Bio-psycho-social characteristics of patients with migraine. A cross-sectional review of depersonalized data from the German Pain e-Registry. (BIOMIC)

First published: 12/12/2022

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS50135

Study ID

50136

DARWIN EU® study

No

Study countries

Germany

Study description

Migraine is a common headache disorder and one of the most disabling disorders globally. It is responsible for more than 50% of all years lost due to neurological disorder-related disability and is the first cause of disability in patients younger than 50 years. Migraine significantly impacts physical/biological, psychological, as well as social/occupational function. Its global prevalence in males vs. females, is 9.8% vs. 18.9%, respectively (overall prevalence is 14.4%). The incidence of migraine peaks at 35–45 years, and the female to male ratio is estimated to be three to one in reproductive ages. Although migraine is associated with a considerable burden, it can be well controlled using pharmacological and non-pharmacological approaches if treatment approaches follow current guidelines and evidence-based treatments.

Study status

Finalised

Research institutions and networks

Institutions

Institute for Neurological Sciences (IFNAP)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Michael Ueberall

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/09/2022

Actual: 24/09/2022

Study start date

Planned: 10/10/2022

Actual: 10/10/2022

Data analysis start date

Planned: 24/10/2022

Actual: 24/10/2022

Date of final study report

Planned: 11/12/2022

Actual: 11/12/2022

Sources of funding

- Other

More details on funding

German Pain Association, IFNAP - private Institute of Neurological Sciencess

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

Data collection methods:

Secondary use of data

Main study objective:

Characterisation of the bio-psycho-social profile of patients suffering from migraine in Germany.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Migraine

Population studied

Short description of the study population

Patients with migraine identified from the German Pain e-Registry.

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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 migraine

Estimated number of subjects

15.919

Study design details

Data analysis plan

Purely descriptive evaluation of depersonalized data provided by the German Pain e-Registry. Biometric analyses will be performed using the descriptive procedures suitable for the respective data format. Mean data will be presented with standard deviation, median, range, and 95% confidence intervals (CI), proportions will be expressed in percent (%) and if necessary, adjusted for the number of patients with available data (a%). All analyses will be conducted with PASW Statistics version 18.

Data management

Data sources

Data sources (types)

Disease registry

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