US Population-Based Longitudinal Survey in Migraine: ObserVational survey of the Epidemiology, tReatment and Care Of MigrainE (OVERCOME)

First published: 10/08/2020

Last updated: 02/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS36296

Study ID

40122

DARWIN EU® study

No

Study countries

United States

Study status

Ongoing

Research institutions and networks

Institutions

Kantar Health

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Institution

Contact details

Study institution contact

Louise Lombard lombard_louise@lilly.com

Study contact

lombard_louise@lilly.com

Primary lead investigator

Louise Lombard

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 29/03/2018

Study start date

Actual: 21/09/2018

Date of final study report
Planned: 30/06/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

2017-6229 US OVERCOME_Changes for Cohort 3 02Nov2020_Amendment(c)_Approved 11NOV2020.pdf (1).pdf (855.94 KB)

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:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The primary objective of this research is to monitor and understand changes in health care delivery, acute/preventive migraine medication use, and impact to people with migraine with the introduction of new classes of migraine medications

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

GALCANEZUMAB

LASMIDITAN

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

60.000

Study design details

Outcomes

Address changes in health care delivery, migraine care, and outcomes from a baseline state (pre-/peri-approval of novel acute and preventive migraine medication classes) to a future state (post-approval of novel acute and preventive migraine medication classes), Compare cohorts of people with migraine on novel treatments compared with SOC treatments for migraine

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Data analysis plan

Analyses are grouped into five general categories: cross-sectional cohort analyses, differences between cohort analyses, longitudinal follow-up analyses, linked claims, and non-migraine population analysis. Descriptive statistics will be conducted to provide summaries for all variables in each cohort and specific subgroups of interest. Continuous variables will be summarized as means with standard deviations, or medians and ranges, as appropriate. Categorical variables will be summarized as frequencies and percentages.

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