Kesimpta (ofatumumab) pregnancy and infant safety study using real world data

First published: 18/09/2023

Last updated: 26/07/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS106133

Study ID

106134

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Sweden
- [ ] United States

Study description

The study is an observational retrospective cohort study using longitudinal secondary data. The objective of the study is to compare the risk of adverse pregnancy and infant outcomes in female MS patients exposed to Kesimpta versus female MS patients unexposed to Kesimpta. The primary objective concerns the risk of major congenital malformations among live births (MCM). The secondary objectives concern the risk of spontaneous abortion, elective termination, stillbirth, preterm birth, preeclampsia, eclampsia, and having an infant that is small for gestation age (SGA).

Study status

Ongoing

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Novartis Clinical Disclosure Officer
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Study contact

Trialandresults.registries@novartis.com

Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/04/2021

Actual: 22/04/2021

Study start date

Planned: 30/06/2024

Actual: 30/06/2024

Data analysis start date

Planned: 01/02/2028

Date of final study report

Planned: 03/12/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis

Study protocol

OMB157G2405 - V1.0 --protocol_Redacted.pdf (1.99 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

COMB157G2405

Link to ClinicalTrials.gov registration

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To compare the risk of Major Congenital Malformations among live births (pregnancies ending in at least one live birth) between the three cohorts, as follows: Primary comparison: Kesimpta-exposed versus MSDMD-exposed, Secondary comparison: Kesimpta-exposed versus MSDMD-unexposed.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational, secondary use of data

Study drug and medical condition

Medicinal product name

KESIMPTA

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

OFATUMUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AA52) ofatumumab

ofatumumab

Medical condition to be studied

Multiple sclerosis

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

1500

Study design details

Outcomes

Major Congenital Malformations, Spontaneus abortion, elective termination, stillbirth, pre-term birth, preeclampsia, eclampsia, SGA.

Data analysis plan

All analyses are conducted within the individual data sources. Both unadjusted and adjusted outcomes analyses are conducted. The adjustment is performed by means of propensity score weighting using overlap weights (PSOW). The

results at the data source level are then combined, using meta-analysis. - Characteristics summary: descriptive statistics of the population baseline characteristics are provided by exposure cohort and for the overall population in each individual database - Outcome analysis: The analytical approaches are outcome specific. Appropriate analyses, including but not limited to the methods below, are conducted to compare the Kesimptaexposed cohort to the MSDMD-exposed cohort and to the MSDMD-unexposed cohort. - Meta-analysis: a meta-analysis of results across the data sources is conducted using aggregated data from each source.

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 source(s)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Danish registries (access/analysis)

Data source(s), other

- Birth Defects Registry, Sweden
- Birth Defect Registry, Denmark

- Healthcore Integrated Research Database, United States

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