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 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] Multi Dose Vial [MDV]

Protocol Number: C4841001

Dates of Study: 24 June 2024 to 20 September 2024

Title of this Study: A study in Healthy Female Adults to Look at the Safety and Immune Response of RSV Prefusion F (preF) Subunit Vaccine Formulated in MDV

[A Phase 3, Randomized, Open-label Trial to Evaluate the Safety, Tolerability, and Immunogenicity of Respiratory Syncytial Virus (RSV) Prefusion F Subunit Vaccine Formulated in Multidose Vials in Healthy Female Adults]

Date of this Report: 21 July 2025

Pfizer

– 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?

Respiratory syncytial [sin-SISH-ul] virus (RSV) is a common and contagious virus that infects the lungs and breathing passages. Healthy people who have RSV infection usually experience mild cold-like symptoms and recover in a few days. However, RSV infection can be serious in infants, older adults and adults with long-term medical conditions like lung diseases such as asthma. It can lead to more serious illnesses like difficulty in breathing, pauses in breathing, and lung infection leading to hospitalization and death.

> A long-term medical condition is any health issue that lasts for a long time or needs ongoing medical care.

Vaccines are used to help prevent the risk of serious diseases caused by viruses. Currently, multiple vaccines are approved to prevent diseases caused by different types (strains) of this virus.

What is RSVpreF vaccine?

RSV stabilized prefusion F subunit (RSVpreF) is an injectable vaccine that may help the body's immune system to protect against RSV disease.

The single dose vial (SDV) RSVpreF has been approved by health agencies in the United States (US) and other countries for use in pregnant women to protect their infants from RSV. The SDV RSVpreF is also approved for use in older adults to protect them from RSV. The multidose vial (MDV) RSVpreF is being investigated to support the global outreach of this vaccine by ensuring protection from a preventable disease.

The RSVpreF vaccine presentations tested in this study are listed below:

- MDV presentation which contains three doses of RSVpreF with an added preservative called 2-phenoxyethanol (2-PE) to help prevent growth of bacteria or fungi in the vials. It helps to ensure that the vaccine is safe and effective to use over time. In this study, only one dose was given from each MDV.
- SDV presentation which contains one dose of RSVpreF without the preservative 2-PE.

This study compared RSVpreF with an added preservative called 2-PE from an MDV, to RSVpreF without an added preservative, from an SDV.

What was the purpose of this study?

The main purpose of this study was to learn about the immune response and safety of the MDV RSVpreF compared to SDV RSVpreF in study participants that received the vaccine.

When a person first gets a vaccine, the body's response includes making antibodies and it is called an immune response. Antibodies fight infections and help prevent diseases.

In this report, the MDV RSVpreF and SDV RSVpreF are referred to as **study vaccines**.

To learn about the immune response, researchers measured the effect of MDV RSVpreF and the effect of SDV RSVpreF.

To learn about the safety, researchers looked for any local reactions, systemic events and medical problems, after the participants received the vaccines.

- A **local reaction** includes symptoms such as redness, swelling, or pain at the injection site. The injection site is the skin area where the needle was inserted to administer the vaccine.
- A **systemic event** includes symptoms like fever, tiredness, headache, vomiting, nausea, diarrhea, muscle pain, or joint pain.

  These are common and expected events after a vaccine is given.
- A **medical problem** includes all other symptoms except for local reactions and systemic events.

Researchers wanted to know:

- **What was the difference in the immune responses before and 1 month after participants were given the study vaccines?**
- **How many participants had local reactions within 7 days after vaccination?**
- **How many participants had systemic events within 7 days after vaccination?**
- **How many participants had medical problems within 1 month after vaccination?**
- **How many participants had serious medical problems throughout the study?**

What happened during the study?

How was the study done?

This study compared MDV RSVpreF to SDV RSVpreF. All participants received a single shot of the vaccine given as 120 micrograms (mcg), either as MDV RSVpreF or the SDV RSVpreF on Day 1 of the study (Visit 1).

Study participants were assigned equally to 1 of the 2 vaccine groups by chance alone. This process is called "randomization". The vaccines were given as an injection into the muscle in the upper arm.

In this study, the participants and the researchers knew which injection each participant received. This is known as an "open-label" study.

Each participant was given an electronic diary to record details of any local reactions or systemic events. This information was collected for about 7 days after vaccination.

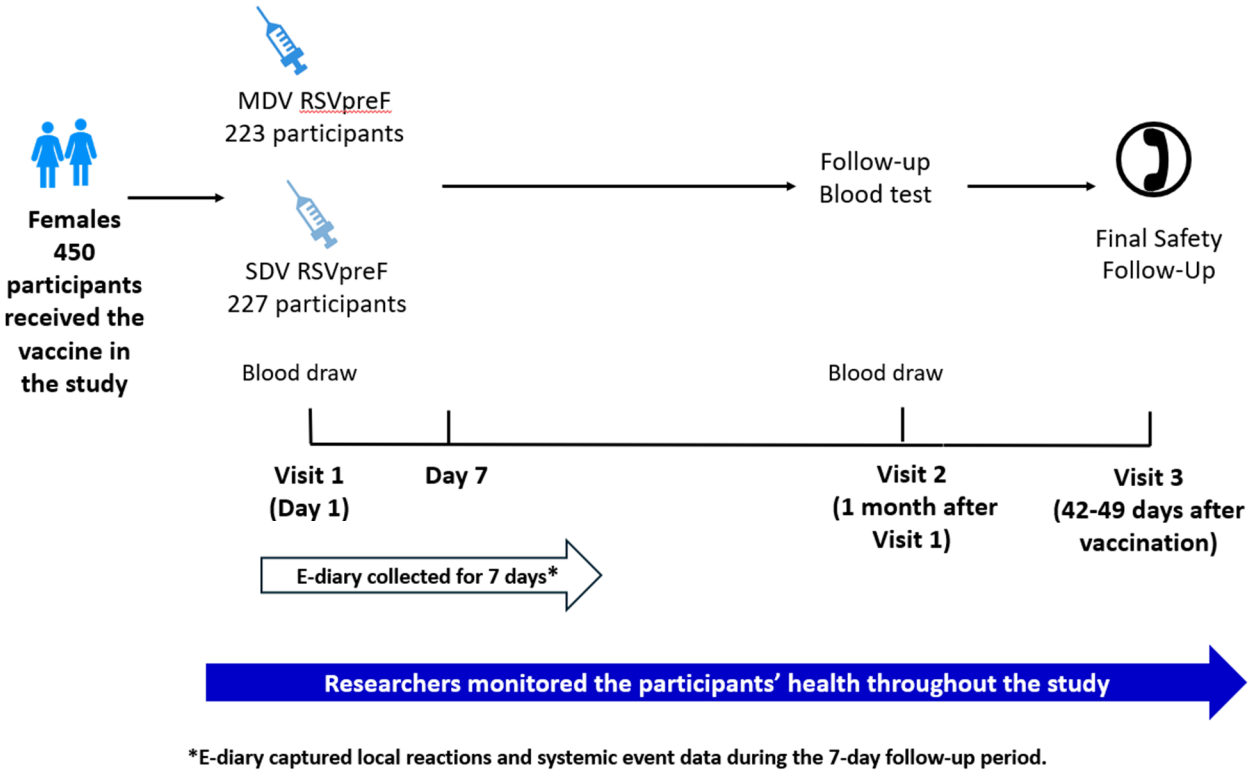
Follow-up:
Participants had two health checks after receiving their vaccine: about 1-month after vaccination visit and about 6 weeks after vaccination for the final visit.

During the study, researchers checked how participants were feeling and asked about medicines they might be taking. Researchers also took samples of blood from participants for testing. This was done to measure the antibody levels against RSV before and after their vaccination in this study.

Researchers compared the results of participants in each vaccine group.

Figure 1 below shows a timeline of what happened in the study.

Figure 1: What happened in the study



*E-diary captured local reactions and systemic event data during the 7-day follow-up period.

Where did this study take place?

The Sponsor ran this study in the United States.

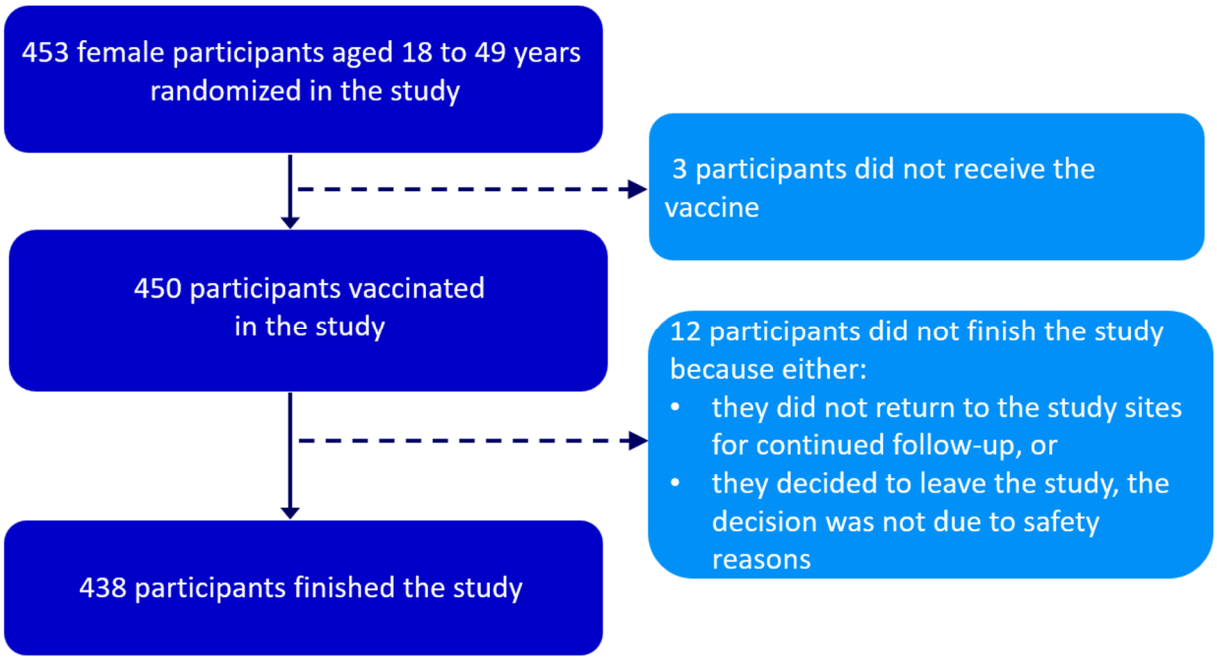
When did this study take place?

It began 24 June 2024 and ended 20 September 2024.

Who participated in this study?

The study included non-pregnant and non-breastfeeding healthy females between 18 and 49 years of age. **Figure 2** below gives the details of the participants enrolled in the study.

Figure 2: Study participants



How long did the study last?

Study participants were in the study for about 6 weeks. The entire study took around 3 months to complete. The study was completed as planned.

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 was the difference in the immune responses before and 1 month after participants were given the study vaccines?

After 1 month of vaccination, researchers found that the participants who received MDV RSVpreF produced comparable (non-inferior) immune responses to the participants who received SDV RSVpreF.

Researchers found that the immune responses produced by the participants who received MDV RSVpreF was as good as those for the participants who received SDV RSVpreF.

How many participants had local reactions within 7 days after vaccination?

The most frequently reported local reaction in both MDV and SDV RSVpreF groups was pain at the injection site. Local reactions were mostly mild or moderate in severity for both the groups.

The percentage of participants who reported local reactions after receiving the MDV RSVpreF was generally similar compared to the SDV RSVpreF group.

Figure 3 below shows the percentage of participants with local reactions in each vaccine group.

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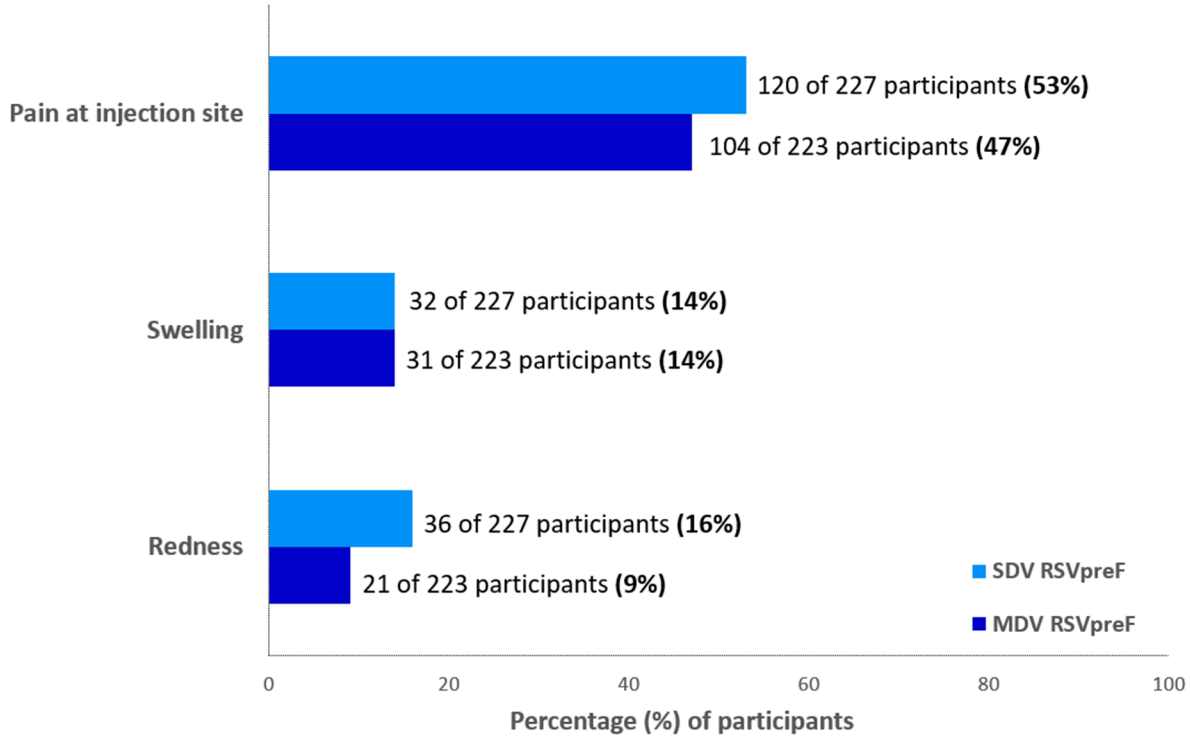
Figure 3: Percentage of participants with local reactions in both the vaccine group



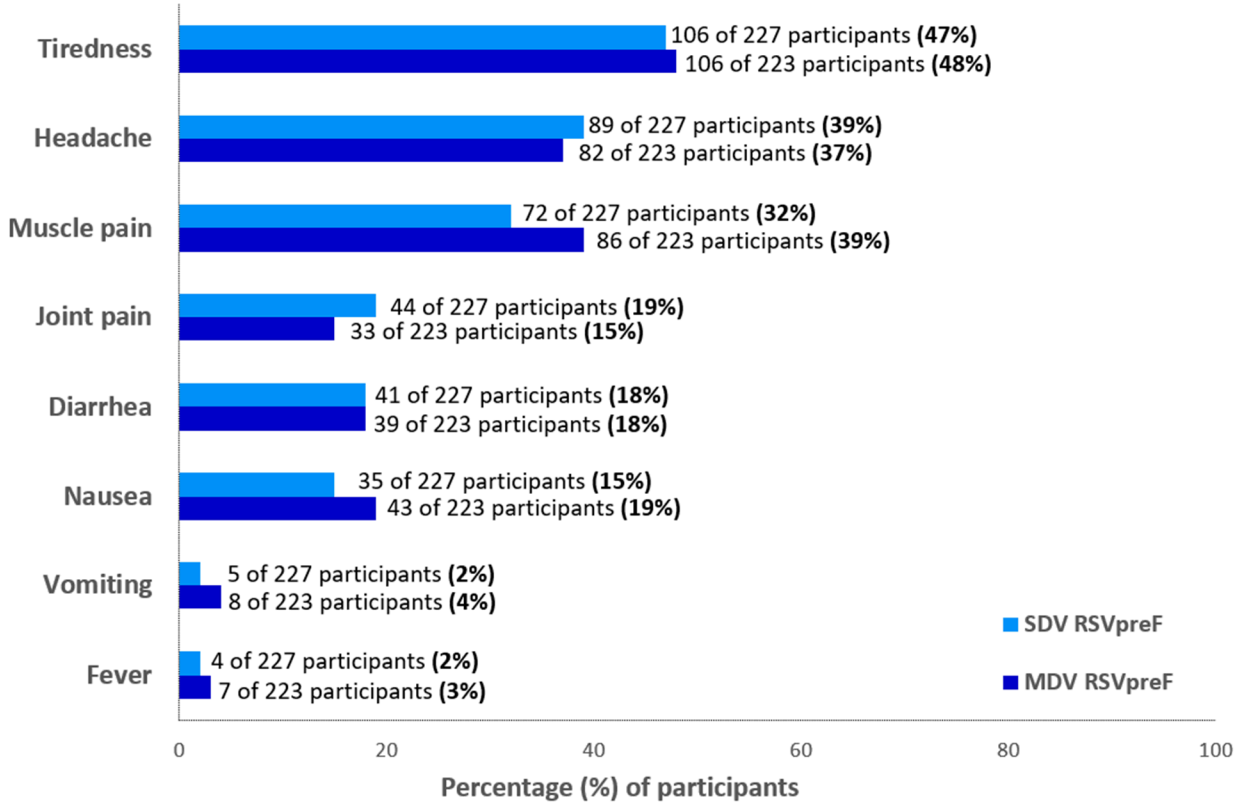
How many participants had systemic events within 7 days after vaccination?

The most frequently reported systemic events in both MDV and SDV RSVpreF groups were tiredness and headache. Systemic events were mostly mild or moderate in severity for both the vaccine groups.

The percentage of participants who reported systemic events after receiving the MDV RSVpreF was generally similar compared to the SDV RSVpreF group.

Figure 4 below shows the percentage of participants with systemic events in each vaccine group.

Figure 4: Percentage of participants with systemic events in both the vaccine group



The answers for the below questions are discussed in the next section.

How many participants had medical problems within 1 month after vaccination?

How many participants had serious medical problems throughout the study?

Based on these results, the researchers have decided that the results are valid and not likely the result of chance. 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.

In this study, 20 out of 223 participants (9%) in the MDV RSVpreF group and 19 out of 227 participants (8%) in the SDV RSVpreF had at least 1 medical problem within 1 month after vaccination. None of the participants left the study because of the medical problems. The most common medical problems reported by at least 2 participants – are described below in **Table 1.**

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 by at least 2 participants are listed.
- The **2nd** column tells how many of the 223 participants who received the MDV RSVpreF reported each medical problem. Next to this

number is the percentage of the 223 participants who received the MDV RSVpreF reported the medical problem.

- The **3rd** column tells how many of the 227 participants who received the SDV RSVpreF reported each medical problem. Next to this number is the percentage of the 227 participants who received the SDV RSVpreF reported the medical problem.
- Using these instructions, you can see that 2 out of the 223 (1%) participants receiving the MDV RSVpreF reported COVID-19 infection. A total of 1 out of the 227 (less than 1%) participants receiving the SDV RSVpreF reported COVID-19 infection.

Table 1. Commonly reported medical problems by study participants		
Medical Problem	**Group 1 MDV RSVpreF (223 Participants)**	**Group 2 SDV RSVpreF (227 Participants)**
COVID-19 infection	2 out of 223 participants (1%)	1 out of 227 participants (less than 1%)
Dizziness	0 out of 223 participants	2 out of 227 participants (1%)
Infection of the parts of the body that collect and pass out urine	2 out of 223 participants (1%)	0 out of 227 participants
Inflammation of the nose and throat	0 out of 223 participants	2 out of 227 participants (1%)
Nose and throat infection	2 out of 223 participants (1%)	2 out of 227 participants (1%)
Trouble thinking clearly	2 out of 223 participants (1%)	0 out of 227 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, 3 participants had serious medical problems which required hospital care. Of these 3 participants:

- One (1) out of 223 participants (less than 1%) who received the MDV RSVpreF had a road accident which caused multiple fractures in ankle, rib and tibia
- Two (2) out of 227◦participants (1%) received SDV RSVpreF. One participant had appendicitis, and the other one had sudden, severe allergic reaction (with swelling of the tongue and hoarseness of her voice, as well as generalized itching). The participant was treated and fully recovered the following day. Researchers believed that this was related to study vaccine.

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 **C4841001**
www.clinicaltrials.gov	Use the study identifier **NCT06473519**

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!

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