Prospective pregnancy study to assess maternal and fetal outcomes following exposure to galcanezumab (I5Q-MC-B005)

First published: 04/12/2019

Last updated: 21/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS28151

Study ID

43321

DARWIN EU® study

No

Study countries

☐ United States

Study status

Ongoing

Research institutions and networks

Institutions

Syneos Health

United Kingdom

First published: 23/04/2015

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Krista Schroeder

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/02/2019

Actual: 19/02/2019

Study start date
Planned: 30/04/2020

Actual: 03/05/2021

Date of final study report
Planned: 30/11/2033

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly & Co.

Study protocol

I5Q-MC-B005 v1_Redacted.pdf (9.38 MB)

Lilly I5Q-MC-B005 v5.0_Galcanezumab_PregReg_Protocol_Amendment_CLEAN_Redacted.pdf (655.58 KB)

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 evaluate maternal and fetal outcomes associated with exposure to galcanezumab

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Pregnancy registry

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)

Infants and toddlers (28 days – 23 months)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

1260

Study design details

Outcomes

-Major malformations up to 1-year after birth (adjudication needed)-Minor malformations up to 1 year after birth-Pre-eclampsia and hypertension during pregnancy-Spontaneous abortions-Stillbirths-Elective terminations-Preterm births -Small-for-gestational-age births-Postnatal growth and development (not defined by the agency, welcome your suggestions) through the first year of life

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Data analysis plan

TBD

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)

Other

Data sources (types), other

Prospective patient-based data collection

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