Kesimpta Pregnancy and Infant Safety Study Using Real World Data

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Kesimpta (Ofatumumab) Pregnancy and Infant Safety Study Using Real World Data
ClinicalTrials.gov Identifier:
NCT06156683
Novartis Reference Number:COMB157G2405
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All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The study is an observational retrospective cohort study using longitudinal secondary data. Pregnant women with MS are assessed for exposure to Kesimpta and other MS disease modifying drugs (MSDMD) and followed up for adverse pregnancy and infant outcomes. Outcomes among Kesimpta exposed pregnancies are compared primarily to MSDMD-exposed pregnancies and secondarily to MSDMD-unexposed pregnancies.

The main research question is to determine whether the exposure during pregnancy to Kesimpta increases the risk of adverse pregnancy and infant outcomes in women with MS.

The risk period is defined as the 1st trimester of pregnancy for analyses of Major congenital malformations and the entire duration of pregnancy for all other outcomes.

The data for this study is retrieved from data sources from Denmark, Sweden, and the US, based on an assessment of feasibility.

Condition
Multiple Sclerosis
Overall Status
Recruiting
Number of Participants
1500
Start Date
Jun 30, 2024
Completion Date
Feb 01, 2028
Gender
Female
Age(s)
18 Years - (Adult, Older Adult)

Interventions

Other

Multiple sclerosis disease modifying drug

There is no treatment allocation. Women with multiple sclerosis with a recorded pregnancy outcome during the inclusion period will be recruited.

Eligibility Criteria

Inclusion Criteria:

The following overall criteria for study inclusion are applied:

* Pregnancy with a recorded start and end of pregnancy outcome (live birth, spontaneous abortion, elective termination, stillbirth, or ectopic pregnancy) during the inclusion period
* Age 18-49 years at index date
* A diagnosis of MS before the index date. This inclusion criterion is based on diagnosis codes, as recorded in the different data sources
* Availability of information on exposure to MSDMDs and maternal baseline characteristics for a minimum of 12 months before the index date

In addition, the following outcome and objective specific inclusion criteria are applied:

* For analyses of MCMs in live births (primary objective): pregnancy ending in at least one live birth
* For analyses of spontaneous abortion, elective termination of pregnancy, stillbirth, preeclampsia, eclampsia (secondary objectives): pregnancy ending in at least one live birth, spontaneous abortion, elective termination, stillbirth, or ectopic pregnancy
* For analyses of preterm birth, SGA (secondary objectives): pregnancy ending in at least one live birth
* For analyses of MCMs among live births, spontaneous abortions, stillbirths, and elective terminations (exploratory objective): pregnancy ending in at least one live birth, spontaneous abortion, still birth, or elective termination
* For analyses of neonatal infection: live newborn
* For analyses of SII: newborn alive at 29 days after birth

Exclusion Criteria:

The following overall criteria for exclusion are applied:

* Pregnancy exposed to a MSDMD that have a known teratogenic effect, determined based on the date of prescription, estimated supply duration, and the drug-specific window of clearance
* Pregnancy exposed to a non-MSDMD that have a known moderate to high teratogenic effect, determined based on the date of prescription, estimated supply duration, and the drug-specific window of clearance

The following outcome specific exclusion criteria are applied:

* For analyses of MCMs and exploratory analyses of MCMs: pregnancies with a record of a chromosomal abnormality or a genetic syndrome
* For analyses of preterm birth, pre-eclampsia, eclampsia and SGA, pregnancies involving multiples
* For Kesimpta and MSDMD-exposed cohorts: pregnancies not exposed during the outcome specific risk period

Switzerland

Novartis Investigative Site

Recruiting

Basel,Switzerland

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

Novartis Pharmaceuticals

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06156683*

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