Ocrelizumab Pregnancy Registry

First published: 10/09/2019
Last updated: 14/03/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/35186

EU PAS number
EUPAS31342

Study ID
35186

DARWIN EU® study
No

Study countries
Germany
United States

Study description
This is a prospective observational registry that will collect primary data from 290 pregnant women with multiple sclerosis (MS) from the United States and Germany, who have been exposed to ocrelizumab during the 6 months prior to their last menstrual period (LMP) or at any time during pregnancy, and 290 pregnant women who have not been exposed to ocrelizumab. Frequency of exposed pregnancy outcomes will be compared with the unexposed group and with available background prevalence from external comparators, namely the Metropolitan Atlanta Congenital Defects Program(MACDP) and the European Surveillance of Congenital Anomalies (EUROCAT).

Study status
Ongoing

Research institution and networks

Institutions

F. Hoffmann-La Roche

First published: 01/02/2024
Last updated 01/02/2024

Institution

1 centre Germany, 2 centres United States

Contact details

Study institution contact

Marta Pereira

Study contact

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Primary lead investigator

Marta Pereira

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
01/08/2018

Study start date
Planned:
07/10/2019
Actual:
04/11/2019

Date of final study report
Planned:
26/04/2031

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Roche

Study protocol

Prot WA40063 OCREVUS v1_Redacted.pdf(2.1 MB)

Prot WA40063 ocrelizumab v2_Redacted.pdf(1.18 MB)

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Other study registration identification numbers and links

WA40063

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:

The main objective of the study is to assess and characterize frequency of maternal, fetal, and infant outcomes among women with MS exposed to ocrelizumab during the 6 months before the estimated date of conception or at any time during pregnancy.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

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

Medical condition to be studied
Multiple sclerosis

Population studied

Age groups
Preterm newborn infants (0 – 27 days)
Term newborn infants (0 – 27 days)
Infants and toddlers (28 days – 23 months)
Adults (18 to < 46 years)
Adults (46 to < 65 years)

Special population of interest
Pregnant women

Estimated number of subjects
580

Study design details

Outcomes
- Frequency of selected adverse pregnancy outcomes - Frequency of selected adverse fetal/neonatal/infant outcomes - Compare the maternal, fetal, and infant outcomes with unexposed comparator

Data analysis plan
Descriptive statistics will be used to summarize the findings, specifically, overall frequency (prevalence, 95% CI) of selected adverse pregnancy outcomes will be calculated, as well as frequencies of specific outcomes.Prevalence and associated 95% CIs will also be calculated for selected adverse fetal, neonatal, and infant outcomes at birth and through at least the first year of life of infants from pregnancies in women with MS exposed to ocrelizumab.The comparison to ocrelizumab-exposed women to the internal unexposed comparator will be performed using risk ratios (95% CIs) unadjusted and adjusted to relevant covariates, if sufficient number of outcomes are available.

Data management

Data sources

Data sources (types)
Disease registry
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