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: Sisunatovir

Protocol Number: C5241007

Dates of Study: 08 December 2023 to 30 September 2024

Title of this Study: A Study to Learn About the Study Medicine Sisunatovir in Adults With Respiratory Syncytial Virus (RSV) Infection

[An Interventional Phase 2/3, Adaptive, Multi-Center, Randomized, Double-Blind Study to Investigate Efficacy and Safety of Oral Sisunatovir Compared With Placebo in Non-Hospitalized Symptomatic Adults With Respiratory Syncytial Virus Infection Who Are at Risk of Progression to Severe Illness]

Date of this Report: 08 May 2025

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– 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?

What is respiratory syncytial virus infection?

Respiratory syncytial virus (RSV) is a virus that infects the nose, throat, and lungs. In most people it is similar to a bad cold. However, RSV can cause more severe respiratory problems in people with other medical conditions or advanced age, like trouble breathing, and requiring hospitalization.

What is sisunatovir?

The study medicine, sisunatovir, is being investigated as a treatment for RSV infection in adults who are at increased risk of developing severe illness. Sisunatovir works by blocking the virus from spreading to lung cells and thus preventing progression to severe illness.

What was the purpose of this study?

The purpose of the study was to find out how many participants became hospitalized with RSV or died from any cause, within 28 days after taking sisunatovir or placebo.

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

The study stopped early due to business reasons. There were no safety concerns in the decision to stop the study.

Researchers wanted to know:

What effect did taking sisunatovir have on RSV-related hospitalizations or death from any cause, after 28 days?

This study stopped early and was not completed as planned. As a result, not enough participants were enrolled, and therefore, the results for the main research question are not meaningful. There is not enough information to reach a conclusion.

What happened during the study?

How was the study done?

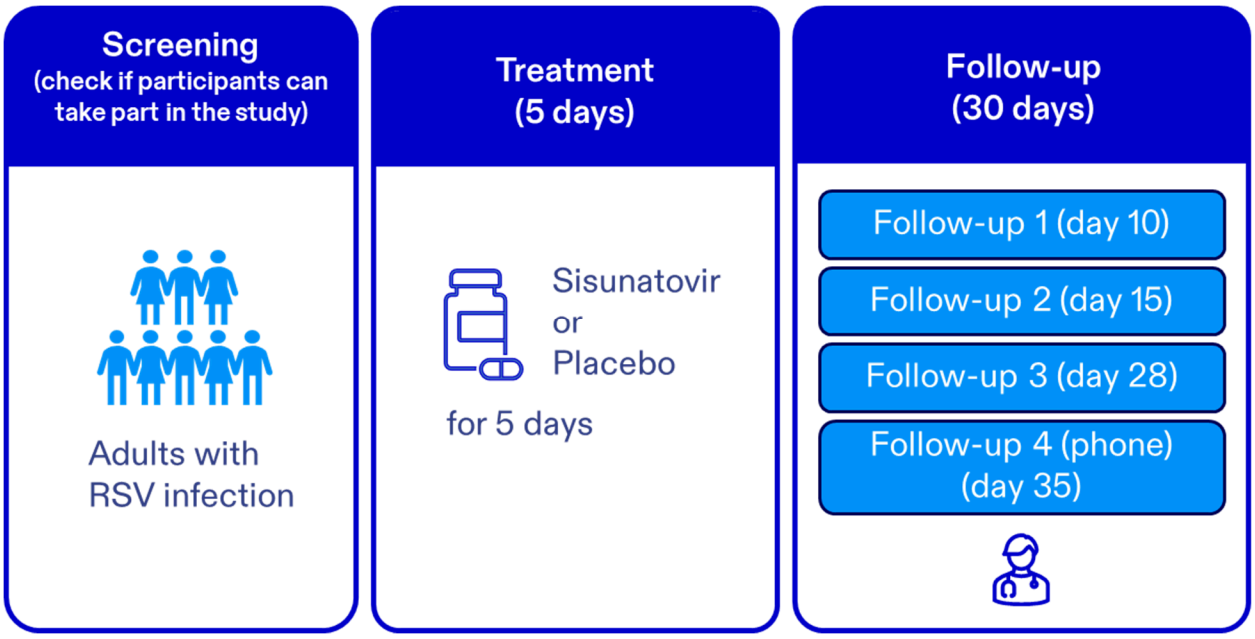
Researchers tested sisunatovir in a group of study participants with RSV to find out if taking sisunatovir or placebo had any effect on RSV-related hospitalizations or death from any cause, after 28 days. (Figure 1)

Researchers then compared the results of study participants taking sisunatovir to the results of study participants taking a placebo.

The study participants and researchers did not know who took sisunatovir and who took the placebo. This is known as a "blinded" study. Study participants were assigned to each group by chance alone. This is known as "randomization".

Participants took sisunatovir or placebo for 5 days during the study. After the last treatment dose, the participants were assessed for another 30 days in a follow-up safety period.

Figure 1: What happened during the study



Where did this study take place?

The Sponsor ran this study at 16 locations in 4 countries: in the United States of America, China, Japan and India.

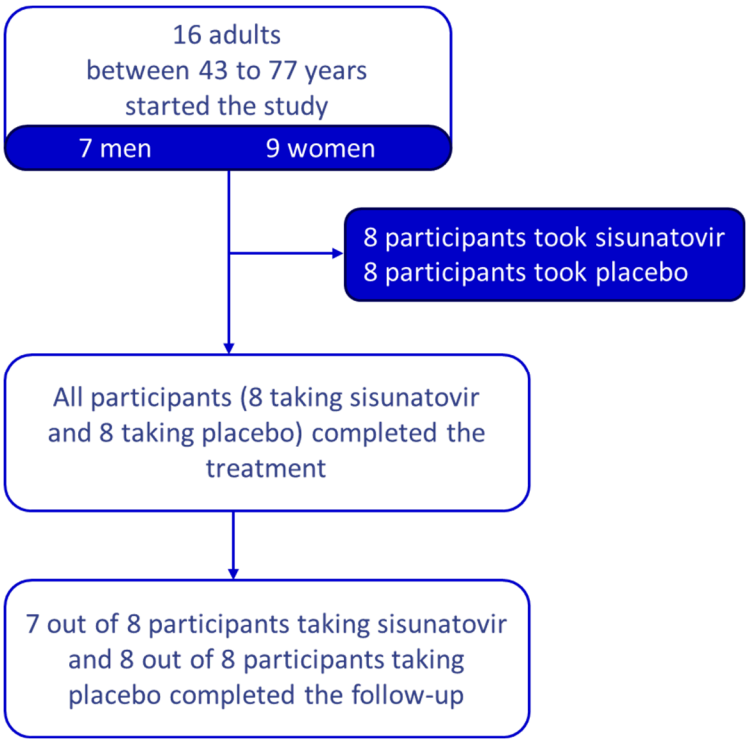
When did this study take place?

It began on 08 December 2023 and ended on 30 September 2024.

Who participated in this study?

The study included adult participants aged 18 years or older, with diagnosis of RSV infection and who were at increased risk of progression to severe illness, as 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 5 weeks. The study was open for 10 months.

This study stopped early and was not completed as planned due to business reasons. There were no safety concerns in the decision to stop the study.

When the study ended in September 2024, 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?

What effect did taking sisunatovir have on RSV-related hospitalizations or death from any cause, after 28 days?

This study stopped early and was not completed as planned. The results shown below for the main research question are not meaningful. There is not enough information to reach a conclusion.

Based on the limited data, there were no RSV-related hospitalizations or deaths from any cause after 28 days, in either treatment group.

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 medicine might have on a participant.

Five out of 16 participants (31%) in this study had at least 1 medical problem. None of the participants left the study because of medical problems. All medical problems were reported in 1 participant each, as described in Table 1 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 the study. These medical problems were reported by 1 participant each.
- The **2nd** column tells how many of the 8 participants who took sisunatovir reported each medical problem. Next to this number is the percentage of the 8 participants who took sisunatovir and reported the medical problem.
- The **3rd** column tells how many of the 8 participants who took a placebo reported each medical problem. Next to this number is the percentage of the 8 participants who took a placebo and reported the medical problem.
- Using these instructions, you can see that 1 out of the 8 participants (13%) who took sisunatovir reported headache. A total of 1 out of the 8 participants (13%) who took a placebo reported constipation.

Table 1. Commonly reported medical problems by study participants

Medical Problem	Sisunatovir (8 Participants)	Placebo (8 Participants)
Headache	1 out of 8 participants (13%)	0 participants
Constipation	0 participants	1 out of 8 participants (13%)

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Table 1. Commonly reported medical problems by study participants		
Medical Problem	**Sisunatovir (8 Participants)**	**Placebo (8 Participants)**
Infection of nose and throat	0 participants	1 out of 8 participants (13%)
Increase of an enzyme called alanine aminotransferase in the blood	0 participants	1 out of 8 participants (13%)
Increase of an enzyme called gamma glutamyl transferase in the blood	0 participants	1 out of 8 participants (13%)
Discomfort in the head	0 participants	1 out of 8 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.

None of the participants had serious medical problems.

No participants died during the study.

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 **C5241007**

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

www.clinicaltrials.gov

Use the study identifier **NCT06079320**

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!

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