Evaluation of pregnancy and infant outcomes in Mayzent patients using PRegnancy outcomes Intensive Monitoring (PRIM) data – The Mayzent-PRIM study

First published: 21/03/2022

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Study Ongoing

Administrative details

EU PAS number

EUPAS45875

Study ID

49696

DARWIN EU® study

No

Study countries

Switzerland

Study description

The Mayzent PRIM study is a secondary use of data, non-interventional study (NIS) based on Novartis' pharmacovigilance (PV) system leveraging data collected via PRIM using a set of targeted checklists with structured follow-up on pregnancies spontaneously reported to the Novartis global safety database (Argus). Although pharmacovigilance data may be collected from any country in the world where the product is approved, the anonymized patient level data will be analyzed at a global level in Switzerland.

Study status

Ongoing

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Contact details

Study institution contact

Novartis Clinical Disclosure Officer
trialandresults.registries@novartis.com

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: 15/02/2019

Actual: 15/02/2019

Study start date

Planned: 25/03/2022

Actual: 25/03/2022

Data analysis start date

Planned: 25/03/2031

Date of interim report, if expected

Planned: 03/06/2023

Date of final study report

Planned: 03/06/2031

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharmaceuticals

Study protocol

BAF312A2411 protocol V1.0_Redacted.pdf (824.61 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

CBAF312A2411

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 proportion of major congenital malformations associated with exposure to siponimod immediately before (up to 10 days before LMP) and during pregnancy among (i) live births and (ii) live births, stillbirths, and termination of pregnancy for fetal anomaly (TOPFA).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

SIPONIMOD

Medical condition to be studied

Multiple sclerosis

Pregnancy

Congenital anomaly

Foetal malformation

Stillbirth

Abortion spontaneous

Exposure during pregnancy

Drug exposure before pregnancy

Population studied

Age groups

- Adolescents (12 to < 18 years)
- Infants and toddlers (28 days – 23 months)
- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

500

Study design details

Outcomes

Major congenital malformation, To estimate the proportion of minor malformations, pregnancy outcomes, overall malformations, physical and cognitive development and serious infections in infants up to one year of age

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Data analysis plan

A statistical analysis plan (SAP) detailing the analysis to be conducted will be developed prior to the first data lock point. Annual interim reports will be

provided as described in the Milestones section below. The primary Mayzent-PRIM analysis cohort will constitute of the prospectively reported pregnancies associated with maternal exposure during pregnancy or up to 10 days before LMP. Since retrospective cases may be subject to reporting biases but still be informative, these will be analyzed and reported separately. Note that comparison with external background data will only be performed for the primary cohort, due to the high risk of bias for retrospective reports. Data analysis will include the estimation of proportion and 95% confidence intervals (CI) of malformations and specific pregnancy and infant outcomes. The proportion of congenital malformations will be calculated amongst (i) live births, and (ii) live births, stillbirths, and TOPFA.

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), other

Novartis global safety database Switzerland

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

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