Barriers to Care in Migraine in Germany

First published: 01/12/2021

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS44516

Study ID

50348

DARWIN EU® study

No

Study countries

Germany

Study description

The study is a prospective anonymous cross-sectional study using a web-based survey. Participants with headache are eligible to enter the survey. First step will be a screening for potential migraine using the ID-MigraineTM questionnaire. Participants will be subsequently stratified to three different

questionnaires based on their potential migraine diagnosis not made by a physician (survey1), migraine with a medical diagnosis (without preventive medication experience) (survey 2), migraine with medical diagnosis (with preventive medication experience) (survey 3). The study will address the impact of potential predictors of barriers to migraine

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Fleischmann Robert

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/06/2021

Actual: 17/06/2022

Study start date

Planned: 02/12/2021

Actual: 02/12/2022

Date of final study report
Planned: 01/12/2022

Actual: 03/01/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Teva GmbH

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To explore the proportion of patients with migraine symptoms undiagnosed by physician

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Headache

Migraine

Population studied

Short description of the study population

A web-based survey of participants with headache in Germany.

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)

Special population of interest

Other

Special population of interest, other

Patients with headaches and migraine headaches

Estimated number of subjects

10.000

Study design details

Outcomes

percentage of pts with migraine symptoms undiagnosed by physician, To explore the difference in distribution of the variables of interest in patients diagnosed with migraine and no prophylactic treatment and patients diagnosed with migraine and prophylactic treatment for guideline-guided therapy To explore the difference in distribution of the variables in subset of patients who qualify for prophylactic treatment in group 2 for guideline-guided therapy

versus

Data analysis plan

All variables will be summarized descriptively. For continuous variables, descriptive statistics (n, mean, standard deviation, standard error of mean, median, minimum, and maximum) will be provided. For categorical variables, frequency and percentage will be provided. The 95% confidence intervals will be provided for point estimate, if appropriate. Regression models will be employed to provide an estimate of the predictive value of endpoints for being correctly diagnosed with migraine and/or the use of an indicated preventive medication.

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