

# Plain Language Clinical Study Summary

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study medicine works, how it works, and if it is safe to prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

**Sponsor:** Pfizer Inc.

**Medicine Studied:** Zavegepant

**Protocol Number:** C5301008

**Dates of Study:** 29 November 2023 to 30 May 2025

**Title of this Study:** A Study to Learn About Zavegepant as the Acute Treatment of Migraine in Asian Adults

[A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Zavegepant Intranasal (IN) for the Acute Treatment of Migraine in Asian Adults]

**Date of this Report:** 28 January 2026

– Thank You –



If you participated in this study, Pfizer, the Sponsor, would like to thank you for your participation.

This summary will describe the study results. Do you have any questions about the study or the results? If so, please contact the doctor or staff at your study site.



## Why was this study done?

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### What is migraine?

Migraine is characterized by moderate to severe episodic unilateral pulsating headaches that last for 4 to 72 hours. The pain often gets worse with movement, causing nausea, feeling or being sick and/or sensitivity to bright lights and sound. Some medications and lifestyle changes may help reduce attacks and make them less severe.

### What is zavegepant?

Zavegepant (za-ve-je-pant) is an investigational drug for the acute treatment of migraine in adults. This treatment works by blocking a protein called calcitonin gene-related peptide (CGRP), involved in migraine attacks. By blocking CGRP, zavegepant helps stop the migraine process by reducing headache and other associated symptoms like sensitivity to light. It also avoids the cardiovascular effects produced by the narrowing of blood vessels (vasoconstriction) associated with the current standard triptan therapy.

In this study, zavegepant was given as a nasal spray. This formulation helps the absorption through the nasal cavity into the blood, skipping the stomach and liver. This may help to avoid migraine associated symptoms like nausea and/or vomiting.

### What was the purpose of this study?

The purpose of this study was to learn about the effects and safety of zavegepant compared to placebo in the acute treatment of migraine in Asian adults.

A “placebo” does not have any medicine in it, but it looks just like the study medicine.

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## Researchers wanted to know:

- How many participants were free from migraine pain at 2 hours after taking zavegepant or placebo?
  - How many participants were free from the most bothersome symptom at 2 hours after taking zavegepant or placebo?
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## What happened during the study?

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### How was the study done?

Researchers tested zavegepant in a group of study participants to find out how many participants were free from migraine pain as well as how many participants were free from the most bothersome symptom at 2 hours after taking zavegepant or placebo. Researchers then compared the results of study participants taking the zavegepant to the results of study participants taking placebo.

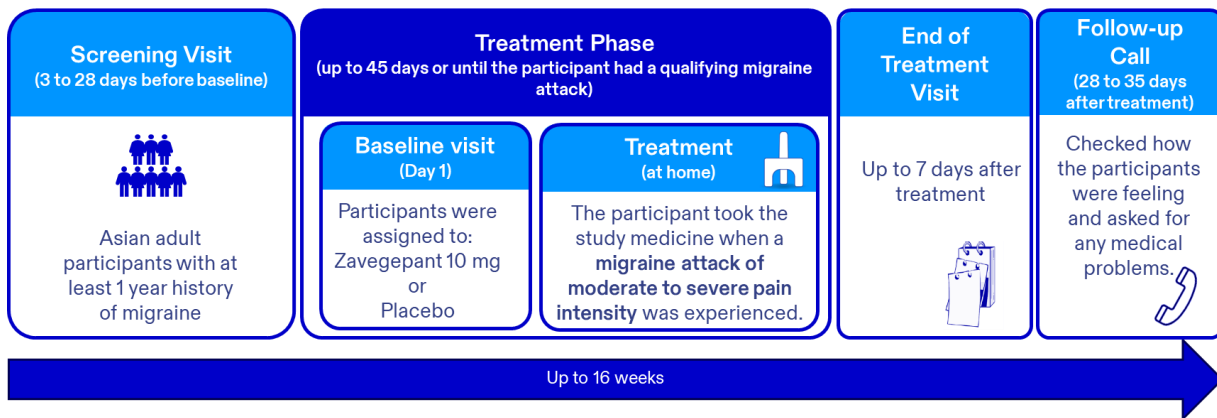
Participants had 3 study visits at the study clinic (screening, baseline and end of treatment visits) and 1 telephone call (follow-up visit). At the screening visit, researchers checked if the participants could take part in the study. At the baseline visit, participants were assigned to zavegepant or placebo in a random order, by chance alone. This is called “randomization”. The study participants and researchers did not know who took zavegepant and who took placebo. This is known as a “blinded” study.

Treatment was done at home. Participants were instructed to take the study medicine only once, when a migraine attack of moderate to severe pain intensity was experienced and after answering all the questions (approximately 5 minutes) about the episode of migraine, in an electronic diary (similar to a cell phone).

At the end of treatment visit, researchers took samples of blood and urine for laboratory tests, performed physical examinations and electrocardiogram, checked for any medical problems or non-study medications, collected the electronic diary, and collected used/unused study medicine device.

At the follow-up visit conducted via telephone call, researchers checked how the participants were feeling and asked for any medical problems or non-study medications that happened about 1 month after treatment. Details are shown in Figure 1.

**Figure 1: What happened during the study**



## Where did this study take place?

The Sponsor ran this study at 59 locations in 3 countries/regions in Asia.

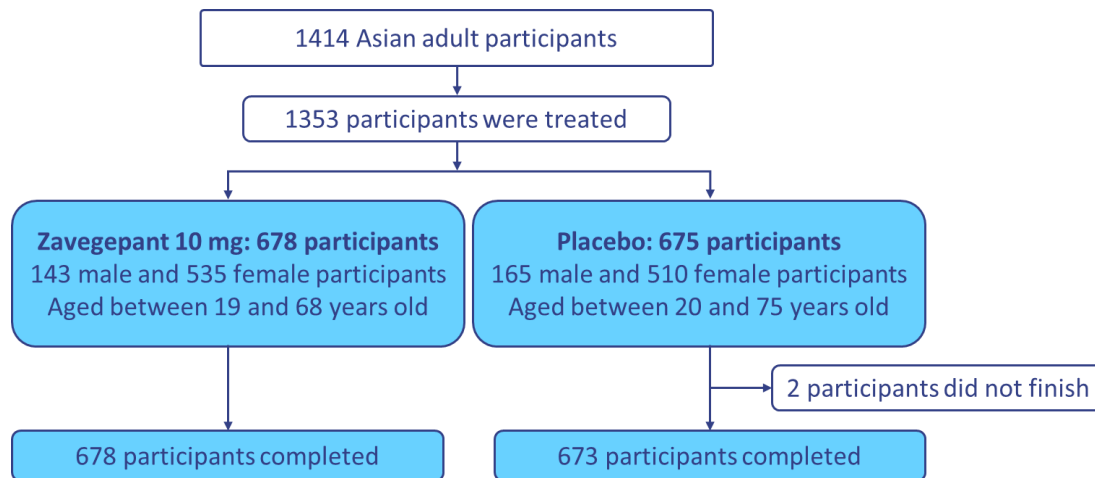
## When did this study take place?

It began on 29 November 2023 and ended on 30 May 2025.

## Who participated in this study?

The study included Asian adult participants with at least 1 year history of migraine. Of the 1414 participants who started the study, 1353 were treated and 1351 completed the study (2 participants did not finish the study, 1 by their choice and 1 who was unable to be contacted). Details are shown in Figure 2.

**Figure 2: The number of participants in the study**



### How long did the study last?

Study participants were in the study for up to about 16 weeks (4 months). The entire study took approximately one and a half years to complete.

When the study ended in May 2025, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

## What were the results of the study?

### How many participants were free from migraine pain at 2 hours after taking zavegepant or placebo?

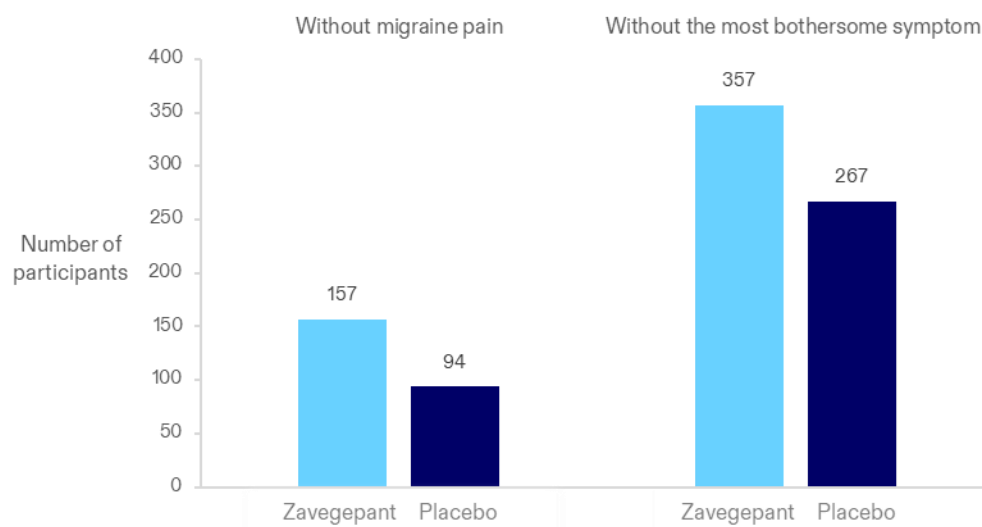
157 out of 677 participants (23%) who took zavegepant and 94 out of 669 participants (14%) who took placebo were free from migraine pain at 2 hours after treatment (Figure 3).

### How many participants were free from the most bothersome symptom at 2 hours after taking zavegepant or placebo?

The most bothersome symptom was selected from nausea, sensitivity to bright lights or sensitivity to sound.

357 out of 677 participants (53%) who took zavegepant and 267 out of 669 participants (40%) who took placebo were free from the most bothersome symptom at 2 hours after treatment (Figure 3).

**Figure 3: How many participants were free from migraine symptoms**



The results from this study have shown that at 2 hours after taking the study medicine, there were more participants in the zavegepant group without migraine pain or without the most bothersome symptom than in the placebo group.

Based on these results, the researchers have decided that the results are not likely due to chance. Zavegepant may therefore, help as an acute treatment for migraine.

This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results.

## What medical problems did participants have during the study?

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The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused by a study treatment or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors try to understand what effects a study medicine might have on a participant.

During treatment, 119 out of 678 participants (18%) who took zavegepant and 76 out of 675 participants (11%) who took placebo had at least 1 medical problem. During the follow-up, 19 out of 678 participants (3%) who took zavegepant and 14 out of 675 participants (2%) who took placebo had at least 1 medical problem. None of the participants left the study because of medical

problems. The most common medical problems – those reported in 1% or more participants in any group – are described below.

Below are instructions on how to read Table 1.

### Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists medical problems that were commonly reported during treatment. All medical problems reported in 1% or more participants in any group are listed.
- The **2nd** column tells how many of the 678 participants who took zavegepant reported each medical problem. Next to this number is the percentage of the 678 participants who took zavegepant and reported the medical problem.
- The **3rd** column tells how many of the 675 participants who took placebo reported each medical problem. Next to this number is the percentage of the 675 participants who took placebo and reported the medical problem.
- Using these instructions, you can see that 25 out of the 678 participants (4%) who took zavegepant reported taste disturbance. A total of 2 out of the 675 participants (less than 1%) who took placebo reported taste disturbance.

**Table 1. Commonly reported (in 1% or more participants) medical problems in study participants, during treatment**

<b>Medical Problem</b>	<b>Zavegepant (678 Participants)</b>	<b>Placebo (675 Participants)</b>
<b>Taste disturbance</b>	25 out of 678 participants (4%)	2 out of 675 participants (less than 1%)
<b>Infection of the structures that carry urine</b>	14 out of 678 participants (2%)	11 out of 675 participants (2%)
<b>Discomfort to the nose</b>	12 out of 678 participants (2%)	1 out of 675 participants (less than 1%)
<b>Nose and throat infection</b>	9 out of 678 participants (1%)	9 out of 675 participants (1%)
<b>Inflammation of the nose and throat</b>	7 out of 678 participants (1%)	2 out of 675 participants (less than 1%)
<b>Decreased white blood cell count</b>	3 out of 678 participants (less than 1%)	7 out of 675 participants (1%)

During the follow-up, the medical problems reported in 2 or more participants were chest pain (2 participants in the zavegepant group), nose and throat infection (3 participants each in the zavegepant and placebo groups) and bulging of spinal disc (2 participants in the zavegepant group).

## Did study participants have any serious medical problems?

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A medical problem is considered “serious” when it is life-threatening, needs hospital care, or causes lasting problems.

During treatment, 3 participants had serious medical problems.

- 1 participant had a lump or swelling in the neck and 1 participant had miscarriage in the zavegepant group.
- 1 participant in the placebo group had heart disease caused by narrowing or blockage of blood vessels.

During the follow-up, 3 participants in the zavegepant group each had 1 serious medical problem (tissue like womb lining growing outside the womb, bulging of spinal disc or stroke).

Researchers believe that none of the serious medical problems reported in the participants were related to the study medicine.

No participants died during the study.

## Where can I learn more about this study?

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If you have questions about the results of your study, please speak with the doctor or staff at your study site.

For more details on your study protocol, please visit:

[www.pfizer.com/research/](http://www.pfizer.com/research/)

Use the protocol number **C5301008**

[research clinical trials/trial results](#)

The full scientific report of this study is available online at:

[www.clinicaltrials.gov](http://www.clinicaltrials.gov)

Use the study identifier **NCT05989048**

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients.

Again, if you participated in this study,  
**thank you** for volunteering.

We do research to try to find the  
best ways to help patients, and you helped  
us to do that!

