

Describing Real-World Rimegepant Utilization Patterns and Understanding Perceptions of Migraine Treatment Optimization from the Perspectives of Patients

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Study

Ongoing

Administrative details

EU PAS number

EUPAS1000000232

Study ID

1000000232

DARWIN EU® study

No

Study countries

 United States

Study description

This is a cross-sectional, observational study that will collect real-world data from surveys completed by participants who reside in the United States with a migraine diagnosis currently being treated with rimegepant. There will be two phases of the study. The first phase will include survey development and cognitive pre-test interviews, and the second phase will include administering the survey and performing analysis and reporting. A closed survey composed of multiple questions will be administered to adults with migraine who reported the use of rimegepant in the three (3) months preceding survey administration. A screener questionnaire will be administered to confirm patient's eligibility. After patient's consent, the participant will be directed to a multiple-choice dynamic survey. Key measures to be collected for the survey include migraine-specific quality of life (QoL), as well as experience, behaviors, and treatments related to migraine. Additionally, patient characteristics will be captured, including general demographic and health information. Participants will be contacted by email and will receive a link to the questionnaires. The initial invitation will be followed by one reminder to enhance participation. The data collection period is expected to last approximately nine (9) weeks.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

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Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jessica Cirillo

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/10/2023

Actual: 16/10/2023

Study start date

Planned: 05/07/2024

Actual: 12/08/2024

Data analysis start date

Planned: 07/11/2024

Actual: 06/01/2025

Date of final study report

Planned: 11/03/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc.

Study protocol

[C4951068 Non Interventional Study Patient Preference Protocol V1 0 17Jun2024 Redacted.pdf](#) (287.2 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:

Disease epidemiology
Drug utilisation
Evaluation of patient-reported outcomes

Data collection methods:

Primary data collection

Study design:

This is a cross-sectional, observational study that will collect real-world data from a survey completed by United States participants with a migraine diagnosis currently being treated with rimegepant.

Main study objective:

The purpose of this research is to obtain real-world evidence (RWE) on key outcomes associated with the use of rimegepant among patients with migraine in the US population.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name, other

Rimegepant (Nurtec 75mg ODT)

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

RIMEGEPANT

RIMEGEPANT SULFATE

Anatomical Therapeutic Chemical (ATC) code

(N02CD06) rimegepant

rimegepant

Medical condition to be studied

Migraine

Population studied

Short description of the study population

US adult participants with migraine diagnosis currently taking rimegepant.

Participants must start taken rimegepant at least 3 months prior to the administering of the survey, and must have taken rimegepant within the past 30 days prior to the administering of the survey. Participants will be enrolled after providing their consent to participate in the study.

Age groups

- **Adult and elderly population (≥ 18 years)**
-

Estimated number of subjects

500

Study design details

Setting

Cognitive pre-test interviews will be conducted with migraine patients via telephone. An individual trained in cognitive interviewing will lead participants through draft survey questions, with predefined probes to understand relevance of the survey questions and patient comprehension. Prior to participating, all respondents will give their informed consent to proceed with the interview and to have their interview recorded for analysis purposes only. Participants will need to be in front of a computer to enable viewing of the moderator's secure desktop sharing application.

Participants for the quantitative survey will be invited by a recruiter agency who will use a multisource recruitment approach, meaning that patients will be recruited through several sources. These sources include patient panels, patient databases, social media, patient associations, and physician referrals. Recruiter patient panels include individuals who would qualify for research studies of diverse topics, and the panel participants are tagged with various demographic and disease-specific categories which will allow for targeted recruitment of patients for this study. The cross-sectional quantitative survey will be conducted online, and participants will complete a self-administered electronic screener to determine eligibility. Prior to participating, all participants will give their informed consent to proceed with the study.

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)

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