# 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.

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| **Sponsor:** | Pfizer Inc. |
| **Medicine(s) Studied:** | Sisunatovir (PF-07923568) |
| **Protocol Number:** | C5241014 |
| **Dates of Study:** | 31 July 2023 to 20 September 2023 |
| **Title of this Study:** | A Study to Learn About the Taste Profiles of Different Suspensions of Study Medicine Called PF-07923568 in Healthy Adult Participants<br><br>[A Randomized, Phase 1, Single-Blind, Multi-Period Study to Investigate the Palatability of PF-07923568 Oral Suspension in Different Liquid Vehicles in Healthy Adult Participants.] |
| **Date(s) of this Report:** | 10 September 2024 |

# – 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 respiratory syncytial virus (RSV) infection?

Respiratory syncytial virus (RSV) is a virus that can cause an infection with symptoms that are similar to a bad cold, such as cough, fever, sore throat, and a runny nose. This infection can be serious in young children, older adults, and in those with underlying medical conditions. People with serious RSV infection may have trouble breathing and may need to be hospitalized.

## What is Sisunatovir (PF-07923568)?

Sisunatovir (si-sue-NAT-oh-veer), also known as PF-07923568, is a capsule that is swallowed. Researchers think sisunatovir may help the body's immune system defend against RSV infection. Sisunatovir blocks a protein in the RSV called the RSV-F protein. By blocking this protein, sisunatovir prevents the virus from entering the human cells and prevents the infection. An investigational medicine is one that is not approved for use outside of research studies.

## What was the purpose of this study?

The purpose of this study was to test how sisunatovir tastes in different formulations (mixes). How acceptable something tastes and feels in the mouth is called its "palatability".

One formulation tested contained Bitrex® rather than sisunatovir. Bitrex is used to make things taste very bitter. It is often used to stop things being eaten by accident. The Bitrex formulation was used as a "control" to see if the participants could taste bitterness as expected.

This study did not test if sisunatovir helps to improve RSV infection.

### Researchers wanted to know:

- **How did participants rate the palatability of different formulations of sisunatovir?**
- **What medical problems did participants have during the study?**

# What happened during the study?

## How was the study done?

Researchers tested the palatability of 5 different formulations of sisunatovir on healthy participants.

Participants were to stay at the study center for 3 days and 2 nights. Over the 2nd and 3rd day of their stay, they were given 6 different formulations to taste and spit out (5 contained sisunatovir, 1 did not). Each sample was 4 mL of liquid (a little less than one teaspoon). Different amounts of sweetener and flavoring were tested to see which was preferred by the participants.

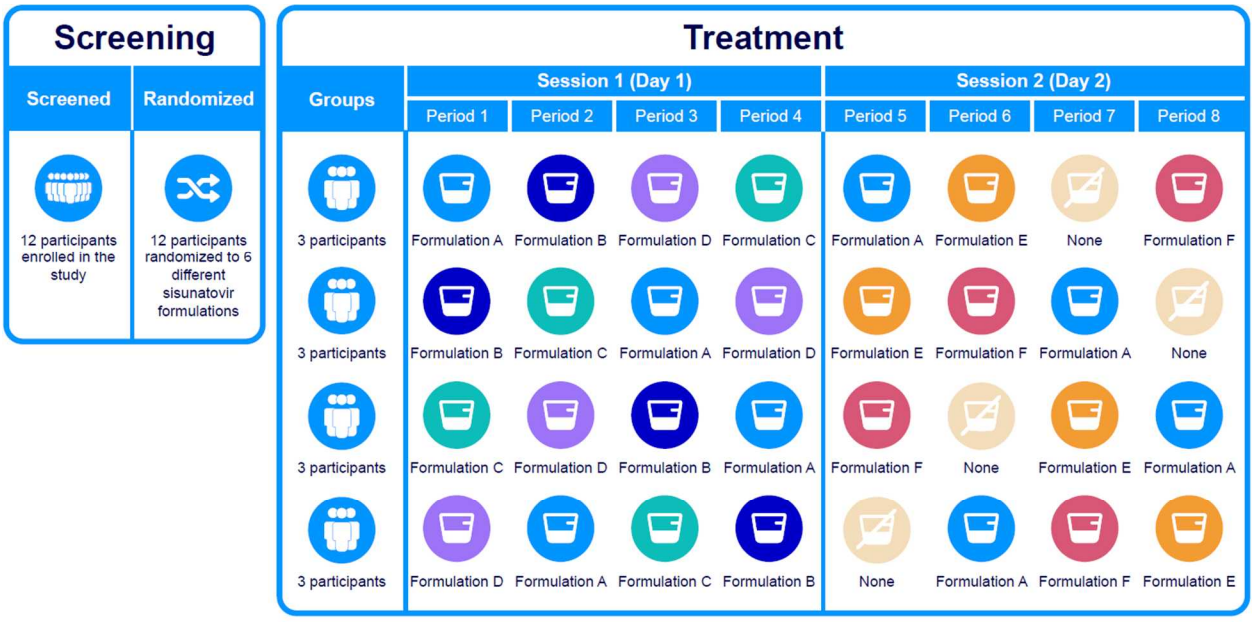
- Formulation A: sisunatovir in slightly salty water (“saline”).
- Formulation B: sisunatovir, flavoring, sweetener, and thickener, in saline.
- Formulation C: Bitrex.
- Formulation D: sisunatovir and sweetener in saline.
- Formulation E: sisunatovir and sweetener in saline.
- Formulation F: sisunatovir, flavoring, sweetener, and thickener, in saline.

All participants tasted Formulations A, B, C, D, E, and F. However, the order (sequence) they received the formulations was different. There were 4 different sequences with 3 participants each.

Participants were assigned to the different sequences by chance (like rolling dice). Formulations B to F were given to each participant once over the 2 days of tasting. Formulation A was given to each participant twice, once on each day.

A diagram showing what happened in the study is provided in Figure 1.

**Figure 1. Sequence of treatment**




*Formulation A: sisunatovir in saline*
*Formulation B: sisunatovir, flavoring, sweetener and thickener in saline*
*Formulation C: Bitrex*
*Formulation D: sisunatovir and sweetener in saline*
*Formulation E: sisunatovir and sweetener in saline*
*Formulation F: sisunatovir, flavoring, sweetener and thickener in saline*
*Note: No treatment was administered during certain periods indicated as 'none'*

Participants did not know which of the formulations they were tasting, but the researchers knew. This is known as a "single-blinded" study.

Participants tasted the formulations 1 at a time. They swirled the sample in their mouth for around 10 seconds then spat it out. They answered a

questionnaire to rate the palatability around 1 minute, 5 minutes, 10 minutes, and 20 minutes after tasting. The questionnaire asked about bitterness, sweetness, sourness, saltiness, tongue/mouth 'burn' feeling, how the sample felt in the mouth, and overall liking. These results were used to make an overall score. Researchers then looked at the results to assess which formulations were most acceptable to participants.

Researchers took samples of blood and urine from participants during the study to check the participants' health during the study. They also asked them how they were feeling.

## Where did this study take place?

The Sponsor ran this study at 1 location in Belgium.

## When did this study take place?

It began 31 July 2023 and ended 20 September 2023.

## Who participated in this study?

The study included healthy participants who met the inclusion/exclusion criteria for things such as age, weight, and existing medical conditions.

- A total of 4 men participated
- A total of 8 women participated
- All participants were between the ages of 23 and 70 years

All of the 12 participants finished the study.

No participants left before the study was over by their choice or due to a doctor deciding it was best for a participant to stop being in the study.

## How long did the study last?

Study participants were in the study for approximately 8 weeks. The entire study took approximately 8 weeks to complete.

When the study ended in September 2023, 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 did participants think of the taste of sisunatovir in different suspensions?

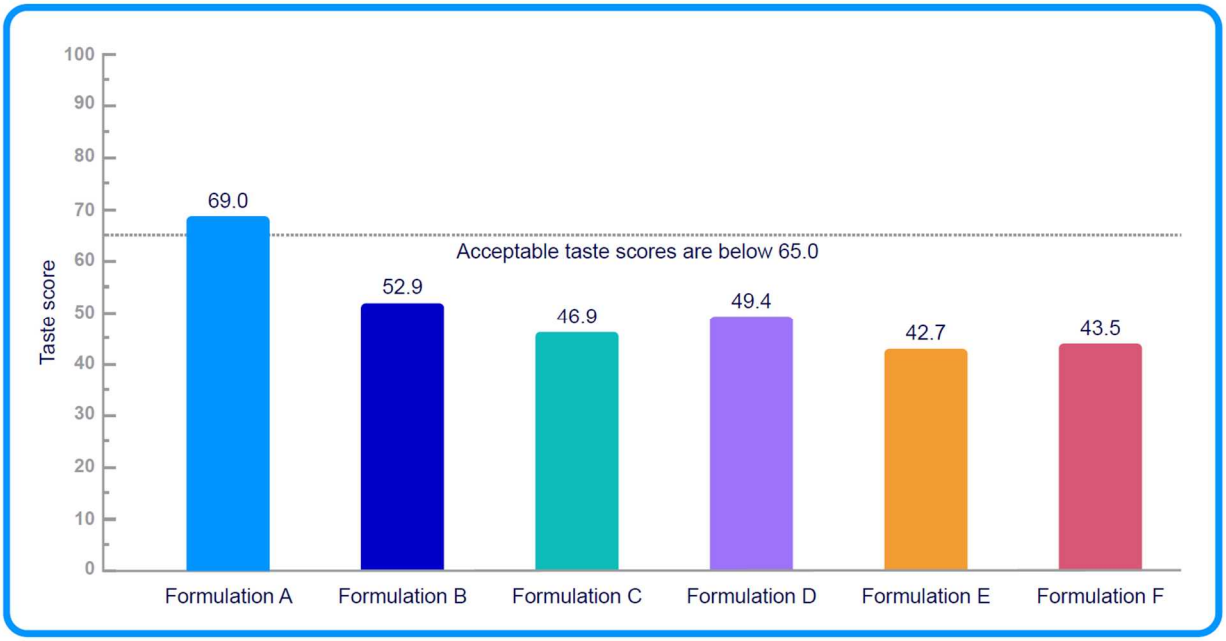
To answer this question, researchers used the results from the participants' taste questionnaires. The average overall score for each formulation was rated on a scale from 0 to 100. Judging how something tastes can vary from person to person. An average score under 65 meant that the taste could be found acceptable.

Average overall scores for the formulations are shown in Figure 2.

- The average overall score for Formulation A was 69.0. A score of greater than 65 was given by 61% of the participants.
- The average overall score for Formulation B was 52.9. A score of greater than 65 was given by 25% of participants.
- The average overall score for Formulation C was 46.9. A score of greater than 65 was given by 15% of participants.
- The average overall score for Formulation D was 49.4. A score of greater than 65 was given by 38% of participants.

- The average overall score for Formulation E was 42.7. A score of greater than 65 was given by 19% of participants.
- The average overall score for Formulation F was 43.5. A score of greater than 65 was given by 17% of participants.

**Figure 2: Overall palatability score for each formulation**




The researchers found that the scores given by the participants improved (got lower) over the 20 minutes after tasting.

Based on all these results, the researchers have decided that Formulations B, D, E, and F may have acceptable palatability and Formulation A may not have acceptable palatability.

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?

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.

Four (4) out of 12 (33.3%) participants in this study had at least 1 medical problem. No participants reported medical problems after tasting Formulations A, C, D, or F.

- After tasting Formulation B:
    - 1 out of 12 participants (8.3%) had dry lips.
    - 1 out of 12 participants (8.3%) reported back pain.
    - 1 out of 12 participants (8.3%) reported runny nose.
- After tasting Formulation E:
    - 1 out of 12 participants (8.3%) reported mouth ulcer.

No participants left the study because of medical problems.

# 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 participants had serious medical problems and 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:

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| www.pfizer.com/research/research_clinical_trials/trial_results | Use the protocol number C5241014 |

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

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| www.clinicaltrials.gov | Use the study identifier **NCT06003829** |
| www.euclinicaltrials.eu | Use the study identifier 2023-504924-24-00 |

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!