Observational cohort study of exposure to lasmiditan during pregnancy (H8H-MC-B002)

First published: 05/01/2022

Last updated: 16/10/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS44982

Study ID

46189

DARWIN EU® study

No

Study countries

United States

Study description

This is a claims-based retrospective cohort study comparing pregnant women exposed to lasmiditan to three unexposed comparator populations.

Study status

Ongoing

Research institutions and networks

Institutions

HealthCore

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Institution

Carelon

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ana Sofia Afonso

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 12/02/2020

Actual: 12/02/2020

Study start date
Planned: 28/01/2022

Actual: 07/12/2021

Date of final study report
Planned: 29/12/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

B002 Non-interventional PASS Protocol_Redacted.pdf (3.23 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

To estimate and compare the prevalence of composite major congenital malformation in infants of women with a dispensing of lasmiditan 30 days prior to last menstrual period and anytime during the first trimester of pregnancy compared to three unexposed comparator groups.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Reyvow

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

LASMIDITAN

Anatomical Therapeutic Chemical (ATC) code

(N02CC08) lasmiditan

lasmiditan

Medical condition to be studied

Migraine

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)

- Adults (85 years and over)

Special population of interest

Pregnant women

Estimated number of subjects

683

Study design details

Outcomes

major congenital malformation, spontaneous abortion, stillbirth, preterm birth, small for gestational age, gestational hypertension, pre-eclampsia, eclampsia.

Data analysis plan

Comparative analysis

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)

Administrative healthcare records (e.g., claims)

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