Ocrelizumab Pregnancy Registry

First published: 10/09/2019

Last updated: 21/07/2025

Study Finalised

Administrative details

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

Finalised

Research institutions 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

Erwan Muros global.clinical_trial_registry@roche.com

Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

Erwan Muros

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

Actual: 11/10/2024

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

Anatomical Therapeutic Chemical (ATC) code

(L04AG08) ocrelizumab

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

455

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.

Documents

Study results

Final CSR, Study WA40063, , Published Output-1_Redacted.pdf (400.98 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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