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: C5241009

Dates of Study: 15 February 2024 to 03 September 2024

Title of this Study: A Study to Learn About the Safety and Tolerability of Sisunatovir in Infants and Children With Pneumonia, Caused by the Respiratory Syncytial Virus

[An Interventional, Phase 1b, Randomized, Double-blind, Sponsor-Open, Placebo-Controlled, Multi-Center, Dose-Finding Study to Evaluate Safety, Tolerability and Pharmacokinetics of Sisunatovir in Pediatric Participants up to Age 60 Months With Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Infection (LRTI)]

Date of this Report: 27 February 2025

Pfizer

– Thank You –

If your child 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 child's study site.

Why was this study done?

What is Respiratory Syncytial Virus infection?

Respiratory Syncytial Virus (RSV) is a leading cause of infections in the airways. Symptoms may include cough, fever, sore throat, and runny nose. RSV infection can become serious, especially in those with underlying medical conditions and in the very young and older age groups. A serious RSV infection may cause lung infections such as pneumonia or bronchiolitis (inflammation of small airways in the lungs). These infections are known as lower respiratory tract infections (LRTIs), which may need to be treated in the hospital.

What is Sisunatovir?

Sisunatovir (si-soo-NAT-oh-veer) is a medicine that is being studied for the treatment of infections caused by RSV. Sisunatovir blocks a protein in the RSV virus called the RSVF protein. By blocking this protein, sisunatovir prevents the virus from entering human cells and spreading the infection. Blocking the RSVF protein may help the immune system to defend the body against severe RSV infection. In this summary, sisunatovir is referred to as the study medicine.

What was the purpose of this study?

The purpose of this study was to learn about the safety and tolerability of sisunatovir in infants and children with RSV-LRTI who were aged 1 day to 60 months. This study was stopped early for business reasons and not due to safety concerns.

Researchers wanted to know:

- **How many children experienced medical problems during the treatment period?**

- **How many children experienced medical problems or serious medical problems that led to their discontinuation from the study?**
- **How many children had abnormal laboratory test results, or changes in vital signs (blood pressure, heart rate, and body temperature), that were considered medically important?**

What happened during the study?

How was the study done?

This study consisted of 3 periods, as follows:

Screening period (1 to 2 days before study start): During the screening period, researchers examined children aged between 1 day to 60 months and identified those who could take part in the study.

Treatment period (up to 5 days): During the treatment period, researchers learned about the safety and tolerability of sisunatovir. Sisunatovir was given orally as a liquid, or via the nose, through a tube into the stomach. Some children were given placebo instead of sisunatovir (or study medicine). A placebo does not have any medicine in it, but it looks just like the study medicine. This was done to help the researchers try to understand if the medical problems that the children had during the study were related to the study medicine or to something else.

The plan was to conduct 3 groups (Group 1, Group 2, and Group 3). Each group was divided into 4 subgroups (A, B, C, D) based on the child's age when they were screened. Each child received either sisunatovir or placebo by chance alone. This process is called "randomization".

The children, their parents or guardians, the study doctors, and the staff at the study site did not know who was given sisunatovir and who was given placebo. This is known as a “blinded” study.

Treatment for Groups 1A, 1B, and 1C started at the same time and was given every 12 hours, for 5 days, as shown below:

Group 1A (children aged 30 days to 6 months): Sisunatovir 2.5 milligrams (mg) per kilogram (kg) of body weight (mg/kg), or placebo

Group 1B (children aged 6 months to 12 months): Sisunatovir 4.5 mg/kg or placebo

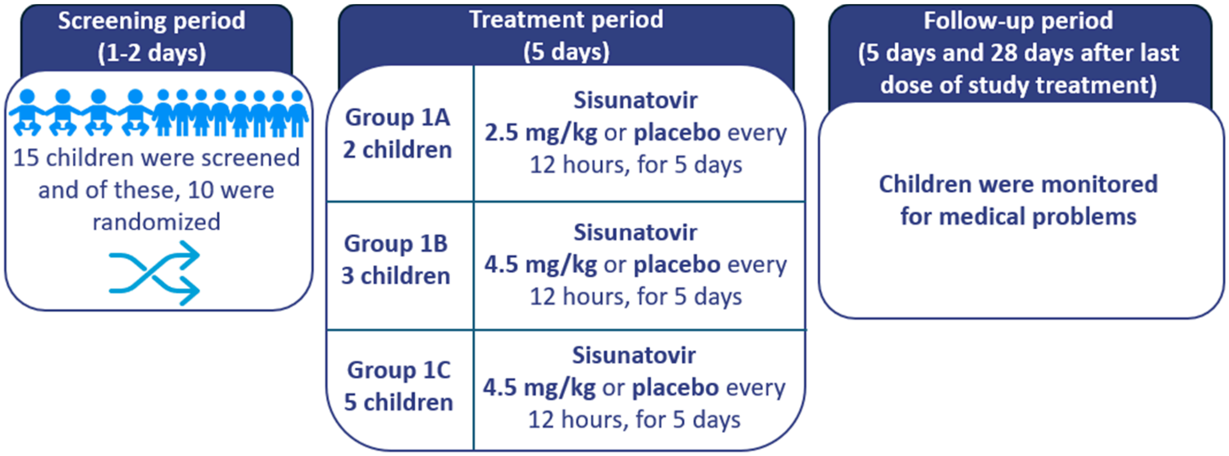
Group 1C (children aged 12 months to 60 months): Sisunatovir 4.5 mg/kg or placebo

If sisunatovir was safe and well tolerated in children in Group 1, and additional doses needed to be evaluated, then Group 2 and subsequently Group 3, would be conducted. However, no children were enrolled in Groups 1D, Group 2, or Group 3. This was due to the study stopping for business reasons, it was not due to any safety concerns.

Researchers took samples of blood and urine from the children during the study to assess safety and response, and to measure the amount of sisunatovir (study medicine) in the blood. Researchers also checked the children’s health during the study. Researchers then compared the results from children who were given sisunatovir to those who were given placebo.

Follow-up period (5 days and 28 days after last dose of study treatment): After completion of the treatment period, researchers continued to monitor the children’s health and checked for any medical problems. Figure 1 below shows the study design in detail.

Figure 1: Study design



Where did this study take place?

The Sponsor ran this study at 65 locations in 8 countries in South America, North America, Asia, and Europe.

When did this study take place?

It began 15 February 2024 and ended 03 September 2024.

Who participated in this study?

The study included newborns, infants, and children (aged 1 day to 60 months old), who weighed between 2.5 kg and 23 kg, and who had an RSV-LRTI.

- A total of 5 boys participated.
- A total of 5 girls participated.
- All participants were between the ages of 4 months and 29 months.

Ten (10) children took part in the study. Of the 10 participants, 2 were in Group 1A, 3 were in Group 1B, and 5 were in Group 1C. All 10 children received study medicine or placebo and completed the study.

How long did the study last?

The children were in the study for about 5 weeks. The entire study was active for about 7 months. This study was stopped early for business reasons and not due to safety concerns.

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?

The purpose of this study was to learn about the safety and tolerability of sisunatovir. The answers to the questions that the researchers had are shown below in the "medical problems" section.

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.

Six (6) children received sisunatovir and 4 received placebo. Seven (7) out of 10 [70%] children in this study had at least 1 medical problem. None of the children stopped the study medicine or left the study because of medical problems. The medical problems reported in the study 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 the study. All medical problems reported are listed.
- The **2nd** column tells how many of the 6 children who took sisunatovir, the study medicine, experienced each medical problem. Next to this number is the percentage of the 6 children who took the study medicine and experienced the medical problem.
- The **3rd** column tells how many of the 4 children who took placebo experienced each medical problem. Next to this number is the percentage of the 4 children who took placebo and experienced the medical problem.
- Using these instructions, you can see that 1 out of the 6 [17%] children taking the study medicine, and 1 out of the 4 [25%] children taking the placebo, experienced common cold.

Table 1. Commonly reported medical problems experienced by the children in the study

Medical Problem	Study Medicine (Sisunatovir) (6 Participants)	Placebo (4 Participants)
Common cold	1 out of 6 children (17%)	1 out of 4 children (25%)
Constipation	0 out of 6 children	1 out of 4 children (25%)

Table 1. Commonly reported medical problems experienced by the children in the study		
Medical Problem	**Study Medicine (Sisunatovir) (6 Participants)**	**Placebo (4 Participants)**
Diarrhea	2 out of 6 children (33%)	0 out of 4 children
Fever	1 out of 6 children (17%)	0 out of 4 children
Inflammation of the airways	2 out of 6 children (33%)	0 out of 4 children
Itchy, red and dry skin	1 out of 6 children (17%)	1 out of 4 children (25%)
Infection in the nose and throat	0 out of 6 children	1 out of 4 children (25%)
Runny nose	1 out of 6 children (17%)	0 out of 4 children
Seizure or fits due to a high fever	0 out of 6 children	1 out of 4 children (25%)
Skin infection caused by a virus	0 out of 6 children	1 out of 4 children (25%)
Tiredness	1 out of 6 children (17%)	0 out of 4 children

Table 1. Commonly reported medical problems experienced by the children in the study		
Medical Problem	**Study Medicine (Sisunatovir) (6 Participants)**	**Placebo (4 Participants)**
Vomiting	1 out of 6 children (17%)	1 out of 4 children (25%)

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.

No children had serious medical problems in this study. No children died during the study.

How many children had abnormal laboratory test results, or changes in vital signs (blood pressure, heart rate, and body temperature), that were considered medically important?

All 10 children [100%] had abnormal laboratory test results during the study. However, none of the abnormalities were considered medically important. No medically important changes were observed in the vital signs.

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.

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 **C5241009**

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

www.clinicaltrials.gov	Use the study identifier **NCT06102174**
www.euclinicaltrials.eu	Use the study identifier **2023-504425-39-00**

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 your child 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!