preventive TReatment of mIgraine: oUtcoMes for Patients in real-world Healthcare systems [TRIUMPH] (15Q-MC-B004)

First published: 14/01/2020

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Study Ongoing

Administrative details

EU PAS number

EUPAS33068

Study ID

41403

DARWIN EU® study

No

Study countries

Germany

Italy

Japan

Spain

United Arab Emirates

United Kingdom

United States

Study description

Research objectives: The overall aim is to estimate real-world effectiveness and associated outcomes, as well as describe treatment patterns, in patients with migraine in routine clinical care who are switching or initiating pharmacologic treatment for migraine prevention. The primary comparison of interest will be between galcanezumab and oral standard of care. However, patients who are initiating other CGRP antagonists or botulinum toxin A or B will also be eligible to participate in the study and included in descriptive and statistical comparisons as sample sizes permit. Design: Prospective, multicenter, international, 2-stage noninterventional study. Stage 1 is a cross-sectional, single-day assessment. Stage 2 is a 24-month longitudinal assessment. Entry into Stage 2 is dependent on which preventive treatment the patient is initiating. During Stage 2: Postbaseline visits will occur at Month 3, 6, 12, 18, 24. Additional office visits are allowed as this is an observational study. Population: Adult patients with migraine who are switching or initiating new preventive treatment in clinical practice settings in multiple countries Variables: o demographics o concomitant medications o medical history and comorbidities o migraine history, migraine treatment history, and current disease state o preventive and acute treatment use and rationale for changes o migraine headache days and headache days, headache hours, severity, and symptoms o health-related quality of life o migraine-related burden and disability o healthcare resource utilization o work productivity and activity impairment o acute treatment outcomes o symptoms of anxiety, depression, and allodynia o medication adherence, persistence, and satisfaction Size: Stage 1 will include a sufficient number of patients to achieve approx 2850 patients total entering

Stage 2, with enrollment targets stratified by country.

Study status

Ongoing

Research institutions and networks

Institutions

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Study timelines

Date when funding contract was signed

Planned: 22/04/2019

Actual: 21/06/2019

Study start date

Planned: 14/02/2020

Actual: 25/02/2020

Date of final study report

Planned: 27/01/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The overall aim is to estimate real-world effectiveness and associated outcomes, as well as describe treatment patterns, in patients with migraine in routine clinical care who are switching or initiating pharmacologic treatment for migraine prevention. The primary comparison of interest will be between galcanezumab and oral standard of care.

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

GALCANEZUMAB

METOPROLOL

ATENOLOL

PROPRANOLOL HYDROCHLORIDE

AMITRIPTYLINE

FLUNARIZINE

BOTULINUM TOXIN TYPE A

BOTULINUM TOXIN TYPE B

ERENUMAB

FREMANEZUMAB

TOPIRAMATE

Medical condition to be studied

Migraine

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

2.850

Study design details

Outcomes

Compare the effectiveness of galcanezumab to oral migraine preventive standard of care overall in adult patients with migraine who are switching or initiating preventive treatment. Specifically, this will estimate the proportion of patients in the longitudinal follow-up who achieve a clinically meaningful reduction from baseline in monthly migraine headache days at Month 3. Compare the long-term, real-world effectiveness of galcanezumab to other migraine preventive treatments on a variety of outcomes including, but not limited to, migraine headache day reduction, responder rates, discontinuation rates, patient-reported outcomes, acute and preventive treatment patterns and outcomes, disease and economic burden.

Data analysis plan

The primary analysis aims to estimate the causal effect of galcanezumab versus oral migraine preventive standard of care when controlling for selection bias and measured confounders. The primary analysis will be performed using propensity score greedy match to assess the differences in outcome between 2

groups. Descriptive summary statistics will be presented at different time points for different treatments and treatment groups and drug classes or individually based on the sample sizes available overall and by countries using treatment as time varying.The secondary objectives for the longitudinal follow-up are to compare the effectiveness of galcanezumab to other migraine preventive treatments on outcomes. The secondary analyses will be performed using MSM, which are multi-step estimation procedure designed to control for the effect of confounding variables that change over time, and are affected by previous treatment.

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