

# 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:** Nurtec<sup>®</sup> ODT (also called rimegepant)

**Protocol Number:** C4951004 (BHV3000-406)

**Dates of Study:** 18 October 2022 to 10 June 2025

**Title of this Study:** Efficacy and Tolerability of Rimegepant for the Acute Treatment of Migraine in Adults Unsuitable for Triptan Use

[A Phase 4, Randomized, Double-Blind Placebo-Controlled, Efficacy and Tolerability Trial of Rimegepant for the Acute Treatment of Migraine in Adults Unsuitable for Triptan Use]

**Date of this Report:** 20 May 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 a migraine?

**Migraine** is a type of headache disorder. It is a condition affecting the brain with recurrent attacks that are characterized by multiple symptoms, including headache of moderate-to-severe intensity, sensitivity to noise or light, as well as nausea and vomiting. Each migraine attack may last 4 to 72 hours if not treated.

### What is rimegepant?

Rimegepant (ri-ME'-je-pant) is a medicine approved for the treatment and prevention of migraine attacks in a number of countries around the world. It is also known as Nurtec® ODT, which is rimegepant in the form of an **orally disintegrating tablet (ODT)**.

Medicines in **ODT** form are placed on or under the tongue and dissolve quickly in the mouth even without water.

“Calcitonin gene-related peptide”, also called **CGRP**, is a protein released in the brain and the nervous system. CGRP is involved in the development of migraine attacks through the transmission of pain signals and swelling of blood vessels. Rimegepant is designed to block CGRP’s effects, thereby relieving symptoms and/or reducing how often people have migraine attacks.



## What was the purpose of this study?

The main goal of this study was to learn if rimegepant works in relieving migraine headache pain in adult participants who cannot take medications called triptans for medical reasons. Triptans are a group of medicines used to treat migraine attacks.

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### Researchers wanted to know:

**Did treatment with rimegepant relieve migraine headache pain?**

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## What happened during the study?

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### How was the study done?

The study had 3 periods: **Double-blind** (or **DB**) treatment period, **Open-label extension** (or **OLE**) period, and **Follow-up** period.

#### **DB treatment period**

During the DB treatment period, participants were assigned by chance to get rimegepant 75 milligrams (mg) or placebo. A placebo does not have any medicine in it, but it looks and feels like rimegepant.

Participants took their assigned study treatment 1 time when they experienced a moderate or severe migraine attack during the DB treatment period.

“Double-blind or DB” means that both participants and researchers did not know which study treatment the participant had been assigned to get. This period lasted up to 45 days or until the participant experienced a moderate or severe migraine attack, whichever happened first.

Participants who completed the DB treatment period and met the rules to continue taking treatment could enter the OLE period. Participants who did not experience a moderate or severe migraine attack in the DB treatment period were not allowed to enter the OLE period.

### OLE period

During the OLE period, participants took rimegepant 75 mg once on days they had a moderate or severe migraine attack. Participants were allowed to take rimegepant up to 18 times in a month (every 28 days).

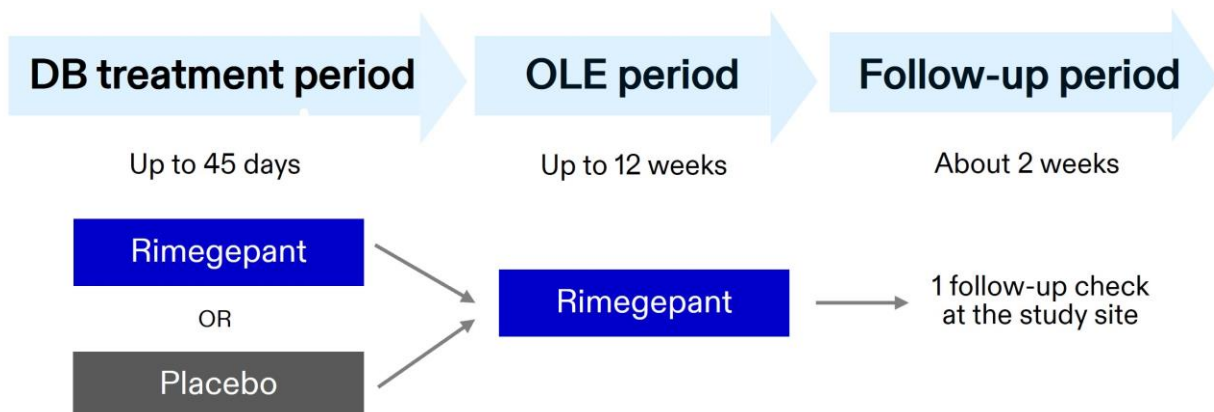
“Open-label” means that both participants and researchers knew that all participants received rimegepant during the OLE period. This period lasted up to 12 weeks (or about 3 months).

### Follow-up period

Throughout the study, participants were asked how they were feeling and what medications they were taking. About 2 weeks after their last visit in the OLE period, participants had 1 follow-up check at the study site.

Figure 1 below shows what happened in each study period.

**Figure 1. Study plan**



## Where did this study take place?

The Sponsor ran this study at 107 locations in 15 countries in Europe, North America, and Oceania regions.

## When did this study take place?

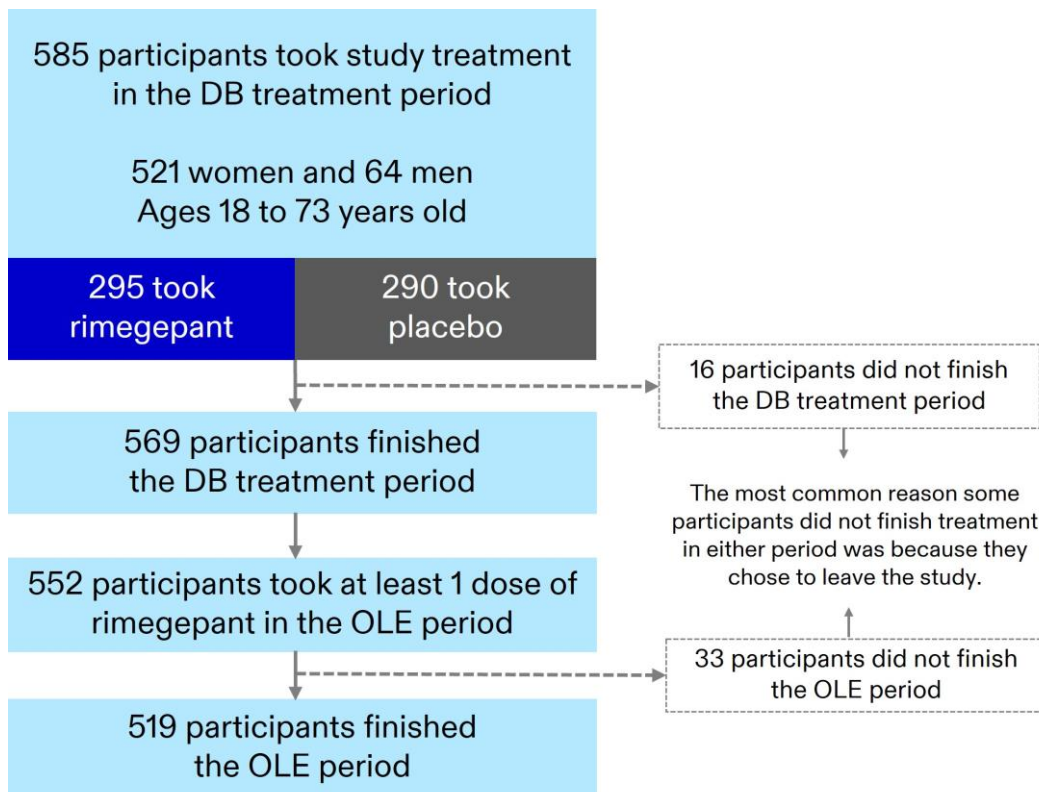
It began on 18 October 2022 and ended on 10 June 2025.

## Who participated in this study?

The study included adult participants with migraine who cannot take triptans for medical reasons. Participants must have had migraine attacks for at least 1 year before starting this study.

Figure 2 shows how many participants were in the study.

**Figure 2. Number of participants in the study**



## How long did the study last?

Study participants were in the study for up to 24 weeks. The entire study took about 2 years and 8 months to complete. The study was completed as planned.

When the study ended in June 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?

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### Did treatment with rimegepant relieve migraine headache pain?

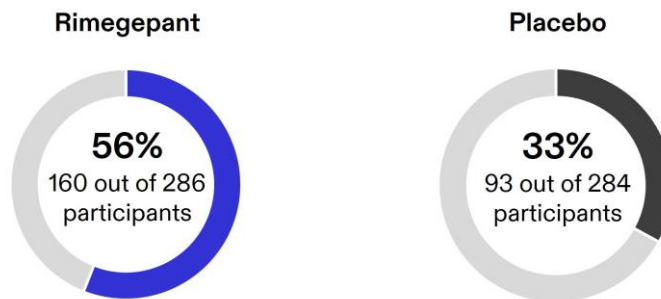
To answer this question, researchers looked at how many participants with moderate or severe migraine attacks reported pain relief 2 hours after taking the study treatment in the DB treatment period. Participants rated their migraine headache pain on a scale of 0 to 3, where:

- 0 = no pain
- 1 = mild pain
- 2 = moderate pain
- 3 = severe pain

In this study, **pain relief** is when participants rated their migraine headache pain as 0 (no pain) or 1 (mild pain).

Researchers then compared the results of those who took rimegepant to those who took placebo.

The charts below show how many participants reported pain relief 2 hours after taking the study treatment in the DB treatment period:



Overall, study results show that rimegepant 75 mg ODT may relieve migraine pain 2 hours after taking it. The researchers have decided that these results are not likely the result of chance.

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.

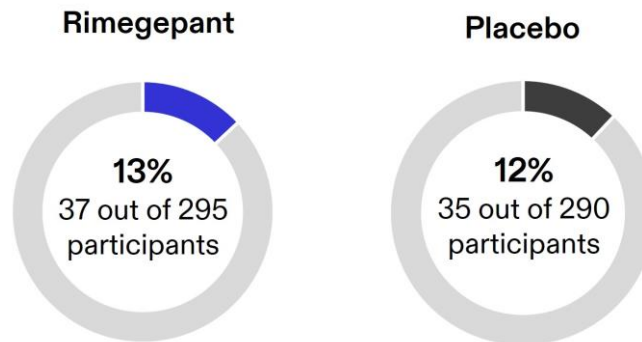
## What medical problems did participants have during the study?

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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.

## DB treatment period

The charts below show how many participants in each treatment group had any medical problems during the DB treatment period.



The most common medical problems during the DB treatment period –reported by at least 1% of participants in any treatment group – were:

- **Common cold** in:
  - 5 out of 295 participants (2%) in the rimegepant group
  - 3 out of 290 participants (1%) in the placebo group
- **High blood levels of “bilirubin”** (a breakdown product of red blood cells, which can cause yellowing of the skin and eyes), indicating liver problems, in:
  - 0 participants in the rimegepant group
  - 3 out of 290 participants (1%) in the placebo group
- **Migraine** in:
  - 0 participants in the rimegepant group
  - 4 out of 290 participants (1%) in the placebo group

No participants in the rimegepant group and 2 out of 290 participants (less than 1%) in the placebo group did not continue to the OLE period because of medical problems.

### **OLE period**

A total of 260 out of 552 participants (47%) who took at least 1 dose of rimegepant in the OLE period had any medical problem. The most common medical problems during the OLE period – reported by at least 3% of participants – were:

- **Common cold** in 57 out of 552 participants (10%)
- **Nose and throat infection** in 20 out of 552 participants (4%)
- **Headache** in 19 out of 552 participants (3%)

A total of 5 out of 552 participants (less than 1%) stopped taking rimegepant because of medical problems.

## **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.

### **DB treatment period**

No participants had any serious medical problems during the DB treatment period.

## OLE period

A total of 2 out of 552 participants (less than 1%) who took at least 1 dose of rimegepant in the OLE period had any serious medical problem. The serious medical problems during the OLE period – reported by 1 participant each – were:

- **“Miscarriage”**, or unexpected loss of pregnancy
- **Thinking about ending one’s life**

Researchers do not believe any of the serious medical problems reported by participants were related to rimegepant.

None of the 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/  
research\\_clinical\\_trials/trial\\_results](http://www.pfizer.com/research/research_clinical_trials/trial_results) Use the protocol number **C4951004**  
**(BHV3000-406)**

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

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) Use the study identifier **NCT05509400**  
<https://clinicaltrialsregister.eu> Use the study identifier  
**2024-513269-37-00**

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!

