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 vaccine 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.
Vaccine Studied:	Respiratory Syncytial Virus (RSV) Stabilized Prefusion F Subunit Vaccine (called RSVpreF or PF-06928316)
Protocol Number:	C3671014
Dates of Study:	21 October 2021 to 04 April 2022
Title of this Study:	A Study to Find Out if the 3 Different Batches of RSVpreF Vaccine Were Safe and Produced the Same Antibody Response Against Respiratory Syncytial Virus [A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, and Immunogenicity of 3 Lots of Respiratory Syncytial Virus (RSV) Prefusion F Subunit Vaccine in Healthy Adults]
Date of this Report:	20 October 2022

– 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?

Respiratory syncytial (sin-SISH-ul) virus, or RSV, can cause an infection of the lungs in people of all ages. Symptoms of RSV are similar to a bad cold, such as cough, runny nose, and fever.

RSV infection can cause severe illness in infants, older adults, and people who have chronic medical conditions. People with serious RSV infection may have trouble breathing and may need to be hospitalized.

What is the respiratory syncytial virus stabilized prefusion F subunit vaccine (RSVpreF)?

> A vaccine can help the body fight infections and prevent diseases.
>
> After a person gets a vaccine, the body makes antibodies, which are proteins that fight off infections. This is called an antibody response.

RSVpreF is an injectable vaccine that was tested in this study. It has not yet been approved by the Food and Drug Administration (FDA) at the time of this study. Researchers think that RSVpreF can help protect against illnesses caused by RSV.

Results of earlier studies of the RSVpreF vaccine have shown that RSVpreF led to antibody responses in older adults and pregnant women. Researchers think that pregnant women who got an RSVpreF shot may pass the RSV-fighting antibodies to their infants during pregnancy. Another study has shown that RSVpreF helped to prevent RSV infection in healthy adults.

What was the purpose of this study?

Making vaccines could involve different batches. This study was done to check if the 3 different batches of RSVpreF were safe and produced the same antibody response against RSV.

Researchers wanted to know:

1. **Did the 3 different batches of RSVpreF produce the same antibody response among participants 1 month after getting the vaccine?**
2. **How many participants had redness, swelling, or pain at the injection area within 7 days of getting RSVpreF?**
3. **How many participants had fever, fatigue, headache, nausea, vomiting, diarrhea, muscle pain, or joint pain within 7 days of getting RSVpreF?**
4. **What medical problems did participants have during the study?**

What happened during the study?

How was the study done?

The researchers tested 3 different batches of RSVpreF and compared them to a placebo. A placebo does not have any medicine in it, but it looks just like RSVpreF. The participants were assigned to 1 of the 4 vaccine groups by chance.

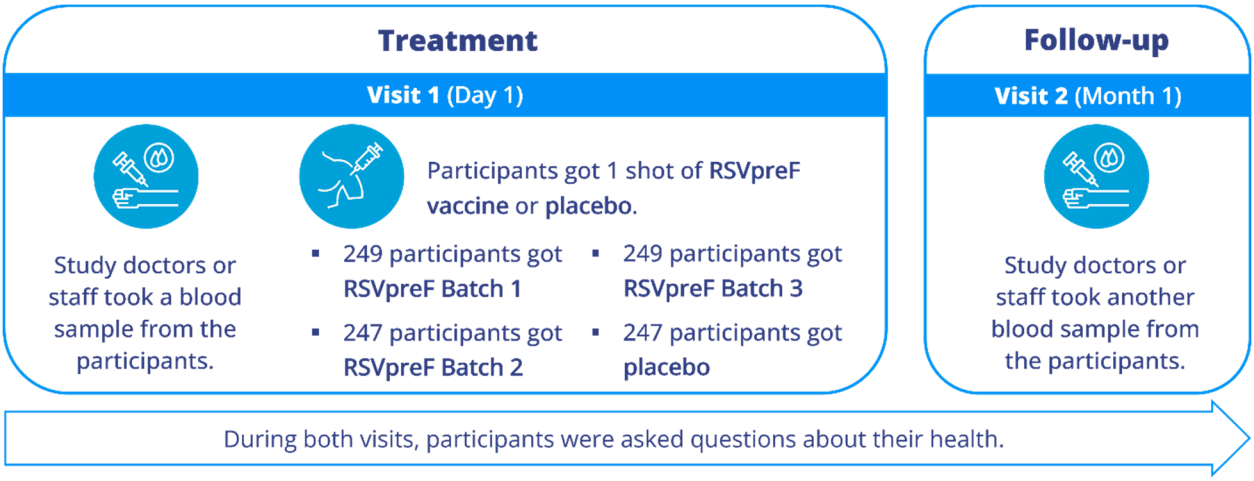
- RSVpreF Batch 1
- RSVpreF Batch 2
- RSVpreF Batch 3
- Placebo

The participants and researchers did not know which study vaccine (RSVpreF or placebo) the participants got. This is known as a "double-blind" study.

Figure 1 below shows that the participants visited the study site at least 2 times.

- On Visit 1, the study doctors or staff took a blood sample from the participants before they got a study vaccine. Then, all participants got 1 shot of 120 micrograms (µg) of RSVpreF or placebo, which was the only shot of the study vaccine they got for the entire study.
- Visit 2 happened 1 month after Visit 1. During Visit 2, the study doctors or staff took another blood sample from the participants.

Figure 1. What happened during the study visits?



Where did this study take place?

The Sponsor ran this study at 17 locations in the United States.

When did this study take place?

It began 21 October 2021 and ended 04 April 2022.

Who participated in this study?

The study included adults who were assessed as healthy by study doctors.

Of the 993 participants who joined the study, 1 participant left the study before getting a study vaccine and 992 participants got a study vaccine.

Of the 992 participants, 399 were men and 593 were women. Participants were between the ages of 18 and 49 years old.

Overall, 970 participants finished the study. Twenty-three (23) participants did not finish the study, and the most common reasons were:

- They left the study by their own choice.
- They could not be reached for follow-up.

How long did the study last?

The participants were in the study for about 1 month. The entire study took about 5 months to finish. This is because participants started the study at different times.

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?

The researchers measured the amount of antibodies against RSV in the participants' blood samples 1 month after getting RSVpreF. Then, the researchers compared the results of the participants who got RSVpreF from each of the 3 batches.

Did the 3 different batches of RSVpreF produce the same antibody response among participants 1 month after getting the vaccine?

One (1) month after getting RSVpreF, participants had the same amount of antibodies against RSV across the 3 different batches. Researchers found that the 3 different batches of RSVpreF produced the same antibody response.

Participants were asked to keep a diary to record how they felt within 7 days of getting RSVpreF. They were asked to note if they had:

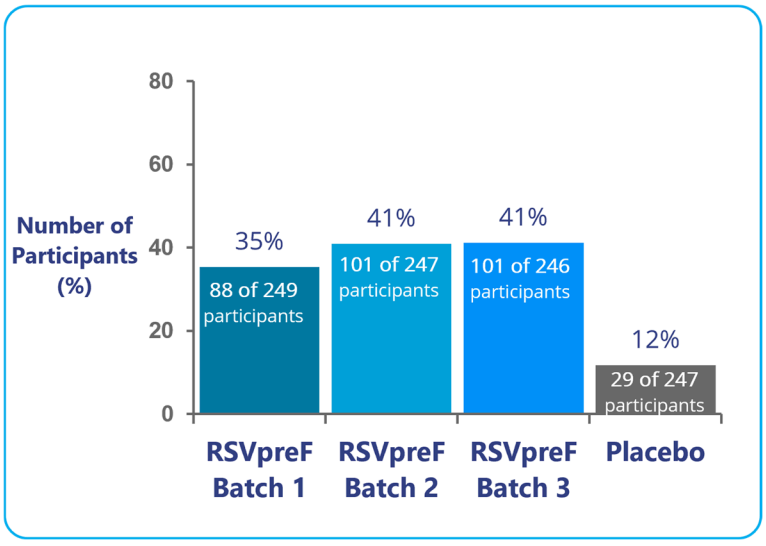
- Reactions over the skin where the needle was injected (or reactions at the injection area), such as redness, swelling, or pain.
- Symptoms of fever, fatigue, headache, nausea, vomiting, diarrhea, muscle pain, or joint pain.

Researchers then checked the records of 989 participants who had diary entries within 7 days after they got their study vaccine.

How many participants had redness, swelling, or pain at the injection area within 7 days of getting RSVpreF?

Figure 2 shows the number of participants who had any reactions of redness, swelling, or pain at the injection area within 7 days of getting a study vaccine. These reactions at the injection area were more common for the 3 groups of participants who got RSVpreF (35% to 41%) compared to those who got placebo (12%).

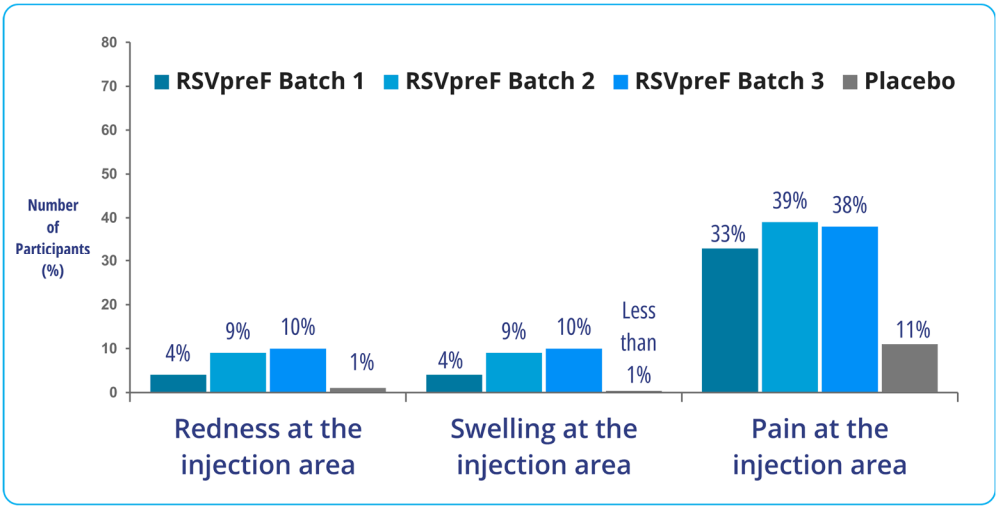
Figure 2. How many participants had any reactions (redness, swelling, or pain) at the injection area within 7 days of getting a study vaccine?



Most of these reactions at the injection area were mild to moderate in intensity and went away after 2 to 3 days.

Figure 3 below shows that pain at the injection area was the most common reaction in all groups.

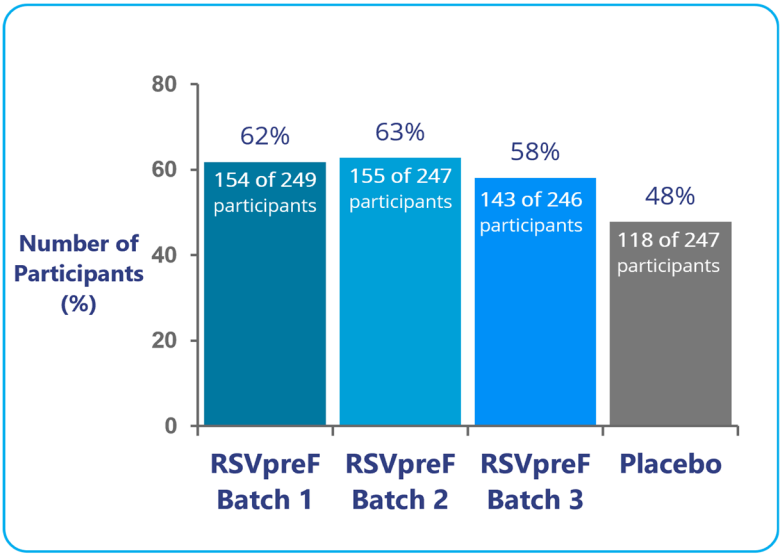
Figure 3. How many participants had each reaction at the injection area within 7 days of getting a study vaccine?



How many participants had fever, fatigue, headache, nausea, vomiting, diarrhea, muscle pain, or joint pain within 7 days of getting RSVpreF?

Figure 4 shows the number of participants who had any symptoms of fever, fatigue, headache, nausea, vomiting, diarrhea, muscle pain, or joint pain within 7 days of getting a study vaccine. These symptoms were more common for the 3 groups of participants who got RSVpreF (58% to 63%) compared to those who got placebo (48%).

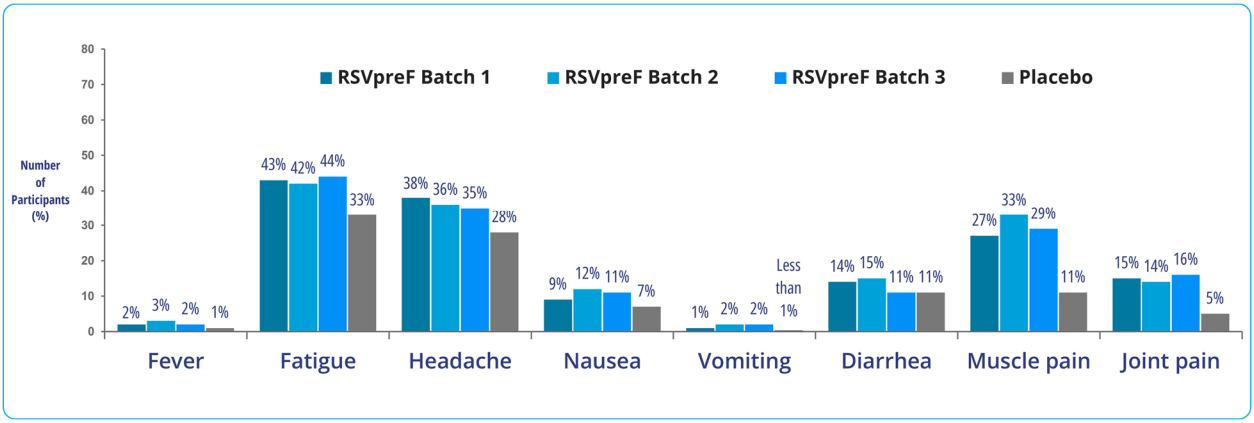
Figure 4. How many participants had any symptoms (fever, fatigue, headache, nausea, vomiting, diarrhea, muscle pain, or joint pain) within 7 days of getting a study vaccine?



Most of these symptoms were mild to moderate in intensity and went away after 1 to 2 days.

Figure 5 below shows that fatigue, headache, and muscle pain were the most common symptoms in all groups.

Figure 5. How many participants had each symptom within 7 days of getting a study vaccine?



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 vaccine or by another medicine the participant was taking. Sometimes, the cause of a medical problem is unknown. By comparing medical problems across many vaccine groups in many studies, doctors try to understand what effects a study vaccine might have on a participant.

Researchers looked at the records of 992 participants who got a study vaccine.

No participant left the study because of a medical problem.

How many participants had medical problems during the study?

In total, 58 out of 992 participants (6%) had at least 1 medical problem during this study.

The list below shows that the number of participants who had medical problems was the same in all 4 vaccine groups.

- RSVpreF Batch 1: 15 out of 249 participants (6%)
- RSVpreF Batch 2: 13 out of 247 participants (5%)
- RSVpreF Batch 3: 15 out of 249 participants (6%)
- Placebo: 15 out of 247 participants (6%)

Table 1 below describes the commonly reported medical problems – those reported by at least 2 participants in any vaccine group – in the study. Table 1 also shows that the most common medical problems were:

- Swollen lymph nodes in the RSVpreF group (Batches 2 and 3).
- Sinusitis in the placebo group.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists the most common medical problems reported during the study. It lists all medical problems reported by at least 2 participants in any vaccine group.
- The **2nd** to **5th** columns tell how many of the participants in each vaccine group had a medical problem. They also show the percentage of participants in each vaccine group who had the medical problem.
- For example, you can see that 2 out of 249 participants (1%) who got RSVpreF Batch 1 had coronavirus disease 2019 (COVID-19). None of the 247 participants (0%) who got RSVpreF Batch 2 had COVID-19.

Table 1. Commonly reported medical problems in the study				
Medical Problem	**RSVpreF Batch 1 (249 participants)**	**RSVpreF Batch 2 (247 participants)**	**RSVpreF Batch 3 (249 participants)**	**Placebo (247 participants)**
COVID-19	2 out of 249 participants (1%)	0 out of 247 participants (0%)	2 out of 249 participants (1%)	1 out of 247 participants (less than 1%)
Swollen lymph nodes	0 out of 249 participants (0%)	2 out of 247 participants (1%)	3 out of 249 participants (1%)	0 out of 247 participants (0%)
Inflammation of the sinuses (sinusitis)	0 out of 249 participants (0%)	1 out of 247 participants (less than 1%)	0 out of 249 participants (0%)	4 out of 247 participants (2%)
Infection of the nose, sinuses, or throat (cold)	2 out of 249 participants (1%)	0 out of 247 participants (0%)	1 out of 249 participants (less than 1%)	0 out of 247 participants (0%)
Asthma	2 out of 249 participants (1%)	0 out of 247 participants (0%)	0 out of 249 participants (0%)	1 out of 247 participants (less than 1%)
Cough	1 out of 249 participants (less than 1%)	0 out of 247 participants (0%)	0 out of 249 participants (0%)	2 out of 247 participants (1%)
Chest pain	2 out of 249 participants (1%)	0 out of 247 participants (0%)	0 out of 249 participants (0%)	0 out of 247 participants (0%)
Inflammation of the airways in the lungs (bronchitis)	0 out of 249 participants (0%)	0 out of 247 participants (0%)	0 out of 249 participants (0%)	2 out of 247 participants (1%)
Blocked nose	0 out of 249 participants (0%)	0 out of 247 participants (0%)	0 out of 249 participants (0%)	2 out of 247 participants (1%)

What medical problems did the study doctors think were related to a study vaccine?

Overall, 9 out of 992 participants (1%) had a medical problem that the study doctors thought was related to a study vaccine. These medical problems were seen in:

- 5 out of 247 participants (2%) who got RSVpreF Batch 2.
- 4 out of 249 participants (2%) who got RSVpreF Batch 3.
- None of the participants (0%) who got RSVpreF Batch 1 or placebo.

The most common of these medical problems in any vaccine group was swollen lymph nodes. This was seen in:

- 2 out of 247 participants (1%) who got RSVpreF Batch 2.
- 3 out of 249 participants (1%) who got RSVpreF Batch 3.

There were other medical problems, but these happened in fewer participants.

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.

During the study, no participant had a serious medical problem and no participant died.

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 **C3671014**

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

www.clinicaltrials.gov

Use the study identifier **NCT05096208**

Please remember that researchers look at the results of many studies to find out which vaccines 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!