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: 28/10/2024





Administrative details

PURI

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

EU PAS number

EUPAS27594

Study ID

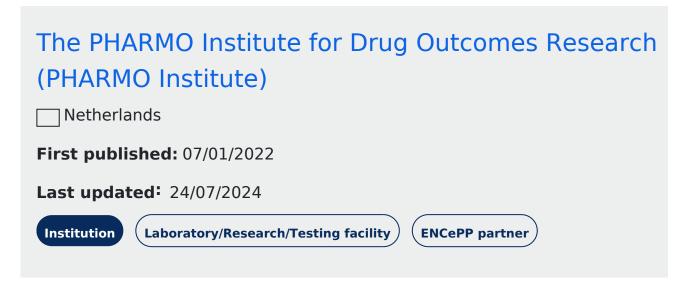
36549

DARWIN EU® study

Nο

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 institutions and networks
Institutions
The PHARMO Institute for Drug Outcomes Research (PHARMO Institute) Netherlands
First published: 07/01/2022
Last updated: 24/07/2024
Institution

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





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 Educational Institution Laboratory/Research/Testing facility Not-for-profit ENCEPP partner



Agenzia regionale di sanità della Toscana (ARS)

First published: 01/02/2024

Last updated: 12/03/2024

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

Enemona Adaji

Study contact

enemona.emmanueladaji@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 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