A prospective, registry based, observational study to asses maternal, fetal and infant outcomes following exposure to lasmiditan

First published: 05/01/2022

Last updated: 21/03/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46192

EU PAS number

EUPAS44973

Study ID

46192

DARWIN EU® study

No

Study countries

☐ United States

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.

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

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Study contact

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Primary lead investigator

Nicole Kellier-Steele

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 14/02/2020

Actual: 14/02/2020

Study start date
Planned: 31/01/2022

Actual: 01/12/2021

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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

Name of medicine, other

Reyvow

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)

Special population of interest

Pregnant women

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.

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

Data sources

Data sources (types)

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No