Teriflunomide Pregnancy Outcome Exposure Registry: An OTIS Autoimmune Diseases in Pregnancy Project (OBS13499)

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Study Finalised

Administrative details

EU PAS number

EUPAS17065

Study ID

41601

DARWIN EU® study

No

Study countries

- ☐ Canada
- ☐ United States

Study description

This is a North American prospective, observational, exposure cohort study of pregnancy outcomes in women with multiple sclerosis (MS) who are exposed to teriflunomide during pregnancy. The outcomes in women exposed to teriflunomide will be compared to those observed in two comparison groups: one in women with MS who have not been exposed to teriflunomide during pregnancy, and the other in women without MS.

Study status

Finalised

Research institutions and networks

Institutions

Organization of Teratology Information Specialists (OTIS)

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Institution

Contact details

Study institution contact

Team Transparency contact-us@sanofi.com

Study contact

contact-us@sanofi.com

Primary lead investigator

Team Transparency

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 12/02/2013

Study start date

Actual: 25/04/2013

Date of final study report

Planned: 29/03/2024

Actual: 22/05/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Study protocol

rdct-obs13499-protocol.pdf(788.35 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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To assess pregnancy outcomes in women with multiple sclerosis (MS) who are exposed to teriflunomide during pregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

AUBAGIO

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

TERIFLUNOMIDE

Anatomical Therapeutic Chemical (ATC) code

(L04AA31) teriflunomide

teriflunomide

Medical condition to be studied

Multiple sclerosis

Population studied

Age groups

Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

325

Study design details

Outcomes

To evaluate any potential increase in the risk of major birth defects, in the first year of life, in teriflunomide-exposed pregnancies. To evaluate the potential effect of teriflunomide-exposure on other adverse pregnancy outcomes including any potential pattern of minor birth defects, spontaneous abortion, stillbirth, preterm delivery, small for gestational age at birth and at 1 year follow-up.

Data analysis plan

Comparison of the pregnancy outcomes in women exposed to teriflunomide for the treatment of MS, with those observed in women with MS who have not been exposed to teriflunomide during pregnancy, and to the pregnancy outcomes of women without MS.

Documents

Study report

rdct-obs13499-addendum to interim report 10.pdf(144.47 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