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

First published: 10/08/2020
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Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/40122

EU PAS number
EUPAS36296

Study ID
40122

DARWIN EU® study
No

Study countries
United States

Study status
Ongoing

Research institution and networks

Institutions

Kantar Health
First published: 01/02/2024
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Institution

Contact details

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Study contact

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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
60000

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

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

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