Fremanezumab versus conventional preventive treatments as ≥2nd line prophylaxis of migraine – propensity score matched multiple cohort comparative retrospective longitudinal analyses of depersonalized 6-months real-world data of the German Pain e-Registry. (Freedom)

First published: 11/07/2023

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS105823

Study ID

105824

DARWIN EU® study

No

Study countries

Germany

Study description

FREEDOM is an exploratory, non-interventional, post-marketing, open-label, retrospective parallel-group, flexible-dose, comparative longitudinal 24-week multiple-cohort-study using depersonalized data of the German Pain e-Registry (GPeR, until September 30, 2022) to assess the effectiveness of the calcitonin gene-related peptide antagonist fremanezumab compared to conventional medications used for the prophylactic treatment in adult patients with migraine who are deemed to be in need of an alternative preventive medication according to the mutual / shared decision of the responsible physician and affected patients.

Study status

Finalised

Research institutions and networks

Institutions

Institute for Neurological Sciences (IFNAP)

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Institution

Contact details

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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: 03/10/2022

Actual: 03/10/2022

Study start date

Planned: 03/10/2022

Actual: 03/10/2022

Data analysis start date

Planned: 10/10/2022

Actual: 10/10/2022

Date of final study report

Planned: 31/03/2023

Actual: 31/03/2023

Sources of funding

- Other

More details on funding

IFNAP - private institute of neurological sciences, O.Meany-MDPM 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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The main objective of this study is the evaluation of the 24-week efficacy and tolerability of fremanezumab vs. traditional prophylactics in comparable populations of migraine patients who participated in the German Pain e-Registry (GPeR).

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Post-marketing, open-label, retrospective parallel-group, flexible-dose, comparative longitudinal 24-week multiple-cohort-study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

PROPRANOLOL HYDROCHLORIDE

METOPROLOL

AMITRIPTYLINE

FLUNARIZINE

TOPIRAMATE

FREMANEZUMAB

Medical condition to be studied

Migraine

Population studied

Short description of the study population

Adult patients treated with fremanezumab versus conventional preventive treatment as ≥2nd line prophylaxis for migraine identified from the German Pain e-Registry (GPeR).

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Special population of interest

Other

Special population of interest, other

Migraine patients

Estimated number of subjects

7434

Study design details

Outcomes

Primary endpoint is the 24-week response rate (i.e. no treatment discontinuation in response or as a consequence of adverse drug reactions plus a reduction of monthly migraine days ?50% in month 4-6 of the evaluation period with medication vs month -3 to -1 prior baseline). Percentage of patients who reported vs. baseline a) a reduction of monthly migraine days with acute medication ?50%, b) a reduction of migraine-related sick leave days ?50%, c) a reduction of the migraine disability assessment score ?50%, d) a reduction of migraine-related disability in daily life ?50%, e) etc.

Data analysis plan

Data analyses will follow a modified intent-to-treat (ITT) approach as any data of patients who (a) take/record at least one dose of the treatments under evaluation and (b) record at least one post-baseline/post-dose measure within the defined 24-week evaluation frame will be evaluated. When changes from baseline to endpoint will be assessed, data will be included in the analysis only if there is a baseline and a corresponding postbaseline measure. All outcomes will be summarized descriptively for baseline and end-of-evaluation timepoint, and absolute and relative change from baseline using appropriate summary statistics and/or frequency distributions. Safety analyses will be conducted on the safety analysis set. All statistical tests will be carried out using a 2-sided significance level of 0.05. Test results will be presented as concrete p scores down to a level of 0.001, lower p scores will be expressed as “?0.001”.

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 source(s), other

German Pain e-Registry (GPeR)

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