# 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 Last updated: 23/04/2024





### 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 nonpharmacological 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

#### **Study status**

Planned

### Research institutions and networks

### Institutions

### Kantar Health

First published: 01/02/2024

Last updated: 01/02/2024

Institution

CRO on behalf of the Sponsor: Eli Lilly & Company

### Contact details

**Study institution 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**

22000

## 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,  $\geq$ 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

#### 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