Non-interventional Safety Study to Investigate Pregnancy Outcomes in Female Patients Exposed to SC Peginterferon Beta-1a and IM Interferon Beta-1a Reported in a German Patient Support Program

First published: 30/11/2020

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Study Finalised

Administrative details

EU PAS number

EUPAS38347

Study ID

49260

DARWIN EU® study

No

Study countries

☐ Germany

Study description

The primary objective(s) of the study is to evaluate the impact of exposure to SC Peginterferon beta-1a or IM Interferon beta-1a before and during pregnancy on pregnancy outcome in female participants who had registered in the German Patient Support Program (PSP) and of whom a pregnancy report and pregnancy outcome report is available. The secondary objectives of this study are applicable for a subpopulation of the above-mentioned population, i.e. for participants of whom data on a standardized questionnaire collected during a telephone interview is available.

Study status

Finalised

Research institutions and networks

Institutions

Biogen

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Institution

Contact details

Study institution contact

Study Director Biogen ctrr@biogen.com

Study contact

ctrr@biogen.com

Primary lead investigator

Study Director Biogen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/10/2020

Actual: 09/12/2020

Study start date

Planned: 30/04/2021

Actual: 01/05/2021

Date of final study report

Planned: 15/12/2021

Actual: 08/07/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Biogen

Study protocol

PRIMA_Phase 4 Observational PASS Protocol_V1.0_final_20201007_Redacted.pdf
(907.26 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

Other study registration identification numbers and links

DE-PEG-11650

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The primary objective(s) of the study is to evaluate the impact of exposure to SC Peginterferon beta-1a or IM Interferon beta-1a before and during pregnancy on pregnancy outcome in female participants who had registered in the German Patient Support Program (PSP) and of whom a pregnancy report and pregnancy outcome report is available.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Voluntary, post-authorization safety study

Study drug and medical condition

Name of medicine

AVONEX

PLEGRIDY

Medical condition to be studied

Multiple sclerosis

Pregnancy

Population studied

Short description of the study population

Female participants diagnosed with multiple sclerosis, aged at least 18 years treated with subcutaneous peginterferon beta-1a therapy or intramuscular interferon beta-1a therapy enrolled in the Patient Support Program (PSP) of Biogen’s German MS Service-Center (MSSC).

Inclusion criteria:

• Female patients of at least 18 years at time of informed consent

• Diagnosed RRMS or CIS (CIS indication only applicable for interferon beta-1a)

• Exposure to either SC Peginterferon beta-1a therapy or IM Interferon beta-1a therapy before or during pregnancy

• Registered in the PSP of the MSSC and agreed in writing to the privacy policy of the registration form

• Reported pregnancy data (pregnancy report and pregnancy outcome report) available at MSSC. Note: only pregnancy data (i.e. obtained until 15 October 2020) will be considered

For the prospective part of the study:

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

study-specific informed consent form (ICF)

• Pregnancy outcome in the retrospectively collected data was a live birth

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

Pregnant women

Special population of interest, other

Multiple Sclerosis patients

Estimated number of subjects

470

Study design details

Outcomes

Percentage of Subjects With Live Births Without Congenital Anomalies, Percentage of Subjects With Live Births With Congenital Anomalies, Percentage of Subjects With Ectopic Pregnancies, Percentage of Subjects With Spontaneous Abortions, Percentage of Subjects With Elective Abortions, Percentage of Subjects With Preterm Births, Percentage of Subjects With Stillbirths. To evaluate exposure to SC Peginterferon beta-1a or IM Interferon beta-1a: before

and during pregnancy on child development, treatment behavior for pregnant women in daily real life, other MS treatment behavior and use of certain concomitant medications taken during/after pregnancy, on MS disease activity, effect of breastfeeding and benefit of exclusive breastfeeding versus complementary feeding.

Data analysis plan

All documented data are analyzed by descriptive statistics, i.e. absolute frequencies and percentages for categorical variables and mean, standard deviation and percentiles for continuous variables. No formal statistical hypothesis will be formulated, and no statistical tests will be carried out.

Documents

Study results

CSR_PASS_PRIMA_V1.0_Final_2022-05-11_signed.docx_Redacted.pdf(327.32 KB)

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

Study with focus on retrospective and prospective parts. Main data source for the retrospective data will be captured from MSSC database, i.e. the entered pregnancy report and pregnancy outcomes report. Prospective data will be captured as standardized ePDF questionnaire completed during telephone interview.

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