

Multisource Surveillance Study of Pregnancy and Infant Outcomes in Ocrelizumab-Exposed Women With Multiple Sclerosis (MELODIC Study)

First published: 28/02/2020

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Study

Planned

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/40211>

EU PAS number

EUPAS33879

Study ID

40211

DARWIN EU® study

No

Study countries

☐ Denmark

☐ United States

Study description

This will be an observational cohort study of ocrelizumab-exposed pregnancies and two matched comparator cohorts through secondary use of data from multiple sources. The study will be conducted in existing population-based health care databases and registries. The proposed data sources include data from the US and Denmark.

Study status

Planned

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)

☐ France

☐ Spain

☐ Sweden

☐ United Kingdom

☐ United Kingdom (Northern Ireland)

☐ United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution

Not-for-profit

ENCePP partner

HealthCore

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Optum

☐ Germany

First published: 03/01/2012

Last updated: 07/02/2014

Institution

Other

ENCePP partner

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

☐ Denmark

First published: 20/07/2021

Last updated: 02/04/2024

Institution

Educational Institution

ENCePP partner

HealthCore Integrated Research DatabaseSM (HIRD) United States

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Andrea Margulis

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 11/09/2017

Study start date

Planned: 30/06/2028

Date of final study report

Planned: 30/06/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Roche

Study protocol

[Prot BA39732 OCREVUS v1_Redacted.pdf](#)(904.19 KB)

[BA39732-protocol-v4-0-2023-03-10-Redacted.pdf](#)(1.11 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)

Other study registration identification numbers and links

BA39732

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 estimate the frequency of pregnancy and infant outcomes in women with MS exposed to ocrelizumab in the 6 months before conception or during pregnancy. To compare the frequency of pregnancy and infant outcomes in the exposed cohort with that in pregnant women with MS unexposed to ocrelizumab (primary comparator) and pregnant women without MS unexposed to ocrelizumab (secondary comparator).

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational study

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)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Pregnant women

Estimated number of subjects

7035

Study design details

Outcomes

Spontaneous abortion, stillbirth, elective termination, preterm delivery, C-section, antenatal urinary tract infections, antenatal infections requiring hospitalization, major congenital malformations, minor malformations (to the extent available), small for gestational age, adverse effects on the infant immune system, infant growth and development (to the extent available)

Data analysis plan

Characteristics of the unmatched and matched cohorts, including frequency of outcomes, will be output. Balance in matching will be assessed by examining the distribution of variables in the cohorts and estimating standardized differences for each variable between the ocrelizumab-exposed and comparator cohorts. Variables with standardized differences above 0.1 will be further evaluated and may lead to a re-evaluation of the propensity score estimation. Unadjusted measures of outcome frequency will be estimated within the matched cohorts. Measures of association will vary across outcomes and include incidence rate ratios and odds ratios. No adjustment is planned beyond matching. Subgroup analyses will include strata of maternal age, calendar year, and others (depending on counts and data availability). Association results will be summarized across data sources using meta-analytic techniques with random effects.

Data management

Data sources

Data source(s)

Danish registries (access/analysis)

Data source(s), other

Danish Registries (access/analysis), DAPI database

Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

[Disease registry](#)

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