The Multi-National Gilenya Pregnancy Exposure Registry in Multiple Sclerosis (Gilenya Pregnancy Registry)

First published: 21/05/2012

Last updated: 10/02/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49237

EU PAS number

EUPAS2569

Study ID

49237

DARWIN EU® study

No

Study countries

☐ Argentina

- [ ] Australia
- [ ] Austria
- [ ] Belgium
- [ ] Canada
- [ ] Cyprus
- [ ] Czechia
- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Ireland
- [ ] Italy
- [ ] Lebanon
- [ ] Mexico
- [ ] Netherlands
- [ ] Poland
- [ ] Portugal
- [ ] Russian Federation
- [ ] Saudi Arabia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Arab Emirates
- [ ] United Kingdom
- [ ] United States

Study description

The Gilenya Pregnancy Exposure Registry is a (at least) six-year, multi-national, prospective observational study.

It is designed as a prospective, observational registry collecting data regarding fingolimod exposure during pregnancy and maternal, fetal and infant outcomes. Early and later term pregnancy outcomes will be solicited at selected gestational time points and at the estimated date of delivery.

Structural and functional congenital anomalies identified in the perinatal period through one year of life will be collected and classified, and developmental status in infants will also be recorded.

In order to reduce the bias that may occur when some outcome information is known prior to enrollment, women are advised to enroll in the registry as soon as their pregnancy is known, preferably in the first trimester before the condition of the fetus has been assessed through targeted prenatal testing.

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 Office

Study contact

Trialandresults.registries@novartis.com

Primary lead investigator

Novartis Clinical Disclosure Office

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/08/2010

Actual: 17/08/2010

Study start date

Planned: 08/03/2011

Actual: 15/10/2011

Data analysis start date

Planned: 29/02/2012

Actual: 29/05/2024

Date of interim report, if expected

Planned: 17/04/2012

Actual: 28/03/2012

Date of final study report

Planned: 31/03/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharma AG

Study protocol

CFTY720D2404-v03--protocol_Redacted.pdf(335.32 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

CFTY720D2404

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Pregnancy exposure registry

Main study objective:

The purpose of the Registry is to continuously monitor, evaluate and assess for major and minor teratogenic effects in the offspring of women exposed to fingolimod before (up to 8 weeks before last menstrual period) and during pregnancy in routine clinical practice.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Sentinel sites, Pregnancy Exposure Registry

Study drug and medical condition

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

FINGOLIMOD HYDROCHLORIDE

Medical condition to be studied

Pregnancy

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

500

Study design details

Outcomes

Major and minor congenital malformations, other adverse maternal and fetal outcomes, physical developmental delays in offspring, adverse immune system effects in offspring.

Data analysis plan

Descriptive statistics will be used to summarize the findings, Specifically, overall frequency (proportions, 95% confidence interval) of major malformations will be calculated as well as frequencies of specific outcomes, e.g. heart defect.

The same will be calculated for minor congenital malformations, spontaneous abortions, stillbirths, elective terminations, adverse effects on immune system

development, and any other adverse pregnancy outcomes.
All primary analyses will be restricted to prospectively identified cases with outcome information.
The findings in the pregnancy exposure registry will be compared to external comparison groups. External comparison groups will include the European Registration of Congenital Anomalies and Twins (EUROCAT) and the Metropolitan Atlanta Congenital Defects Program (MACDP).

Data management

Data sources

Data sources (types)

Non-interventional study

Pregnancy 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