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

First published: 08/09/2020

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Study Planned

Administrative details

EU PAS number

EUPAS37093

Study ID

37094

DARWIN EU® study

No

Study countries

Germany

Spain

Study description

This study is a non-interventional, cross-sectional observational study with data collected via a web-based survey.Research question and objectives: Describe diagnosis, barriers to treatment and pharmacological patterns, as well as non-pharmacological treatment patterns of people with migraine in Spain and Germany who meet the International Classification of Headache Disorders (ICHD)-3 criteria. Secondary objectives aim to evaluate people with migraine regarding certain co-morbidities and migraine risk factors, to understand behavior and symptom severity during their attack, and specifics of attack treatment. The impact of migraine on private and social life will also be evaluated. Furthermore, comparative analyses will be done comparing people with migraine on novel treatments with those on SOC treatments for migraine, looking how novel treatments for migraine influence various clinical, humanistic, and economic outcomes. Subgroups analyses may include comparisons according to different frequency of monthly headache days 0-3, 4-7, 8-14, ≥15.Population: This study will include adult members of a web-survey panel living in Spain and Germany, who meet inclusion and exclusion criteria and who agree to participate. Participants with migraines meeting the ICHD-3 screening criteria will be included in the migraine cohort. Those who do not meet the screening criteria may be included in the non-migraine cohort. Participants who are less than 18 years old, unwilling or unable to provide informed consent, or unable to read and write Spanish or German will be excluded from participation.Variables: Broad range of variables including demographics, health status, medication use, non-pharmacological behavioural treatments, migraine attack frequency/severity, migraine symptoms, quality of life, healthcare resource utilization, barriers to care seeking, stigmaData sources/Data Collection: Web-based survey

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Study status

Planned

Research institutions and networks

Institutions

Kantar Health

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Institution

CRO on behalf of the Sponsor: Eli Lilly & Company

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Treuer Tamas

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/05/2020

Actual: 15/05/2020

Study start date
Planned: 15/10/2020

Date of final study report
Planned: 31/03/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly & 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:

Disease epidemiology

Other

If ‘other’, further details on the scope of the study

To describe diagnosis, barriers to treatment and pharmacological patterns and non-pharmacological treatment patterns of people with migraine in Spain and Germany who meet the International Classification of Headache Disorders (ICHD)-3 criteria.

Main study objective:

Research question and objectives: Describe diagnosis, barriers to treatment and pharmacological patterns, as well as non-pharmacological treatment patterns of people with migraine in Spain and Germany who meet the International Classification of Headache Disorders (ICHD)-3 criteria. Secondary objectives aim to evaluate people with migraine regarding certain co-morbidities and migraine risk factors

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

This study is a non-interventional, cross-sectional observational study with data collected via a web-based survey

Study drug and medical condition

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

22.000

Study design details

Outcomes

The primary objective of this research is to understand barriers to treatment, and treatment patterns of people with migraine who met ICHD-3 criteria with subgroups of different frequency of monthly headache days 0-3, 4-7, 8-14, ≥15. 1. Evaluate people with migraine with regard, but not limited to:a. To report the prevalence of cardiovascular related diseases and risk factors associated with migraineb. To understand the driving attitudes and behavior of people with migraine during their attack.c. To understand the proportion of triptan failures and reasons for stoppingd. To compare triptan responder versus insufficient

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Data analysis plan

Analyses are grouped into two general categories: cross-sectional cohort analyses and non-migraine population analysis. For key analyses, separate data specification plans will be developed that will provide the analytical methods in detail. For analyses, all data will be used. Descriptive statistics will be conducted to provide summaries for all variables in each cohort and specific subgroups of interest (e.g. monthly headache days). 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)

Non-interventional study

Other

Data sources (types), other

Non-interventional, cross-sectional observational study with data collected via a web-based survey

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