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

First published: 04/01/2017
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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/41601

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 institution and networks

Institutions

Organization of Teratology Information Specialists (OTIS)

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Institution

Contact details

Study institution contact
Team Transparency

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

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