

# A prospective, registry based, observational study to assess maternal, fetal and infant outcomes following exposure to lasmiditan (H8H-MC-B001)

**First published:** 05/01/2022

**Last updated:** 16/10/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS44973

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### Study ID

46192

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study description

The purpose of the study is to prospectively evaluate pregnancy/fetal, maternal and infant outcomes through 12 months of age among women exposed to lasmiditan during pregnancy, as well as in a comparator group not exposed to lasmiditan.

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## Study status

Ongoing

## Research institutions and networks

### Institutions

#### Syneos Health

 United Kingdom

**First published:** 23/04/2015

**Last updated:** 06/03/2024

Institution

Non-Pharmaceutical company

ENCePP partner

## Contact details

### Study institution contact

Ana Sofia Afonso [afonso\\_anasofia@lilly.com](mailto:afonso_anasofia@lilly.com)

Study contact

[afonso\\_anasofia@lilly.com](mailto:afonso_anasofia@lilly.com)

### Primary lead investigator

Ana Sofia Afonso

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 14/02/2020

Actual: 14/02/2020

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### **Study start date**

Planned: 31/01/2022

Actual: 01/12/2021

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### **Date of final study report**

Planned: 29/12/2034

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

## Study protocol

[Non-interventional PASS](#)

[Protocol\\_B001\\_v1.0\\_15Sep2021\\_CLEAN\\_Jan22\\_Redacted.pdf](#) (399.88 KB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Main study objective:**

The primary objective is to estimate the risk of major congenital malformations (composite) in infants of women exposed to lasmiditan during the first trimester of pregnancy compared to pregnant women with migraine unexposed to lasmiditan.

## Study Design

## Non-interventional study design

Cohort

## Study drug and medical condition

### Medicinal product name

RAYVOW

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

LASMIDITAN

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### Anatomical Therapeutic Chemical (ATC) code

(N02CC08) lasmiditan

lasmiditan

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### Medical condition to be studied

Migraine

## Population studied

### Age groups

- Preterm newborn infants (0 - 27 days)
- Term newborn infants (0 - 27 days)
- Infants and toddlers (28 days - 23 months)
- Children (2 to < 12 years)
- 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)
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### **Special population of interest**

Pregnant women

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### **Estimated number of subjects**

840

## Study design details

### **Outcomes**

Major congenital malformation, minor congenital malformation, maternal pregnancy complications, pregnancy/fetal outcomes, infant outcomes at birth, other adverse outcomes, including postnatal growth and development abnormalities.

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### **Data analysis plan**

Estimate the risk of pregnancy outcomes among women exposed to lasmiditan during pregnancy compared to women unexposed to lasmiditan before or during pregnancy

## 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)

Other

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### Data sources (types), other

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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## **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No