Prospective observational study of Fremanezumab (Ajovy™) effectiveness in chronic and episodic migraine patients in clinical routine: FINESSE study

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48417

EU PAS number

EUPAS44606

Study ID

48417

DARWIN EU® study

No

Study countries

☐ Austria

☐ Germany

Study status

Ongoing

Research institutions and networks

Institutions

Ludwig-Maximilians-University Munich

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Institution

Contact details

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Primary lead investigator

Xenia Hamann

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 03/09/2019

Study start date
Planned: 18/11/2019

Actual: 18/11/2019

Date of final study report
Planned: 31/12/2024

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

Other study registration identification numbers and links

Paul-Ehrlich-Institut (PEI) NIS-number 506

Methodological aspects

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To evaluate the effectiveness of fremanezumab administered in adult patients with chronic migraine (CM) or episodic migraine (EM) who have at least 4 migraine days per month, including the proportion of patients reaching at least 50% reduction in the monthly average number of migraine days, during the 6-month period after the first dose of fremanezumab, in real-world clinical practice.

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

1000

Study design details

Outcomes

The proportion of patients reaching at least 50% reduction in the monthly average number of migraine days during the 6-month period after the first dose of fremanezumab. Please refer to study protocol section 5.3.2. (Primary and Secondary Endpoints).

Data analysis plan

All treatment period timepoints will be defined in relation to each patient’s first dose of fremanezumab, regardless of their time of enrollment. All outcomes will be reported using summary statistics. No sensitivity analyses are planned. Interim analyses are planned.

Data management

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