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

First published: 16/01/2019

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Study Ongoing

Administrative details

EU PAS number

EUPAS27574

Study ID

48767

DARWIN EU® study

No

Study countries

United States

Study status

Ongoing

Research institutions 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

Enemona Emmanuel Adaji

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: 31/12/2025

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

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

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