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

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Study Finalised

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 administrated 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

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

Study institution 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

Actual: 28/05/2026

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:

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.

Outcomes

9.4.1. Primary outcomes

Objective 1: Patient Demographics and Clinical Characteristics

The primary endpoint for Objective 1 includes a detailed description of patients' demographics, clinical characteristics, and comorbidities. This encompasses migraine characteristics such as the time of migraine diagnosis, headache pain, and symptoms, as well as the treatment history of migraine, including the types and number of medications used for acute and preventive treatments. Disease

history and migraine treatment history
were also included.
Objective 2: Treatment Satisfaction and Health-Related Quality of Life (HRQoL)
The primary endpoint for Objective 2 focuses on patients' treatment satisfaction and HRQoL. The outcomes measured include scores from the Migraine-Specific Quality-of-Life Questionnaire (MSQ), the 4-item Migraine Interictal Burden Scale (MIBS), the 2-item Patient Health Questionnaire (PHQ-2), the 2-item Generalized Anxiety Disorder (GAD-2) scale,
work productivity and activity impairment measures, the 9-item Treatment Satisfaction Questionnaire for Medication (TSQM-9), and the 4-item Migraine Treatment Optimization Questionnaire (mTOQ-4).
Objective 3: Treatment Use
The primary endpoint for Objective 3 describes treatment use, including the frequency, duration, timing, and reasons for taking rimegepant. It also covers the wearing-off effect, specific situations, and migraine triggers for which rimegepant was used for short-term preventive (STP) treatment, how participants learned about rimegepant for STP, and details about appointment types, healthcare providers, and the doctor's instructions when rimegepant was first prescribed.
Objective 4: Comparison of Rimegepant Users
The primary endpoint for Objective 4 involves comparing groups of rimegepant users based on their usage patterns (acute, STP, or LTP treatment) across all variables described in the previous outcomes.

Data analysis plan

9.9. Statistical methods
All analyses were performed using Statistical Package for the Social Sciences (SPSS) v28.0 (IBM Corp, 2021) and R v4.3.1 (R Project for Statistical Computing). Further details of the statistical methods are available in the

Statistical Analysis Plan V1.0, 04-December-2024.

9.9.1. Main summary measures

Summary measures included means, medians, standard deviations (SDs), first and third quartiles (Q1 and Q3, respectively), minimums, and maximums for continuous, interval, or discrete/count data, with frequencies and percentages for categorical or binary data.

9.9.2. Main statistical methods

Patient demographics and patient health characteristics were reported descriptively, using counts, means, SDs, minimums, and maximums, and medians and interquartile ranges (where appropriate) for continuous or discrete/count variables and frequencies and percentages for categorical variables. These analyses helped to describe the overall sample for future publications, as well as to identify possible post-hoc stratification variables for select subgroup comparisons. Descriptive analyses were performed on the full data set. One-way analysis of variance (ANOVA) tests or independent-samples t-tests (depending upon the number of levels of the grouping variable) for continuous variables, with chi-square tests for categorical variables, were conducted for subgroup comparisons on PROs. Kruskall-Wallis tests or Fisher's exact tests/Fisher-Freeman-Halton tests were implemented
in the event of extreme skewness or sparse cell counts (<5), respectively. P-values <0.05 (2-tailed) were considered statistically significant for all subgroup comparisons.

9.9.3. Missing values

No imputation was used to statistically fill missing values. Some measures do not use the
full sample due to skip patterns and eligibility for specific questions.

Summary results

Among 425 participants, the sample was predominantly composed of married, White, non-Hispanic women with college degrees; approximately 30% were

covered by Medicaid. Across acute, STP, and LTP user groups, participants reported moderate to high satisfaction with rimegepant effectiveness, yet migraine burden remained substantial, with severe interictal burden, impaired work productivity and daily activities, and the greatest absenteeism observed among LTP users. QoL impairment was similar across groups, and anxiety and depression were common, with over half screening positive for anxiety and nearly half for depression. Real-world treatment patterns reflected flexibility in rimegepant use: among STP users, about half also used rimegepant for LTP and three-quarters for acute treatment, with daily and every-other-day STP dosing used at similar rates and high satisfaction across regimens. Stress was the most common trigger, and many non-STP users expressed willingness to consider STP for predictable triggers, although lack of physician discussion, efficacy concerns, and insurance coverage were reported as barriers.

Documents

Study results

C4951068_Patient Survey Final Report v1.0_21May2026_Redacted.pdf (1.74 MB)

Abstract of study report

C4951068_NIS Study Report Abstract_V1.0_21May2026_Redacted.pdf (593.65 KB)

Data management

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