therapies with regard to frequency of injection site reactions (ISR) and flu-like symptoms (FLS) as reported by the relapsing-remitting multiple sclerosis (RRMS) participants.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Post-authorization safety study

Study drug and medical condition

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

INTERFERON BETA-1A

INTERFERON BETA-1B

Medical condition to be studied

Relapsing-remitting multiple sclerosis

Population studied

Short description of the study population

Adult relapsing-remitting multiple sclerosis (RRMS) patients receiving a Subcutaneous (SC) Interferon beta therapy.

Inclusion criteria

• Ability to understand the purpose of the study and provide signed and dated informed consent

• At least 18 years at time of informed consent

• Diagnosed relapsing-remitting multiple sclerosis

• Currently receiving a SC Interferon beta treatment (label conform)

• Stable on SC Interferon beta treatment for three months or longer (switch between SC Interferon beta treatments possible)

Exclusion criteria

• Contraindications according to the “Fachinformation” (German equivalent to Summary of Product Characteristics [SmPC])

• Therapy with Glatiramer acetate or intramuscular (IM) Interferon beta-1a

• Participation in a non-interventional or interventional clinical study of Biogen

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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

Other

Special population of interest, other

Relapsing-remitting multiple sclerosis patients

Estimated number of subjects

626

Study design details

Outcomes

• Percentage of Participants with at Least one Injection Site Reaction (ISR) as Reported by the Participants• Percentage of Participants with at Least one Flu-like Symptoms (FLS) as Reported by the Participants, Participants with at Least 1 ISR (FLS), Types of ISR, Duration and Time of Occurrence of ISR Reported by Participants, Nurses, and PhysicianInterference Score of ISR With Participant’s Daily ActivitiesParticipants Taking Actions to Relieve the ISR (FLS) and Resulting in Relief of ISR/FLSParticipants With Reducing/Increasing Frequency and Intensity of ISR/FLS Compared to Previous Therapy

Data analysis plan

All documented data are analyzed by descriptive statistics, that is, no formal statistical hypothesis will be formulated and no statistical tests will be carried out. All analyses will be performed based on the data set of patients who were eligible for participation according to inclusion criteria and completed the

questionnaire. If a patient omits a specific question, he will be set to missing in all analyses referring to this question. No data imputation will be performed.

Documents

Study results

GER-PEG-16-10988_CSR Synopsis_16-Jun-2020.pdf(267.14 KB)

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