Clinical Study Results

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 medication 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: Zavzpret™ (zavegepant, also known as PF-07930207 or BHV-3500)

Protocol Number: BHV3500-203 (C5301004)

Dates of Study: 25 April 2020 to 29 April 2022

Title of this Study: A Study of Zavegepant Given Through The Nose Compared With Placebo in Hospitalized Adults With COVID-19 Who Needed Supplemental Oxygen

[Phase 2/3: Double-Blind, Randomized, Placebo Controlled, Safety, and Efficacy Trial of Zavegepant (BHV-3500) Intranasal (IN) for Hospitalized Patients With COVID-19 Requiring Supplemental Oxygen]

Date of this Report: 2 August 2023

– 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. If you have any questions about the study or the results, please contact the doctor or staff at your study site.

Why was this study done?

What is COVID-19?

Coronavirus disease 2019 (COVID-19) led to a global pandemic in 2020. COVID-19 infection is caused by a virus that is easily spread.

People who test positive for COVID-19 can show symptoms such as fever, dry cough, and shortness of breath. Symptoms can quickly become very serious and result in the need for supplemental oxygen, which is an extra oxygen given to someone through tubes or a mask.

When it gets worse, COVID-19 infection may also lead to the insertion of a tube into the person's windpipe to help with breathing (also known as intubation), or may even lead to death.

What is zavegepant?

The study medication Zavzpret™ (also called zavegepant) is given through the nose as a nasal spray. It can be used to treat a type of headache called migraine. Researchers think that zavegepant may also help treat people with COVID-19.

What was the purpose of this study?

The main purpose was to see if zavegepant can safely treat hospitalized adults with COVID-19 who needed supplemental oxygen compared with placebo. A placebo does not have any medicine in it, but it looks, feels, and operates just like the actual zavegepant device.

Researchers wanted to know:

Did taking zavegepant for 15 days help participants get better from COVID-19 compared with those who took placebo?

What happened during the study?

How was the study done?

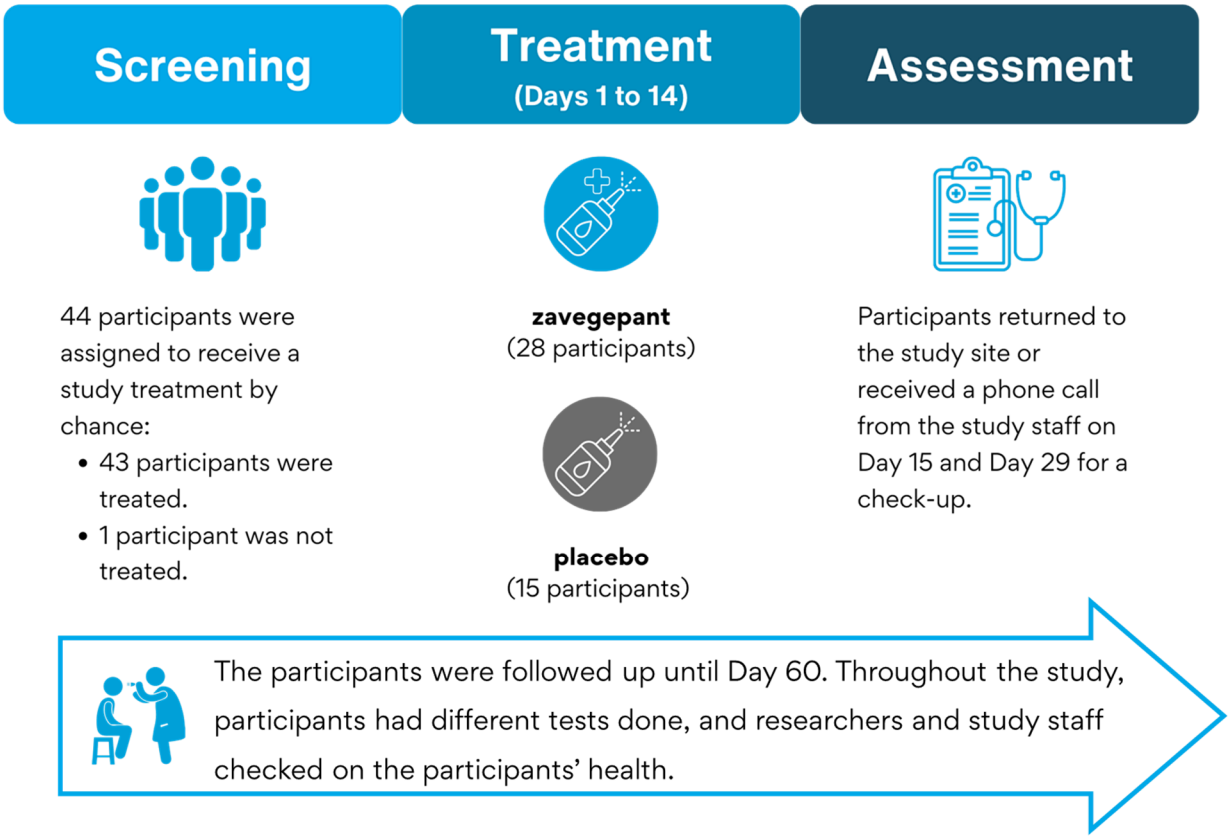
Researchers tested zavegepant on a group of study participants who were hospitalized and needed supplemental oxygen. Researchers wanted to see how many of those who took zavegepant got better from COVID-19.

Researchers then compared the results of those who took zavegepant with the results of those who took placebo. A placebo does not have any medicine in it, but it looks, feels, and operates just like the actual zavegepant device.

The study participants and researchers did not know who took zavegepant and who took placebo. This is known as a “blinded” study. Study participants were assigned to each group by chance alone.

Figure 1 shows what happened during the study.

Figure 1. Overall study design



Where did this study take place?

The Sponsor ran this study at 3 locations in 1 country (the United States of America).

When did this study take place?

It began 25 April 2020 and ended 29 April 2022.

Who participated in this study?

The study included hospitalized adults with COVID-19 who needed supplemental oxygen.

- A total of 27 men and 16 women participated.
- All study participants were between the ages of 31 and 80 years.

Of the 43 study participants who took a study medication:

- 5 finished the treatment period.
- 38 did not finish the treatment period. The most common reason for stopping treatment was because they were discharged from the hospital.

How long did the study last?

Study participants were in the study for up to 60 days. The entire study took 2 years to complete.

The Sponsor ended the study earlier than planned because of the small number of participants who signed up. It was not due to safety concerns with zavegepant.

When the study ended in April 2022, 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?

Did taking zavegepant for 15 days help participants get better from COVID-19 compared with those who took placebo?

The study wanted to compare how zavegepant worked as a COVID-19 treatment compared with placebo. However, the tests for comparison were not done because the study ended earlier than planned due to the small number of participants who signed up.

The answers to the study question are not shown in this summary because it was not possible for researchers to find out if there was a difference between zavegepant and placebo in treating hospitalized adults with COVID-19 who needed supplemental oxygen because the study ended up being too small.

What medical problems did participants have during the study?

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 medication might have on a participant.

Overall, 36 out of 43 participants (84%) had at least 1 medical problem. These were seen in:

- 23 out of 28 participants (82%) who took zavegepant.
- 13 out of 15 participants (87%) who took placebo.

A total of 3 out of 43 participants (7%) had to stop treatment because of medical problems. Table 1 shows the most common medical problems – those seen in 10% or more of participants overall.

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 the study. All medical problems seen in 10% or more participants overall are listed.
- The **2nd** column tells how many of the 28 participants taking zavegepant reported each medical problem. Next to this number is the percentage of the 28 participants taking zavegepant who reported the medical problem.
- The **3rd** column tells how many of the 15 participants taking placebo reported each medical problem. Next to this number is the percentage of the 15 participants taking placebo who reported the medical problem.
- Using these instructions, you can see how many participants had a change in the sense of taste:
    - 16 out of 28 participants (57%) who took zavegepant.
    - 1 out of 15 participants (7%) who took placebo.

Table 1. Commonly reported medical problems by study participants		
Medical Problem	**Zavegepant (28 Participants)**	**Placebo (15 Participants)**
Change in the sense of taste	16 out of 28 participants (57%)	1 out of 15 participants (7%)
Low levels of sodium in blood	4 out of 28 participants (14%)	5 out of 15 participants (33%)
High levels of potassium in blood	5 out of 28 participants (18%)	2 out of 15 participants (13%)
Stuffy nose	3 out of 28 participants (11%)	4 out of 15 participants (27%)
Nose bleed	3 out of 28 participants (11%)	2 out of 15 participants (13%)
High levels of white blood cells	8 out of 28 participants (29%)	3 out of 15 participants (20%)
Low levels of red blood cells	4 out of 28 participants (14%)	3 out of 15 participants (20%)
Getting admitted to the intensive care unit of the hospital	7 out of 28 participants (25%)	3 out of 15 participants (20%)
Insertion of a tube into the person's windpipe (intubation)	3 out of 28 participants (11%)	2 out of 15 participants (13%)

Did study participants have any serious medical problems?

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

In total, 8 out of 43 participants (19%) had at least 1 serious medical problem. These were seen in:

- 6 participants who took zavegepant.
- 2 participants who took placebo.

The list below shows the most common serious medical problems – those seen in 2 or more participants in either treatment group:

- **Intubation** was seen in:
  - 3 out of 28 participants (11%) who took zavegepant.
  - 2 out of 15 participants (13%) who took placebo.
- **Getting admitted to the intensive care unit of the hospital** was seen in 3 out of 28 participants (11%) who took zavegepant.
- **Inability to breathe** was seen in 3 out of 28 participants (11%) who took zavegepant.

Researchers did not think that any of the serious medical problems were related to zavegepant.

There were 6 out of 43 participants (14%) who died during the study. They happened in:

- 1 participant from each group during the treatment period.
- 4 participants from the zavegepant group during follow-up.

Where can I learn more about this study?

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

Use the protocol number **C5301004 (BHV3500-203)**

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

www.clinicaltrials.gov

Use the study identifier **NCT04346615**

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!