Vumerity (Diroximel Fumarate) Prospective MS Pregnancy Exposure Registry

First published: 31/08/2023

Last updated: 15/03/2024

Study **Planned**

Administrative details

EU PAS number

EUPAS106453

Study ID

106454

DARWIN EU® study

No

Study countries

Australia

France

Germany

Ireland

Spain

Switzerland

United Kingdom (Northern Ireland)

United States

Study description

Pregnancy Exposure Registry for Vumerity (Diroximel Fumarate)

Study status

Planned

Research institutions and networks

Institutions

Biogen

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Study Director Biogen ctrr@biogen.com

Study contact

ctrr@biogen.com

Primary lead investigator

Study Director Biogen

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 21/01/2021

Study start date
Planned: 31/08/2023

Date of final study report
Planned: 18/05/2034

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Biogen

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

NCT05658497: https://classic.clinicaltrials.gov/ct2/show/NCT05658497

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:

The purpose of this Pregnancy Registry is to better characterize how diroximel fumarate (DRF) may affect pregnancy and infant outcomes.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

VUMERITY

Medical condition to be studied

Multiple sclerosis

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)

Estimated number of subjects

908

Study design details

Outcomes

Number of Major Congenital Malformations (MCMs), Number of: Elective/Therapeutic Terminations, Spontaneous Abortions, Fetal Deaths Including Still Birth, Live Births, Ectopic Pregnancies, Molar Pregnancies, Maternal Deaths, Neonatal Deaths, Perinatal Deaths, Infant Deaths, Serious or Opportunistic Infections in Liveborn Children, Infants with Abnormal Postnatal Growth and Development, Subjects with Pregnancy Complications

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Data analysis plan

All analyses will be conducted on an overall basis, as well as stratified by earliest trimester exposure. For MCMs, analyses will be conducted for participants who only have exposure in the first trimester in the exposed cohort. Participants who had earliest DRF exposure after the first trimester will be excluded from the analysis for MCMs. The prevalence and 95% confidence interval (CIs) of MCMs and spontaneous abortion will be calculated. Other negative pregnancy outcomes will be similarly examined as the sample size permits. Infants with minor malformations, chromosomal abnormalities, genetic syndromes, positional defects, and prematurity-related defects will be excluded from the primary outcome analyses related to MCM prevalence.

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)

Disease 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