A Post Marketing Safety Study of Lasmiditan (REYVOW®) to describe the use in pregnant women and pregnancy outcomes using the Japan Medical Data Center Database (H8H-MC-B011)

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Study Planned

Administrative details

EU PAS number

EUPAS106766

Study ID

106767

DARWIN EU® study

No

Study countries

☐ Japan

Study description

To describe lasmiditan use during pregnancy and to estimate the prevalence of pregnancy adverse events (spontaneous abortions, stillbirths, major congenital malformations, low birth weight, and preterm births) in pregnant women with migraine who are exposed to lasmiditan.

Study status

Planned

Research institutions and networks

Institutions

Eli Lilly and Company

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Machiko Minatoya

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 19/09/2023

Study start date
Planned: 01/06/2022

Date of final study report
Planned: 30/09/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly Japan K.K.

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To describe lasmiditan use during pregnancy and to estimate the prevalence of pregnancy adverse events (spontaneous abortions, stillbirths, major congenital malformations, low birth weight, and preterm births) in pregnant women with migraine who are exposed to lasmiditan.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N02CC08) lasmiditan

lasmiditan

Medical condition to be studied

Migraine

Population studied

Age groups

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

1000

Study design details

Outcomes

pregnancy adverse events (spontaneous abortions, stillbirths, major congenital malformations, low birth weight, and preterm births)

Data analysis plan

Descriptive statistics will be used to describe variables listed in the study protocol. For continuous variables, mean and SD, and median and IQR will be presented. For categorical and binary variables, frequency and percentage will be calculated.

Data management

Data sources

Data source(s), other

JMDC Japan

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