Biogen Idec Multiple Sclerosis Pregnancy Exposure Registry

First published: 07/05/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS3976

Study ID

48161

DARWIN EU® study

No

Study countries

- ☐ Australia
- ☐ Canada
- ☐ France
- ☐ Germany
- ☐ Ireland
- ☐ Italy

- [ ] Poland
- [ ] Spain
- [ ] United Kingdom
- [ ] United States

Study description

The primary objective of the study is to prospectively evaluate pregnancy outcomes in women with multiple sclerosis (MS) who were exposed to a Registry-specified Biogen Multiple Sclerosis product during the eligibility window for that product. The Registry-specified Biogen MS products being studied are dimethyl fumarate and and peginterferon beta-1a. The secondary objective is to prospectively evaluate pregnancy outcomes in women with MS who were unexposed to disease-modifying therapy (DMTs).

Study status

Finalised

Research institutions and networks

Institutions

Biogen

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Institution

Multiple centres: 17 centres are involved in the study

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: 03/06/2013

Actual: 21/06/2013

Study start date

Planned: 03/06/2013

Actual: 30/10/2013

Date of final study report

Planned: 18/07/2029

Actual: 18/01/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Biogen

Study protocol

109MS402 EU V5 Protocol_Redacted.pdf(1.75 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

109MS402 NCT01911767

https://clinicaltrials.gov/ct2/show/NCT01911767?term=109ms402&rank=1

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

Pregnancy Exposure Registry

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The primary objective of the study is to prospectively evaluate pregnancy outcomes in women with multiple sclerosis who were exposed to a Registry-specified Biogen Multiple Sclerosis product during the eligibility window for that product. The Registry-specified Biogen MS products being studied are dimethyl fumarate and peginterferon beta-1a.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective, observational registry

Study drug and medical condition

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

DIMETHYL FUMARATE

PEGINTERFERON BETA-1A

Medical condition to be studied

Exposure during pregnancy

Multiple sclerosis

Population studied

Short description of the study population

The study population included pregnant women diagnosed with multiple sclerosis (MS) who were exposed to a registry-specified Biogen MS product or who were unexposed to DMTs during the eligibility window for that product.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Other

Pregnant women

Special population of interest, other

Patients with multiple sclerosis

Estimated number of subjects

1125

Study design details

Outcomes

Pregnancy loss: elective or therapeutic pregnancy terminations, spontaneous abortions (<22 weeks of gestation), fetal death/stillbirths (fetuses born dead at >=22 weeks of gestation), further classified as early fetal loss (fetal death occurring at >=22 weeks but <28 weeks of gestation) or late fetal loss. Live birth: premature or full-term birth (delivered <37 weeks or >=37 weeks respectively).

Data analysis plan

All cases will be reviewed based on earliest exposure within the associated eligibility window to a Registry-specified Biogen MS product. If a patient is exposed to multiple Registry-specified Biogen MS products within the product's eligibility window, the case will be reviewed based on the earliest exposure. The Coordinating Center and Biogen Safety and Benefit-Risk Management will carefully review each pregnancy outcome and the calculations of risks of negative pregnancy outcomes. The prevalence of birth defects and spontaneous abortions and 95% confidence intervals (CIs) for the Registry population will be calculated to assess the presence or absence of any excessive risk associated with exposure to a Registry-specified Biogen MS product. All analyses will be conducted on an overall basis, as well as stratified by earliest trimester exposure. Other negative pregnancy outcomes will be similarly examined as sample size in each cohort permits.

Documents

Study results

109MS402 CSR Synopsis V1 PASS Final_18Jan2023_Redacted.pdf(253.79 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Post-marketing setting -Other clinical studies for a Registry-specified Biogen MS product (patients may be dually enrolled in a clinical study and in the registry)

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