Observational Cohort Study of Lasmiditan Exposure and Motor Vehicle Accidents in the United States (MI DRIVE) H8H-MC-B006

First published: 24/10/2024

Last updated: 20/11/2024

Study Planned

Administrative details

EU PAS number

EUPAS1000000347

Study ID

1000000347

DARWIN EU® study

No

Study countries

☐ United States

Study status

Planned

Research institutions and networks

Institutions

Eli Lilly and Company

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Maryline Le Noan-Lainé

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/05/2019

Actual: 29/05/2019

Study start date
Planned: 04/03/2025

Date of final study report
Planned: 31/12/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

LY573144 B006 NI PASS Protocol v1_Redacted.pdf (671.42 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Safety in operating heavy machinery

Data collection methods:

Primary data collection

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

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

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.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

Prospective direct-to-participant data collection

Data sources (types)

Non-interventional study

Patient surveys

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