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

PURI

https://redirect.ema.europa.eu/resource/43321

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

Krista Schroeder

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 list

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

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