Real-World Observational Study to Assess Drug Utilisation Patterns in the US Among Migraine Patients Treated with Lasmiditan (H8H-MC-B005)

First published: 16/03/2023

Last updated: 22/11/2024

Study Finalised

Administrative details

EU PAS number

EUPAS45442

Study ID

1000000091

DARWIN EU® study

No

Study countries

☐ United States

Study description

This is a retrospective cohort database study evaluating real-world utilization patterns among patients treated with lasmiditan in the US using IBM® MarketScan commercial administrative claims. This study will describe real-world utilization patterns for patients treated with lasmiditan and patient characteristics including demographics, comorbidities, and concomitant medication use.

Study status

Finalised

Research institutions and networks

Institutions

Eli Lilly and Company

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

Kellier_Nicole_A@lilly.com

Primary lead investigator

Nicole Kellier-Steele

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 02/02/2022

Study start date

Planned: 31/01/2022

Actual: 22/05/2023

Date of final study report

Planned: 31/12/2023

Actual: 18/12/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

B005 05 Protocol PASS(v0.1)_Redacted.pdf(4.43 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

This study aimed to describe utilization patterns in the US for patients treated with lasmiditan in
routine clinical practice using administrative claims data.
The primary objectives of this study are to: describe real-world utilization of lasmiditan using prescription data over a period of 3 years after market availability to identify potential patterns of drug misuse or abuse; identify patients treated for longer than 1 year and describe treatment patterns; assess off-label treatment with lasmiditan among paediatric and adolescent patients

with migraine, and; describe characteristics of lasmiditan-treated patients, including patients treated beyond 1year.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

RAYVOW

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

LASMIDITAN

Anatomical Therapeutic Chemical (ATC) code

(N02CC08) lasmiditan

lasmiditan

Medical condition to be studied

Migraine

Population studied

Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Study design details

Outcomes

Misuse/abuse, off-label treatment in pediatric & adolescent patients, drug-utilization characteristics

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Data analysis plan

All data will be summarized using descriptive statistics. Categorical variables will be presented using percentages and frequencies. Continuous variables will be presented as means and medians with associated standard deviations.

Documents

Study report

LY573144 B005 Noninterventional PASS Final Study Report – Basic Version 1_Redacted.pdf(373.42 KB)

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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