US-based cross-sectional survey in patients taking lasmiditan: Functional REstoration with rEyvow (FREE)

First published: 17/11/2020

Last updated: 13/12/2024

Study Finalised

Administrative details

EU PAS number

EUPAS37245

Study ID

41778

DARWIN EU® study

No

Study countries

☐ United States

Study description

The objective of the study is to assess patients' ability to return to their usual daily activities after treating a migraine attack with lasmiditan. Study data will be collected by conducting a 15-minute web-based cross-sectional survey in adult patients in US who have redeemed a REYVOW savings card and have taken lasmiditan at least once in the past month for treatment of a migraine attack.

Study status

Finalised

Research institutions and networks

Institutions

Clinical, Regulatory and Safety, Cerner Enviza

Germany

First published: 15/03/2022

Last updated: 05/02/2025

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Amit Qamra

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 08/07/2020

Study start date

Actual: 16/11/2020

Data analysis start date

Planned: 01/12/2020

Actual: 01/12/2020

Date of final study report

Planned: 01/06/2021

Actual: 15/06/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

FREE study_protocol_final.pdf(1011.12 KB)

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

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The objective of the study is to assess patients’ ability to return to their usual daily activities after treating a migraine attack with lasmiditan.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

LASMIDITAN

Medical condition to be studied

Migraine

Population studied

Short description of the study population

Adult patients in US who have redeemed a REYVOW savings card and have taken lasmiditan at least once in the past month for treatment of a migraine attack prior to completing the survey.

Inclusion Criteria

The study will include all participants who meet the following criteria:

1. Age ≥18 at time of study
2. Enrolled in US REYVOW patient support program
3. Redeemed a REYVOW Savings Card
4. Provide informed consent to participate in the study
5. Have taken lasmiditan in the past month prior to completing the survey

Exclusion Criteria

Participants will be excluded from the study:

1. Cannot read or understand English
2. Cannot use a computer or smart device with internet access

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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

Migrane patients

Estimated number of subjects

250

Study design details

Outcomes

Ability to perform and the time taken to return to usual daily activities engaged in when the migraine attack started, and Ability to return to planned activities for that day and level of impairment of those activities, Activity that was most impacted by their migraine attack prior to taking lasmiditan, the activity that the patient was most concerned about prior to taking lasmiditan, and the level of impairment of usual activities during an untreated or unsuccessfully treated attack prior to when lasmiditan was initiated

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Data analysis plan

All study measures will be reported descriptively using means, standard deviations, medians, and 95% confidence intervals for continuous outcome variables and frequencies and percentages for categorical outcome variables. Differences between subgroups will be evaluated: analyses will be conducted to examine whether the select study outcome measures differ by each of the subgroups, using chi-square tests for categorical variables and one-way analysis-of-variance tests (ANOVAs) for continuous variables. P-values will be provided for the omnibus test (one-way ANOVA) and pair-wise testing between the groups. It should be noted that all comparisons are conditional on whether each subgroup results in adequate sample size.

Documents

Study results

REYVOW FREE Report_ENCePP version. 14 JUN 2021_APPROVED.pdf(5.17 MB)

Study publications

Schwedt TJ, Lombard LA, Doty E, Vincent M, Mills KM, Ayer DW, et al. Functional…

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

Electronic one-time 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