Evaluating reduction of opioid and barbiturate use following rimegepant initiation in the United States

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000755

Study ID

1000000755

DARWIN EU® study

No

Study countries

United States

Study description

This is a non-interventional, retrospective, observational, cohort study that will assess changes in opioid and barbiturate utilization after initiation of rimegepant among adults in the US. This study will analyze an administrative claims database (IQVIA PharMetrics Plus) with information on individuals in the US with commercial, managed Medicare, or managed Medicaid health plans. This database includes information captured in medical and pharmacy claims (eg, dates of service, diagnosis codes, procedure codes, medications dispensed, demographics, health plan enrolment).

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Simon Dagenais

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2023

Actual: 01/07/2023

Study start date

Planned: 21/08/2023

Actual: 21/08/2023

Date of final study report

Planned: 01/03/2026

Study protocol

C4951089_NIS protocol_V1.0_12Nov2025_public.pdf (973.97 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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

This is a non-interventional, retrospective, observational, cohort study that will assess changes in opioid and barbiturate utilization after initiation of rimegepant among adults in the US.

Main study objective:

The study aims to assess changes in opioid and barbiturate utilization patterns after the initiation of rimegepant among US adults with migraine.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Nurtec

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

RIMEGEPANT

Anatomical Therapeutic Chemical (ATC) code

(N02CD06) rimegepant

rimegepant

Medical condition to be studied

Migraine

Population studied

Short description of the study population

The study includes adult patients who had their first prescription for rimegepant between March 1, 2020, and October 1, 2022, with an initial fill of 8 tablets intended for acute migraine treatment. Eligible participants must have used rimegepant for at least 180 days, be 18 years or older on the index date, and maintain continuous commercial health plan enrollment with both medical and pharmacy benefits before and after the index date. Additionally, patients must have a recorded diagnosis of migraine and at least one prior prescription for certain drugs, including opioids, barbiturates, alprazolam, rescue inhalers, or statins. Individuals are excluded if they previously used other novel acute migraine treatments, such as ubrogepant or lasmiditan, or have a diagnosis of malignant neoplasm (cancer) during the designated periods.

Estimated number of subjects

4.000

Study design details

Setting

This study will analyze an administrative claims database (IQVIA PharMetrics Plus) with information on individuals in the US with commercial, managed Medicare, or managed Medicaid health plans. The study will examine data from September 1, 2019, to March 31, 2023. The first date of rimegepant initiation during this period will be defined as the index date.

Outcomes

Outcomes include changes in opioid and barbiturate utilization patterns before and after rimegepant initiation, measured by prescription fills, quantity dispensed, average dose, duration of use, and discontinuation. Key covariates are demographic and clinical characteristics (age, sex, region, comorbidities, chronic pain, prior preventive treatments) assessed during the baseline period.

Data analysis plan

Among each medication use group, a report with descriptive statistics of the demographic and clinical baseline characteristics as well as medication use prior to rimegepant will be created.

Data management

Data sources

Data source(s), other

IQVIA PharMetrics Plus longitudinal health plan database

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