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

First published: 28/02/2020
Last updated: 02/07/2024

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 institution 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 19/02/2024

Institution | ENCePP partner | Not-for-profit

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 | ENCePP partner | Other

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 data (e.g. claims)
Disease registry
Drug dispensing/prescription data

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