

# 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)

**First published:** 24/11/2022

**Last updated:** 08/08/2024

Study

Ongoing

## Administrative details

### **PURI**

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

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### **EU PAS number**

EUPAS49803

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### **Study ID**

49804

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## **DARWIN EU® study**

No

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### **Study countries**

Canada

Germany

United States

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### **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.

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### **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

**First published:** 01/02/2024

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Network

## Contact details

### Study institution contact

Novartis Clinical Disclosure Officer

## Study contact

[Trialandresults.registries@novartis.com](mailto: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

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### Study start date

Planned: 31/01/2023

Actual: 05/01/2023

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### Data analysis start date

Planned: 28/02/2033

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### 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

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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### **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

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#### **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

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

OFATUMUMAB

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**Anatomical Therapeutic Chemical (ATC) code**

(L04AA52) ofatumumab

ofatumumab

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**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)

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## **Special population of interest**

Pregnant women

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## **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
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## 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.

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#### Data sources (types)

[Disease registry](#)



Other

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**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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No