Observational Cohort Study of Exposure to Galcanezumab during Pregnancy (I5Q-MC-B003)

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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/48767

EU PAS number
EUPAS27574

Study ID
48767

DARWIN EU® study
No

Study countries
United States

Study status
Ongoing

Research institution and networks

Institutions

HealthCore

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Institution

Contact details

Study institution contact
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Study contact

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Primary lead investigator
Francis Mawanda
Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
21/01/2019
Actual:
25/01/2019

Study start date
Planned:
31/10/2020
Actual:
30/10/2020

Date of final study report
Planned:
31/12/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

I5Q-MC-B003 v1_Redacted.pdf(3.93 MB)

I5Q-MC-B003 Protocol Amendment(c)_Redacted.pdf(784.79 KB)

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness
Drug utilisation

Main study objective:
To monitor exposure to galcanezumab during pregnancy among women with migraine or cluster headache and study the incidence of pregnancy outcomes in women with migraine exposed to galcanezumab.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

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

Medical condition to be studied
Migraine
Cluster headache

Population studied

Age groups
Preterm newborn infants (0 – 27 days)
Term newborn infants (0 – 27 days)
Adults (18 to < 46 years)
Adults (46 to < 65 years)

Special population of interest
Pregnant women

Estimated number of subjects
100

Study design details

Outcomes
Maternal, foetal, and/or infant outcomes

Data analysis plan
The incidence of pregnancy outcomes (maternal, foetal, and/or infant outcomes) in pregnancies of galcanezumab-exposed migraine patients will be compared to other women with migraine unexposed to prophylactic migraine medication and women with migraine treated with other prophylactic migraine medication.

Data management

Data sources

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