A Retrospective Cohort Study to Assess Drug Utilisation and Long-Term Safety of Galcanezumab in European Patients in the Course of Routine Clinical Care (I5Q-MC-B002)

First published: 17/01/2019
Last updated: 21/05/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/36549

EU PAS number
EUPAS27594

Study ID
36549

DARWIN EU® study
No

Study countries
France
Germany
Italy
Netherlands
Spain
Sweden
United Kingdom

Study description
To evaluate the utilisation and long-term safety of galcanezumab in Europe, in routine clinical practice.

Study status
Ongoing

Research institution and networks

Institutions

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands
First published: 07/01/2022
Last updated 24/07/2024

Institution | Laboratory/Research/Testing facility | ENCePP partner

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany
First published: 29/03/2010
Last updated 26/02/2024

Institution | Not-for-profit | ENCePP partner

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands
First published: 07/01/2022
Last updated 24/07/2024

Institution

Laboratory/Research/Testing facility

ENCePP partner

Quantify Research

Sweden
First published: 09/07/2020
Last updated
14/02/2023

Institution

ENCePP partner

Other

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain
First published: 05/10/2012
Last updated
23/02/2024

Institution

Laboratory/Research/Testing facility

Not-for-profit

Educational Institution

ENCePP partner

Bordeaux PharmacoEpi, University of Bordeaux

France
First published: 07/02/2023
Last updated
08/02/2023

Institution

Hospital/Clinic/Other health care facility

Not-for-profit

Educational Institution

ENCePP partner

Agenzia regionale di sanità della Toscana (ARS)

Italy
First published: 01/02/2024
Last updated
12/03/2024

Institution

EU Institution/Body/Agency

ENCePP partner

University of Basel, in collaboration with the Boston Collaborative Drug Surveillance Program United Kingdom, University Institute for Primary Care Research Jordi Gol and University of Oxford Spain, Agenzia regionale di sanita della Toscana Italy, Quantify Research Sweden

Contact details

Study institution contact

Lilly GPS Pharmacoepidemiology

Study contact

LillyGPSPE@lilly.com

Primary lead investigator

Eline Houben

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned:
17/01/2019
Actual:
18/01/2019

Study start date

Planned:
30/06/2020
Actual:
30/06/2020

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-B002 Galcanezumab_EU Long Term Safety_Drug Utilization_Protocol_amendment_Redacted.pdf(3.6 MB)

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 Europe, 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

Data sources

Data source(s)
Clinical Practice Research Datalink
The Information System for Research in Primary Care (SIDIAP)
PHARMO Data Network
German Pharmacoepidemiological Research Database
ARS Toscana

Data source(s), other
CPRD, SIDIAP, PHARMO Data Network, GePaRD, ARS

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