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

First published: 21/05/2012

Last updated: 04/06/2025

Study Finalised

Administrative details

EU PAS number

EUPAS2569

Study ID

49237

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Australia
- [ ] Austria
- [ ] 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 was a (at least) six-year, multi-national, prospective observational study.

It was 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 were 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 were collected and classified, and developmental status in infants was also recorded.
In order to reduce the bias that may occur when some outcome information is known prior to enrollment, women were advised to enroll in the registry as soon as their pregnancy was known, preferably in the first trimester before the condition of the fetus was assessed through targeted prenatal testing.

Study status

Finalised

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
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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

Actual: 04/02/2025

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 topic:

Disease /health condition

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 was 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

Anatomical Therapeutic Chemical (ATC) code

(L04AE01) fingolimod

fingolimod

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

303

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 were used to summarize the findings. Specifically, overall frequency (proportions, 95% confidence interval) of major malformations was calculated as well as frequencies of specific outcomes, e.g. heart defect.
The same was 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 were restricted to prospectively identified cases with outcome information.
The findings in the pregnancy exposure registry were compared to external comparison groups. External comparison groups included the European Registration of Congenital Anomalies and Twins (EUROCAT) and the Metropolitan Atlanta Congenital Defects Program (MACDP).

Documents

Study report

cfty720d2404--report-body_Redacted.pdf(2.21 MB)

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 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