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

PURI
https://redirect.ema.europa.eu/resource/106767

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 institution and networks

Institutions

Eli Lilly and Company
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Institution

Contact details

Study institution contact

Machiko Minatoya

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 list

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

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 data (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