Assessment of pregnancy outcomes in patients treated with Ajovy (fremanezumab): pregnancy database study

First published: 07/12/2020

Last updated: 19/02/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/40050

EU PAS number

EUPAS38434

Study ID

40050

DARWIN EU® study

No

Study countries

United States

Study status

Ongoing

Research institutions and networks

Institutions

HealthCore

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Sigal Kaplan

Study contact

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Primary lead investigator

Sigal Kaplan

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 18/02/2020

Study start date
Planned: 31/12/2020

Actual: 09/12/2020

Date of final study report
Planned: 31/12/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Teva Branded Pharmaceutical Products R&D, Inc.

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:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

to assess major congenital malformations, spontaneous abortions, stillbirths, preeclampsia, eclampsia, preterm delivery, low birth weight, and small-for-gestational age births in women exposed to AJOVY during pregnancy compared to comparison groups unexposed to AJOVY.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

AJOVY

Medical condition to be studied

Migraine

Population studied

Age groups

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

1000

Study design details

Outcomes

major congenital anomalies, spontaneous abortions, stillbirths, preeclampsia, eclampsia, preterm delivery, low birth weight, and small-for-gestational age births.

Data analysis plan

Study data will be summarized using descriptive statistics. The prevalence of major congenital malformations and secondary endpoints will be calculated as the proportion of events identified in the database of all live births or of pregnancies, as applicable. Analyses of the primary and secondary endpoints between the AJOVY group and Comparison Groups I and II are the primary comparisons of interest. Analyses using Comparison Groups III and IV are considered supportive. Analyses will be performed to compare the rates of major congenital malformations between the AJOVY group and each of Comparison Groups I and II, using a generalized linear model, adjusting for mother’s age as a continuous covariate, and stratified by gestational timing of exposure.

Data management

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