An International Pregnancy Exposure registry of Women With Multiple Sclerosis (MS) exposed to Teriflunomide (OBS12751)

First published: 21/01/2014

Last updated: 25/06/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/43003

EU PAS number

EUPAS5602

Study ID

43003

DARWIN EU® study

No

Study countries

☐ Australia

- [ ] Austria
- [ ] Belgium
- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Ireland
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

Study description

This is a voluntary, international, prospective, observational, non-interventional, exposure registration study examining the risk of major congenital malformations (birth defects) among the infants and fetuses of women with MS who are exposed to teriflunomide during pregnancy. The birth defect rate will be compared to published birth defect rates from the EUROCAT (EUROCAT, 2013).

Study status

Finalised

Research institutions and networks

Institutions

Syneos Health

United Kingdom

First published: 23/04/2015

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

INC Research

Contact details

Study institution contact

team Transparency

Study contact

contact-us@sanofi.com

Primary lead investigator

Stéphanie Tcherny-Lessenot

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/06/2013

Actual: 28/06/2013

Study start date
Planned: 31/01/2015

Actual: 25/11/2015

Date of final study report
Planned: 30/09/2023

Actual: 31/07/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Study protocol

rdct-obs12751-amended-protocol03-pdfa.pdf(1.85 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)

Methodological aspects

Study type

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:

Primary data collection

Main study objective:

This registry aims to monitor pregnancies among women with MS who were inadvertently exposed to teriflunomide during pregnancy to evaluate the risk of birth defects in their infants and fetuses. In addition, the registry will evaluate the potential impact of prenatal teriflunomide exposure on pregnancy and infant health, growth, and development.

The primary objective of this registry is:

-To compare the rate of birth defects (major congenital malformations diagnosed up to one year of age, fetal deaths occurring at 20 gestation weeks or later, and termination of pregnancy for fetal anomaly following prenatal diagnosis (TOPFA)) with the rate of the same birth defects reported by the European Surveillance of Congenital Anomies (EUROCAT), a population based birth defect surveillance system.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Voluntary, international, prospective, observational, exposure registration study

Study drug and medical condition

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

TERIFLUNOMIDE

Medical condition to be studied

Multiple sclerosis

Population studied

Short description of the study population

The study population included pregnant women with multiple sclerosis (MS) received treatment with teriflunomide identified from the multiple countries: Australia, Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Spain, Sweden, Switzerland, and the United Kingdom.

Inclusion criteria:

- Is pregnant

- Has MS and was exposed to teriflunomide during pregnancy as defined below: a/ inadvertently received any teriflunomide dose at any time during pregnancy (from the first day of the last menstrual period to end of pregnancy), regardless

of the dose or duration of use, OR b/ received any teriflunomide dose prior to pregnancy start and had teriflunomide plasma concentration greater than or equal to 0.02 mg/L measured during pregnancy and available/retrievable for the confirmation of enrolment
- Has provided written informed consent to participate in the registry, through her HCP
- Authorizes the release of medical information to the National Coordinator for herself and her live born infant(s), as applicable
- Agrees to provides contact information for herself, her HCP, and her infant's HCP, as applicable

Exclusion criteria
- Does not receive health care in a country in which the registry is operational
- Was participating in a clinical trial investigating teriflunomide at the time of pregnancy exposure

Age groups

Adults (18 to < 46 years)

Special population of interest

Other

Pregnant women

Special population of interest, other

Patients with multiple sclerosis

Estimated number of subjects

196

Study design details

Outcomes

major congenital malformations diagnosed up to one year of age, fetal deaths occurring at 20 gestation weeks or later, and termination of pregnancy for fetal anomaly following prenatal diagnosis (TOPFA), Pregnancy outcomes including live born infants, recognized spontaneous abortions occurring at less than 20 gestation weeks, fetal deaths occurring at 20 gestation weeks or later, induced abortions without reported evidence of birth defects, TOPFA, ectopic pregnancy, and molar pregnancy Pregnancy exposure to teriflunomide and the elimination procedure

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Data analysis plan

For the primary analysis, the rate of birth defects among infants and fetuses prenatally-exposed to teriflunomide and reported to the Registry is calculated by dividing the number of birth defects among live born infants (LB), fetal deaths (>20 weeks' gestation) (FD), and TOPFA (at any gestational age) by the total number of LB, FD, and TOPFA with and without birth defects.

Documents

Study results

rdct-obs12751-pass-final-abstract-2023-PDFA.pdf(885.59 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