A Retrospective Cohort Study to Assess Drug Utilisation and Long-Term Safety of Galcanezumab in US Patients in the Course of Routine Clinical Care (I5Q-MC-B001)

First published: 17/01/2019

Last updated: 21/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS27597

Study ID

39914

DARWIN EU® study

No

Study countries

☐ United States

Study description

To evaluate the utilisation and long-term safety of galcanezumab in the United States, in routine clinical practice.

Study status

Ongoing

Research institutions and networks

Institutions

HealthCore

First published: 01/02/2024

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Institution

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: 21/01/2019

Actual: 25/01/2019

Study start date
Planned: 31/12/2020

Actual: 21/12/2020

Date of final study report
Planned: 31/12/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

I5Q-MC-B001 Protocol v1_Redacted.pdf(735 KB)

I5Q-MC-B001_Galcanezumab_US_LongTermSafety_Protocol_Amend(b)_Redacted.pdf (804.54 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:

Drug utilisation

Main study objective:

To evaluate the utilisation and long-term safety of galcanezumab in the United States, in routine clinical practice.

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

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

100

Study design details

Outcomes

Cardiovascular, malignancy, and serious hypersensitivity.

Data analysis plan

Descriptive analysis

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