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, and 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: Abrysvo® Respiratory syncytial virus (RSV) stabilized prefusion F subunit vaccine (RSVpreF) (PF-06928316)

Protocol Number: C3671053

Dates of Study: 07 October 2024 to 03 February 2025

Title of this Study: A Study to Assess the Safety, Tolerability, and Immunogenicity of RSVpreF in Older Adults in Korea

[A Phase 3 Study to Evaluate the Safety, Tolerability, and Immunogenicity of Respiratory Syncytial Virus (RSV) Prefusion F Subunit Vaccine in Older Adults in Korea]

Date(s) of this Report: 25 November 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 virus that affects the lungs and breathing passages.

It can cause cold-like symptoms in most people. Babies, older adults, and those with certain health problems can get very sick. It can cause pneumonia (an infection in the lungs) or bronchitis (swelling in the tubes that carry air).

The virus spreads easily through coughing, sneezing, or touching contaminated surfaces. Most people get better in a week or 2, but some may need a doctor if symptoms become severe.

What is RSVpreF vaccine?

A vaccine can help prevent an infection or a disease. The body makes antibodies to fight off germs like RSV after getting the vaccine.

Antibodies are proteins that help the body fight germs and prevent illness. After a person receives a vaccine, the body makes antibodies to protect against the disease (called “antibody” or “immune” response).

The RSV stabilized prefusion F subunit (RSVpreF) vaccine, also known by its brand name Abrysvo, is an injectable vaccine designed to help the body make antibodies that protect people from RSV.

Doctors in the United States (US), Europe, Canada and Japan use RSVpreF to protect adults from RSV (“approved”). RSVpreF is also approved for use in pregnant people to help prevent RSV-related illness in their babies. The use of RSVpreF in this study was “investigational” (tested), which means it is not approved by the Korean health agency for use outside of research studies.

Researchers think that vaccination with RSVpreF may also help to protect older Koreans against RSV disease.

What was the purpose of this study?

Because older adults in Korea are at risk and there's little local data, this study was done to test the vaccine in **Korean older adults**. The main purpose of this study was:

- to evaluate how **safe** the RSVpreF vaccine is, and
- how well it helps the body **produce an immune response** in Korean older adults.

RSVpreF was compared against a "placebo" (a shot that does not have the vaccine) to help researchers understand how the vaccine performs.

Researchers wanted to know:

- **What were participants' levels of antibodies to RSV before and 1 month after vaccination?**
- **How many participants had pain, redness, or swelling at the injection site within 7 days after vaccination?**
- **How many participants had fever, fatigue (tiredness), headache, muscle pain, joint pain, nausea (feeling sick), vomiting (being sick), or diarrhea (loose stools) within 7 days after vaccination?**
- **How many participants had medical problems within 1 month after vaccination?**
- **How many participants had serious medical problems during the study?**
- **How many participants were diagnosed with a new long-term medical condition during the study?**

Pfizer

What happened during the study?

How was the study done?

Participants were assigned by chance alone (like flipping a coin, "randomized") to **receive either RSVpreF or a placebo**.

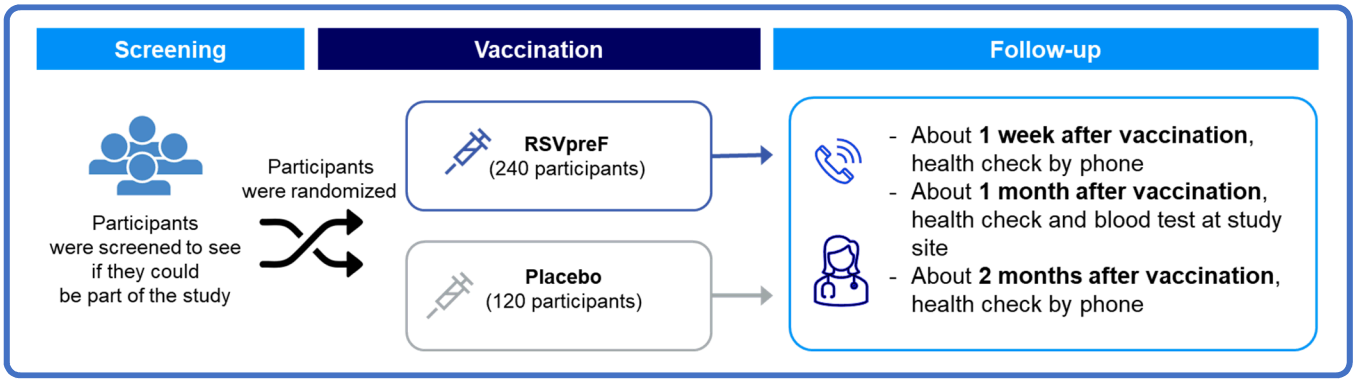
This created 2 different groups:

- RSVpreF: participants were given RSVpreF
- Placebo: participants were given a placebo

RSVpreF or the placebo was given as one injection into the muscle of the upper arm. The researchers and participants did not know which vaccine was given. This is known as a "double-blind" study.

Participants were expected to go to 4 study visits over 2 months. During the study, researchers checked how participants were feeling. Researchers also took samples of blood from participants, to measure the levels of antibody against RSV, before and after vaccination. Figure 1 shows how the study was done.

Figure 1: What happened in the study?



Researchers then compared the results of study participants receiving RSVpreF to the results of study participants receiving placebo.

Where did this study take place?

The Sponsor ran this study at 16 locations in the Republic of Korea.

When did this study take place?

It began 07 October 2024 and ended 03 February 2025.

Who participated in this study?

The study included adults who were **60 years of age or older** in Korea who had stable health.

Of the 378 participants who joined the study, 377 participants received study vaccination. A total of 244 women and a total of 133 men were vaccinated. All participants were between the ages of 60 years and 89 years.

Of the 377 participants who were vaccinated, **251 got RSVpreF**, and **126 got placebo**. A total of 376 participants completed the study.

There was 1 participant who did not finish the study, because of a "protocol deviation" (the participant joined the study but did not meet the study rules to be in the study).

How long did the study last?

Study participants were in the study for about 2 months. The entire study took about 4 months to complete.

When the study completed in February 2025, the Sponsor began reviewing the information collected during the study. The Sponsor then created a report of the results. This is a summary of that report.

Pfizer

What were the results of the study?

What were the participants' levels of antibodies to RSV before and 1 month after vaccination?

Researchers wanted to know if the RSVpreF vaccine helped the body make more antibodies to fight RSV. They studied adults aged 60 years and older. RSV has two types: RSV A and RSV B. The study checked if the vaccine helps the body's immune response to both types.

What did the researchers do?

Researchers measured antibody levels for both RSV A and RSV B before and 1 month after vaccination.

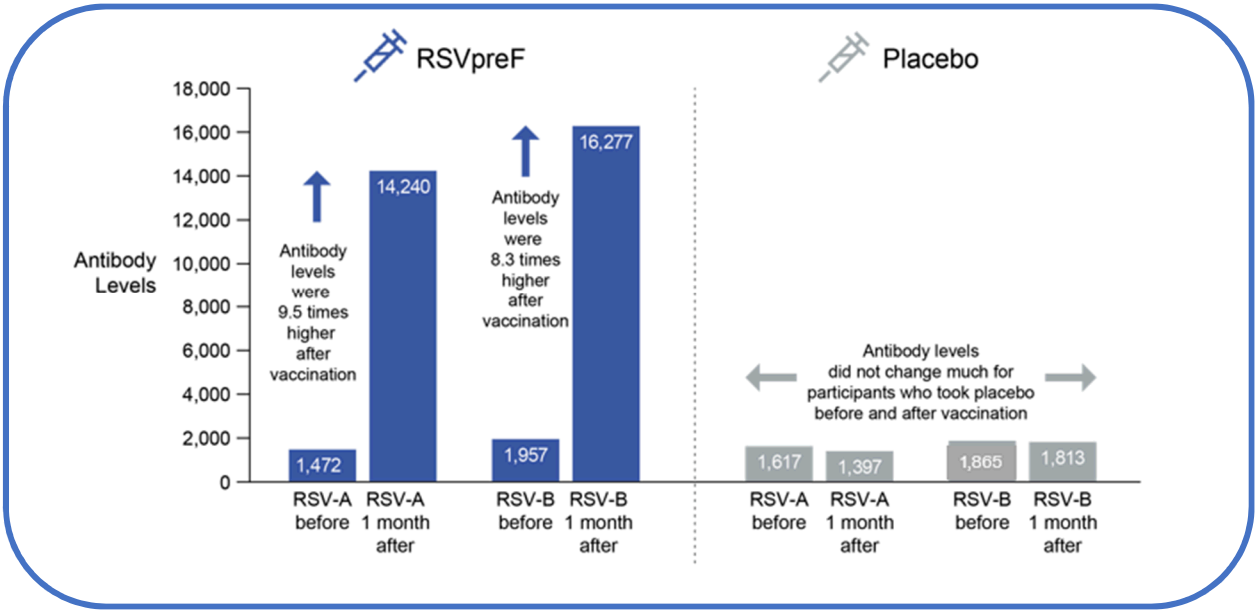
What did they find?

At 1 month after vaccination, people who got the RSVpreF vaccine had much higher antibody levels against both RSV A and RSV B than those who got placebo.

- On average, 1 month after vaccination with RSVpreF, antibody levels were about 9.5 times higher for RSV A and 8.3 times higher for RSV B than before vaccination.
- In the placebo group, antibody levels did not increase.

Figure 2 below shows the antibody levels 1 month after vaccination.

Figure 2: Antibody responses 1 month after vaccination.



What does this mean?

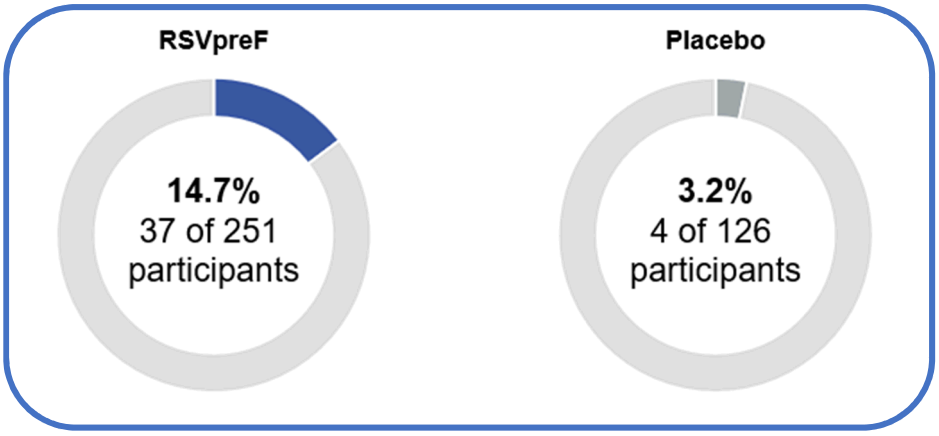
The RSVpreF vaccine helped older adults in Korea make antibodies against RSV A and RSV B. This may help protect them from RSV infection.

How many participants had pain, redness, or swelling at the injection site within 7 days after vaccination?

Participants recorded in an electronic diary if they had any pain, redness, or swelling at the injection site within 7 days after vaccination.

Figure 3 below shows how many participants reported any pain, redness, or swelling at the injection site within 7 days after vaccination. These effects were mostly mild or moderate in how severe they were and lasted for a short time.

Figure 3. How many participants with pain, redness, or swelling at the injection site within 7 days after vaccination?

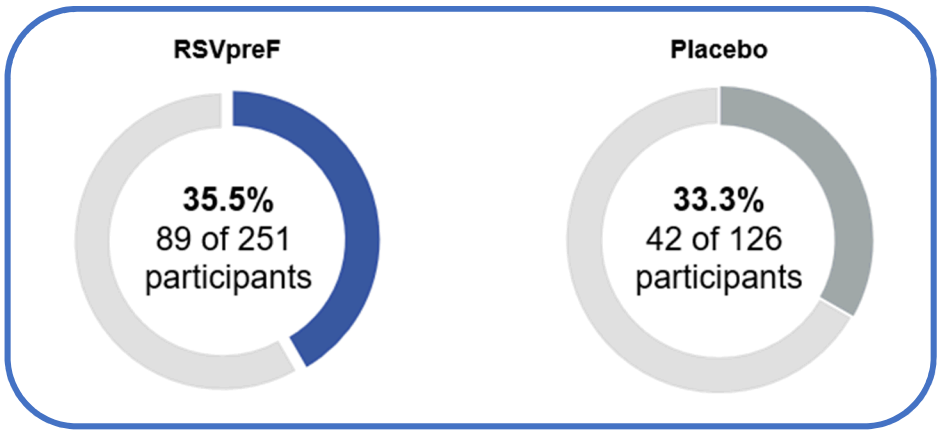


How many participants had fever, fatigue (tiredness), headache, muscle pain, joint pain, nausea (feeling sick), vomiting (being sick), or diarrhea (loose stools) within 7 days after vaccination?

Participants recorded these symptoms in an electronic diary within 7 days after their vaccine. The most common symptoms were fatigue (tiredness) and muscle pain.

Below, in Figure 4, shows how many participants were reporting fever, fatigue (tiredness), headache, muscle pain, joint pain, nausea (feeling sick), vomiting (being sick), or diarrhea (loose stools) within 7 days after vaccination. These effects were mild or moderate in how severe they were and lasted for a short time.

Figure 4: How many participants with fever, fatigue (tiredness), headache, muscle pain, joint pain, nausea (feeling sick), vomiting (being sick), or diarrhea (loose stools) within 7 days after vaccination?



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.

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

- **9 out of 251 people (3.6%)** who got the RSVpreF vaccine had a medical problem within 1 month after vaccination.
- **1 out of 126 people (0.8%)** who got placebo had a medical problem within 1 month after vaccination.
- All medical problems were mild or moderate. None of the medical problems were considered related to the vaccine or placebo by the study doctors.
- The most common specific medical problem was “asthenia” (feeling weak), which was reported by 2 participants in the RSVpreF group.
- In the placebo group, the only medical problem reported was “rhinitis allergic” (allergic runny nose).

Pfizer

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st and 2nd** column of Table 1 lists medical problems that were commonly reported within 1 month after vaccination. All medical problems reported by any participants are listed.
- The **3rd** column tells how many of the participants who took the study vaccine reported each medical problem. Next to this number is the percentage of the participants who took the study vaccine and reported the medical problem.
- The **4th** column tells how many of the participants who took placebo reported each medical problem. Next to this number is the percentage of the participants who took placebo and reported the medical problem.

Using these instructions, you can see that a total of 1 out of 251 participants (0.4%) reported a stomach infection after vaccination in the study vaccine group, RSVpreF group.

Using these instructions, you can see that no participants reported a stomach infection in the placebo group, 0 out of 126 participants (0.0%).

Pfizer

Table 1. Commonly reported medical problems by study participants			
Medical Problem		**RSVpreF Group (251 Participants)**	**Placebo Group (126 Participants)**
Stomach infection	Enteritis	1 out of 251 participants (0.4%)	0 out of 126 participants (0.0%)
Feeling very weak or tired	Asthenia	2 out of 251 participants (0.8%)	0 out of 126 participants (0.0%)
Nose or throat infection	Nasopharyngitis	1 out of 251 participants (0.4%)	0 out of 126 participants (0.0%)
Bladder infection	Urinary tract infection	1 out of 251 participants (0.4%)	0 out of 126 participants (0.0%)
Shingles	Varicella zoster virus infection	1 out of 251 participants (0.4%)	0 out of 126 participants (0.0%)
High cholesterol	Hyperlipidaemia	1 out of 251 participants (0.4%)	0 out of 126 participants (0.0%)
Type 2 diabetes	Type 2 diabetes mellitus	1 out of 251 participants (0.4%)	0 out of 126 participants (0.0%)

Table 1. Commonly reported medical problems by study participants			
Medical Problem		**RSVpreF Group (251 Participants)**	**Placebo Group (126 Participants)**
Allergic runny nose	Rhinitis allergic	0 out of 251 participants (0.0%)	1 out of 126 participants (0.8%)
Runny nose	Rhinorrhea	1 out of 251 participants (0.4%)	0 out of 126 participants (0.0%)
High blood pressure	Hypertension	1 out of 251 participants (0.4%)	0 out of 126 participants (0.0%)

How many serious medical problems did participants have?

A medical problem is considered "serious" when it is life-threatening, needs hospital care, or causes lasting problems.

Three (3) out of 377 participants had serious medical problems:

- **2 out of 251 participants (0.8%)** in the RSVpreF group had serious medical problems. The serious medical problems were "enteritis" (stomach inflammation) and asthma.

Pfizer

- **1 out of 126 participants (0.8%)** in the placebo group had a serious medical problem. The serious medical problem was "retinal detachment" (an eye problem where part of the eye pulls away).

Researchers do not believe any of the serious medical problems were caused by the study vaccination or placebo. No participant left the study because of a medical problem. No participant died during the study.

How many participants were diagnosed with a new long-term medical condition during the study?

- In the **RSVpreF group**, 3 out of 251 participants (1.2%) were diagnosed with a new long-term medical condition. This included:
    - high cholesterol (too much fat in the blood)
    - high blood pressure (too high of a force of blood moving in the body)
    - type 2 diabetes (a condition where the body has trouble using sugar for energy), or
    - osteoporosis (weak bones that break easily).

  None of these were considered related to the vaccine by the study doctors. No participants in the placebo group were diagnosed with a new long-term medical condition.

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 **C3671053**

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

www.clinicaltrials.gov	Use the study identifier **NCT06593587**

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!

Pfizer