International LEMTRADA Pregnancy Exposure Cohort in Multiple Sclerosis (OBS13436)

First published: 08/10/2014

Last updated: 16/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7574

Study ID

50049

DARWIN EU® study

No

Study countries

- ☐ Australia
- ☐ Austria
- ☐ Belgium
- ☐ Canada

- [ ] Denmark
- [ ] Germany
- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom
- [ ] United States

Study description

A voluntary post authorization safety study (PASS). An international, prospective, observational cohort study (registry) of pregnancy outcomes in women with multiple sclerosis exposed to LEMTRADA during pregnancy. The overall goal of the study is to evaluate pregnancy outcomes in women exposed to LEMTRADA during pregnancy and to determine if the risk of any adverse pregnancy outcomes in these women exceeds the risks in women with MS who have not been exposed to LEMTRADA during pregnancy. Specific outcomes to be assessed include: spontaneous abortion, stillbirth, fetal major malformations, preterm birth, and small for gestational age at birth. To further characterize prenatally-exposed live births, outcomes in the neonatal and pediatric periods up to one year of age will be assessed pending available data.

Study status

Finalised

Research institutions and networks

Institutions

Sanofi

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Trial Transparency Team Trial Transparency Team contact-US@sanofi.com

Study contact

contact-US@sanofi.com

Primary lead investigator

Trial Transparency Team Trial Transparency Team

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/09/2014

Actual: 08/09/2014

Study start date

Planned: 30/11/2014

Actual: 01/09/2015

Date of final study report
Planned: 04/11/2022

Actual: 09/11/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Genzyme a Sanofi Company

Study protocol

rdct-obs13436-amended-protocol02-pdfa.pdf(489.47 KB)

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)

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:

To assess adverse pregnancy outcomes in women exposed to LEMTRADA during pregnancy. Pregnancy outcomes assessed will include: spontaneous abortion, stillbirth, fetal major malformations, preterm birth, and small for gestational age at birth.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

International, observational registry

Study drug and medical condition

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

ALEMTUZUMAB

Medical condition to be studied

Multiple sclerosis

Population studied

Short description of the study population

Pregnant women with multiple sclerosis (MS) who had any pregnancy exposure to LEMTRADA between 10 August 2015 and 22 November 2021 from North America, Europe, and the rest of the world.

Inclusion criteria:

- Women with MS who were or became pregnant within the period of time between the first
infusion of a course of treatment with LEMTRADA to 4 months after their last infusion for
that course.
- Able and willing to provide informed consent for study participation and the requirement
of the study. Informed consent will be obtained at the time of enrollment in accordance
with local regulatory requirements.

Exclusion criteria:

- Previous enrollment in this study for a previous pregnancy.

Age groups

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

42

Study design details

Outcomes

To determine if the risk of any adverse pregnancy and fetal outcomes in women exposed to LEMTRADA exceeds the risks in women with MS who have not been exposed to LEMTRADA during pregnancy. To further characterize prenatally-exposed live births, outcomes in the neonatal and pediatric periods up to one year of age, which will be assessed pending available data.

Data analysis plan

Rates and 95% confidence intervals (CI) of pregnancy outcomes for women exposed to LEMTRADA during pregnancy will be calculated. These rates will be compared with corresponding rates in a primary external comparison cohort of women with MS who have not been exposed to LEMTRADA during pregnancy.

Documents

Study results

rdct-obs13436-csr-abstract-pdfa.pdf(740.04 KB)

Data management

Data sources

Data sources (types)

Drug 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