Concept Elicitation Qualitative Study: Migraine Patient Experiences with Zavegepant

First published: 04/04/2025

Last updated: 17/04/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000442

Study ID

1000000442

DARWIN EU® study

No

Study countries

☐ United States

Study description

This is a non-interventional, cross-sectional qualitative study involving one-on-one interviews with participants from United States who have used zavegepant as an acute migraine treatment at least once in the past three months.
This qualitative study will involve conducting a 60-minute one-on-one, semi-structured interviews via online conferencing/telephone.
This methodology allows the collection of patient perception and real-world experiences regarding the use of zavegepant for migraine treatment and will provide an in-depth understanding of patient experience unmet treatment needs.
After providing their consent, a moderator will ask participants questions following a semi-structured interview guide to explore participants' experiences with migraine, zavegepant treatment and experiences.
All interviews will be audio recorded for transcription and qualitative analysis.
Participants will be informed in advance that all information will be anonymized.
Up to 20 participants will be recruited, including a mix of individuals with positive, neutral, and negative experiences with the medication, as well as varying frequencies of use.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

samantha.sweeney@pfizer.com

Primary lead investigator

Samantha Sweeney

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/08/2024

Actual: 22/08/2024

Study start date

Planned: 07/04/2025

Actual: 11/04/2025

Data analysis start date

Planned: 02/06/2025

Date of final study report

Planned: 15/12/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc.

Study protocol

C5301035_NIS protocol_Migraine Patient Experiences with Zavegepant_V1.0_20FEB2025_REDACTED.pdf(260.92 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:

Drug utilisation

Evaluation of patient-reported outcomes

Data collection methods:

Primary data collection

Study design:

This is a non-interventional, cross-sectional qualitative study involving one-on-one interviews with eligible participants.

Main study objective:

The study aims to assess patient´s perceptions and experiences regarding the use of zavegepant as an acute treatment treatment for migraine in the real-world setting in the United States.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine, other

Zavegepant (Zavzpret 10mg)

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

RIMEGEPANT

Anatomical Therapeutic Chemical (ATC) code

(N02CD08) zavegepant

zavegepant

Medical condition to be studied

Migraine

Population studied

Short description of the study population

Adult participants (18 years old or older) who have used zavegepant (Zavzpret) at least once in the past 3 months and who reside in the United States.
Participants who indicates or exhibits speaking or hearing difficulties, or lacks sufficient understanding of English, which would make a telephone conversation challenging will be excluded.
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

20

Study design details

Setting

Participants will be identified and recruited from patient panels.

A third-party vendor will recruit respondents from known migraine patients who have previously opted in to participating in research.

Before providing their informed consent to participate in the study, participants will complete a screener to determine their eligibility and assess their overall experience (positive, neutral, or negative) with the medication.

If eligible, an online conferencing/telephone interview will be conducted.

The recruitment and data collection are expected to take place over a period of 10 weeks.

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

Unknown