Post-Authorization Safety Study for Assessment of Pregnancy and Infant Outcomes in Patients Treated with Kesimpta (ofatumumab) using OTIS Observational Pregnancy Surveillance Program and DMSKW Registry (Kesimpta Pregnancy Registry)

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Last updated: 08/08/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49804

EU PAS number

EUPAS49803

Study ID

49804

DARWIN EU® study

No

Study countries

- [ ] Canada
- [ ] Germany
- [ ] United States

Study description

The Kesimpta Pregnancy Registry is an observational, exposure cohort designed study to examine pregnancy and infant outcomes in women and infants who are exposed to Kesimpta (ofatumumab) during pregnancy to treat MS. The study is expected to enroll for approximately 7 years and follow the pregnant women and their infant(s) over a maximum of 21 months. The primary objective is to estimate and compare the prevalence of major structural defects in fetuses/infants born to Kesimpta exposed pregnant women with MS versus 1) disease-matched pregnant women not exposed to Kesimpta, and 2) healthy pregnant women. The study will be conducted as two sub-studies, namely the Kesimpta-OTIS sub-study and the Kesimpta-DMSKW sub-study, identical in design, run in parallel aiming to combine (meta-analyze) the results obtained from these two sub-studies. Other outcomes of interest include: a pattern of minor structural defects, spontaneous abortion, stillbirth, elective termination, preterm delivery, preeclampsia/eclampsia, small for gestational age infants, and small for age for postnatal growth at one year of age, developmental performance at approximately one year of age, and serious or opportunistic infections in the first year of life.

Study status

Ongoing

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Deutschsprachigen Multiple Sklerose und Kinderwunsch Register (DMSKW), Germany

Networks

Organization of Teratology Information Specialists (OTIS) Network

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Network

Contact details

Study institution contact

Novartis Clinical Disclosure Officer

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: 18/03/2021

Actual: 18/03/2021

Study start date

Planned: 31/01/2023

Actual: 05/01/2023

Data analysis start date

Planned: 28/02/2033

Date of final study report

Planned: 28/02/2034

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharma AG

Study protocol

OMB157G2403 (main) - final protocol V1.0 - for submission_Redacted.pdf(1.29 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

FDA/PMR 3901-2, COMB157G2403

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

The primary objective is to estimate and compare the prevalence of major structural defects in fetus/infants born to Kesimpta exposed pregnant women with MS versus 1) disease-matched pregnant women not exposed to Kesimpta, and 2) healthy pregnant women.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

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

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

725

Study design details

Outcomes

The primary outcome of the study is major structural birth defect.

Secondary outcomes:

- Spontaneous abortion/miscarriage
- Stillbirth
- Elective termination
- Preterm delivery
- Preeclampsia / eclampsia
- Pattern of 3 or more minor structural defects
- Small for gestational age
- Postnatal growth small for age at one year of age
- Developmental performance at approximately one year of age
- Serious or opportunistic infections in the first year

Data analysis plan

The primary outcome will be estimated in each cohort as a proportion (95% confidence interval) in pregnancies ending in at least one live born infant. As primary comparison, the crude RR and 95% CI for Kesimpta-exposed cohort vs. disease-Matched cohort will be estimated. Due to the observational nature of the study, the crude RR estimate will be further adjusted for potential confounders using propensity score (PS) methods. The primary analysis will be performed using the PS via inverse probability of treatment weighting. The secondary endpoints spontaneous abortion/miscarriage, stillbirth and premature delivery will be analyzed using survival analysis methods, elective termination, preeclampsia/eclampsia, small for gestational age will be analyzed like the primary outcome. Since multiple births will be included, minor structural defects, ASQ, and serious or opportunistic infections will be analyzed using generalized estimating equations approach.

Data management

Data sources

Data source(s), other

- Deutschsprachigen Multiple Sklerose und Kinderwunsch Register (DMSKW), Germany.
- Organization of Teratology Information Specialists (OTIS), Canada.
- Organization of Teratology Information Specialists (OTIS), United States.

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