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.

Sponsor:	Pfizer Inc.
Medicine(s) Studied:	Abrysvo™ Respiratory syncytial virus (RSV) stabilized prefusion F subunit vaccine (RSVpreF) (PF-06928316)
Protocol Number:	C3671006
Dates of Study:	13 April 2022 to 12 October 2022
Title of this Study:	Safety and Immunogenicity of RSVpreF Coadministered With SIIV in Adults ⩾65 Years of Age [A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, and Immunogenicity of Respiratory Syncytial Virus Prefusion F Subunit Vaccine When Coadministered With Seasonal Inactivated Influenza Vaccine in Adults ⩾65 Years of Age]
Date(s) of this Report:	01 September 2023

– 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)?

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 runny nose. This infection can be serious in 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 the RSV vaccine (RSVpreF)?

This study is about a vaccine called the respiratory syncytial virus vaccine, or "RSVpreF." A vaccine is used to help prevent infection by helping the body to fight off germs. RSVpreF may be able to help prevent infections caused by RSV.

RSVpreF contains proteins found in the virus that may stimulate the body's response to make antibodies (known as the "immune response" or "antibody response"), which may protect against RSV disease. There is no live virus in RSVpreF.

RSVpreF was an investigational vaccine in this study in Australia. RSVpreF has been approved in the United States in individuals aged 60 years and older to prevent lower respiratory tract disease caused by RSV.

What was the purpose of this study?

The main purpose of this study was to learn about the safety and immune responses of RSVpreF in healthy older adults when it is given at the same time as the seasonal flu vaccine.

Researchers compared the effect of giving RSVpreF at the same time as the flu vaccine to the effect of giving RSVpreF and the flu vaccine 4 weeks (1 month) apart.

The flu vaccine used in this study was Fluad® Quad, that has been approved for use in adults aged 65 years and older in Australia.

Researchers wanted to know:

- **Did participants given RSVpreF and the flu vaccine at the same time have similar immune responses to participants given RSVpreF and the flu vaccine 1 month apart?**
- **How many participants had redness, swelling, or pain at the injection site within 7 days of vaccination?**
- **How many participants had nausea (feeling sick), vomiting (being sick), headache, muscle pain, joint pain, diarrhea (loose stools), tiredness, or fever within 7 days of vaccination?**
- **What medical problems did participants have during the study?**

What happened during the study?

How was the study done?

Participants were assigned by chance alone (“randomized”) into 2 different groups:

- Group A “coadministration”: participants were given the flu vaccine and RSVpreF at Visit 1, and a placebo at Visit 2
- Group B “sequential administration” participants were given the flu vaccine and a placebo at Visit 1, and RSVpreF at Visit 2

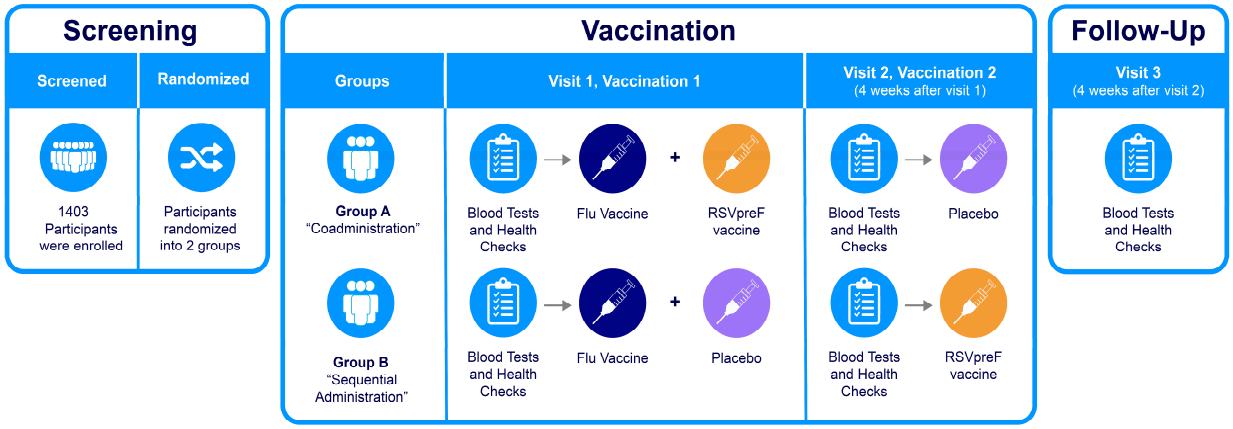
A placebo does not have any vaccine in it, but it looks just like the study vaccination. The vaccines and the placebo were given as injections into the muscle of the arm.

The researchers and participants did not know the order in which the vaccines were given. This is known as a “double-blind” study.

Participants were expected to attend 3 study visits over 2 months. At the visits, vaccines were given when scheduled, blood samples were collected, and participants were checked for any medical problems.

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

Figure 1: Study Plan



***Group A**, coadministration: 705 participants were randomized, 702 participants received Vaccination 1 and 688 participants received Vaccination 2*
***Group B**, sequential administration: 698 participants were randomized, 697 participants received Vaccination 1 and 693 participants received Vaccination 2*

Researchers then compared the results of study participants who received RSVpreF and the flu vaccine at the same time to the results of study participants who received RSVpreF and the flu vaccine 1 month apart.

Where did this study take place?

The Sponsor ran this study at 31 locations in Australia.

When did this study take place?

It began 13 April 2022 and ended 12 October 2022.

Who participated in this study?

The study included participants who were aged 65 years or older and had stable health.

- A total of 629 men participated
- A total of 770 women participated
- All participants were between the ages of 65 and 91 years

A total of 1403 participants joined the study. There were 702 participants in Group A (“coadministration”) and 697 participants in Group B (“sequential administration”) received at least one study vaccination. A total of 1378 participants completed the study. There were 21 participants (1.5%) who left the study early, for the following reasons:

- A total of 10 participants left the study early due to a medical problem
- One participant passed away for a reason that was not related to the study vaccination
- A total of 3 participants were lost to follow up, which means they could no longer be contacted
- A total of 7 participants left before the study was over by their choice or a doctor decided 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 about 2 months. The entire study took 6 months to complete.

When the study ended in October 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?

Did participants given RSVpreF and the flu vaccine at the same time have similar immune responses to participants given RSVpreF and the flu vaccine 1 month apart?

- The researchers measured the amount of antibodies against RSV and flu 1 month after coadministration of RSVpreF and the flu vaccine (Group A).
- For sequential administration of RSVpreF and the flu vaccine (Group B), antibodies against RSV were measured 1 month after RSVpreF was given on its own, and antibodies against the flu were measured 1 month after the flu vaccine was given on its own.

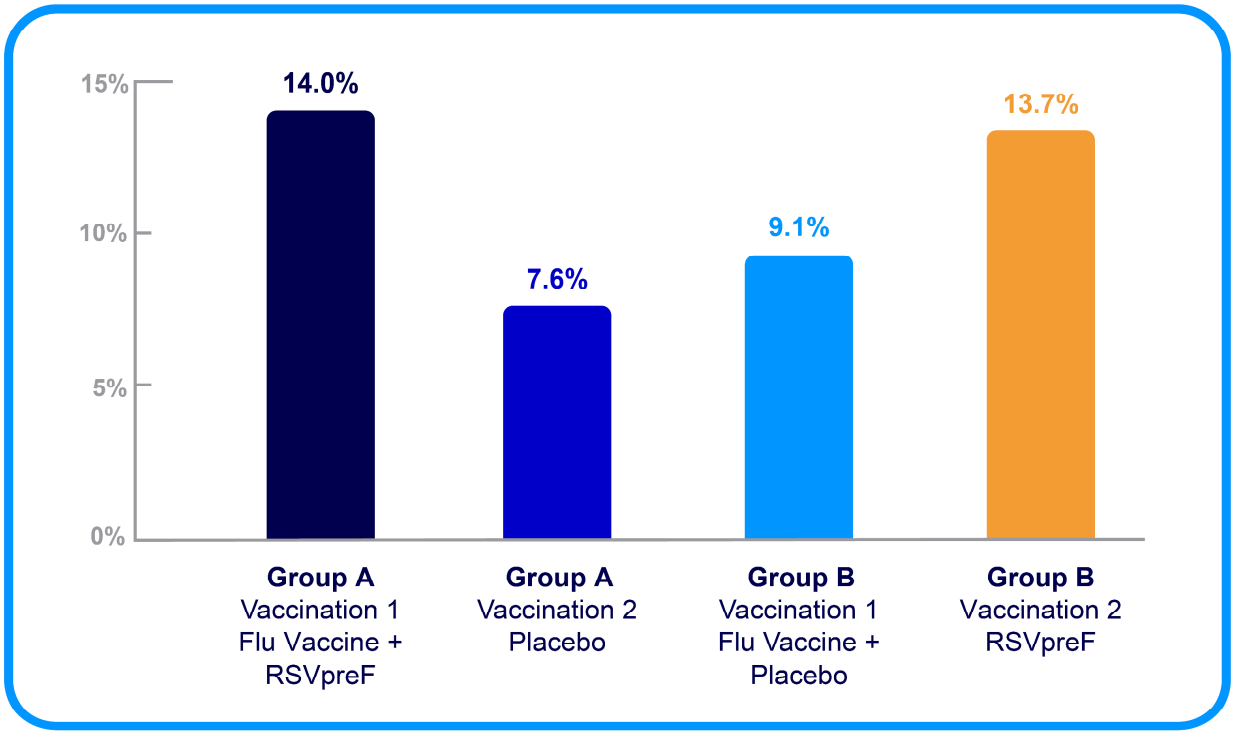
The researchers found that RSV and flu antibody levels for both groups were within a range considered to be comparable. Therefore, the participants who received RSVpreF and the flu vaccine at the same time had immune responses against RSV and flu that were comparable to the participants who received RSVpreF and the flu vaccine 1 month apart.

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

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

The percentage of participants in each group with redness, swelling, or pain at the injection site within 7 days of vaccination are shown in Figure 2 below. Most participants reported these effects were mild or moderate.

Figure 2: Percentage of participants with redness, swelling, or pain at the injection site within 7 days after vaccination

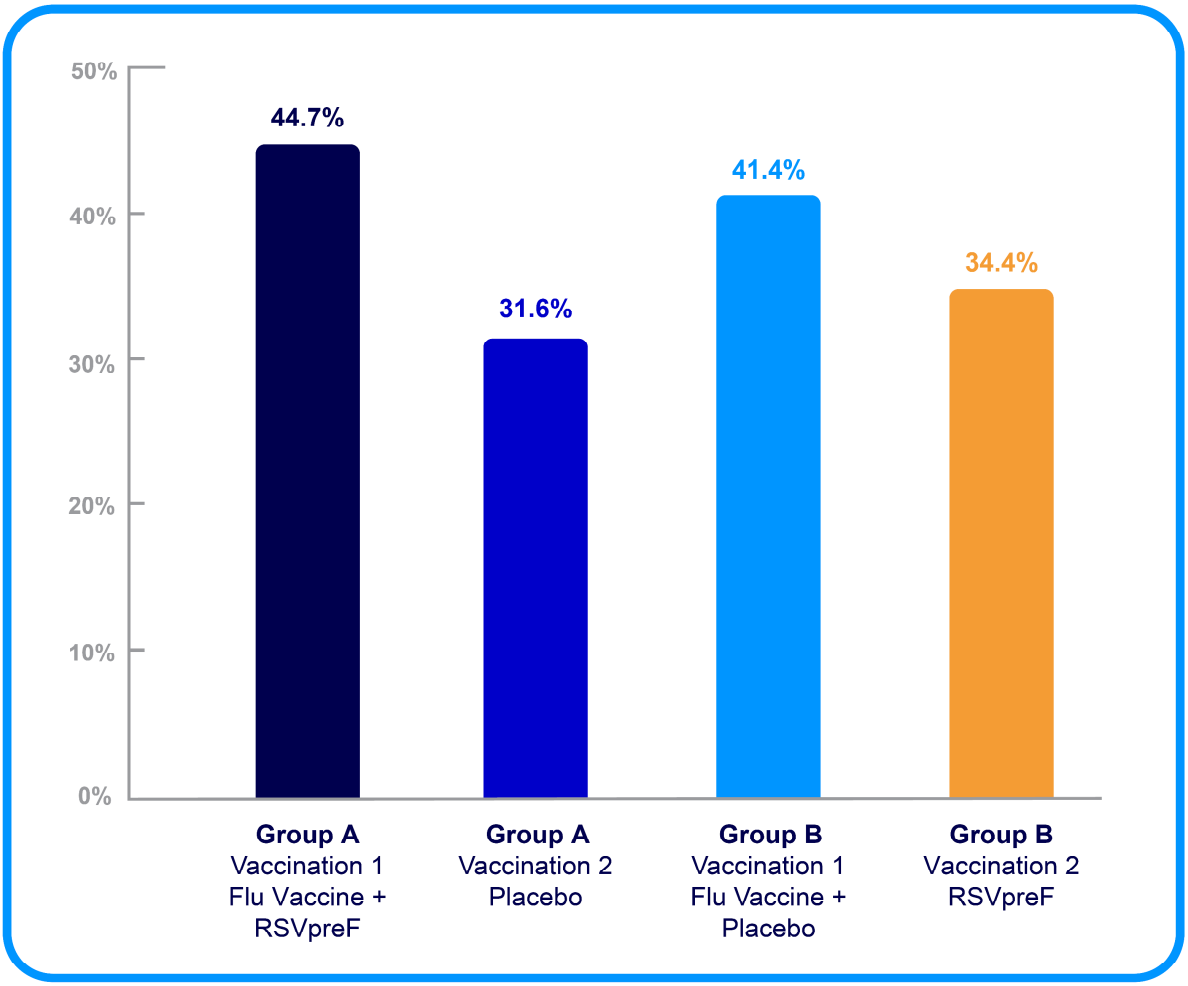


How many participants had nausea (feeling sick), vomiting (being sick), headache, muscle pain, joint pain, diarrhea (loose stools), tiredness, or fever within 7 days of vaccination?

The percentage of participants with nausea (feeling sick), vomiting (being sick), headache, muscle pain, joint pain, diarrhea (loose stools), tiredness,

or fever within 7 days of vaccination are shown in Figure 3 below. Most participants reported these effects were mild or moderate.

Figure 3: Percentage of participants with nausea (feeling sick), vomiting (being sick), headache, muscle pain, joint pain, diarrhea (loose stools), tiredness, or fever 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.

- A total of 154 out of the 703 (21.9%) participants in Group A (coadministration) who received Vaccination 1 had at least 1 medical problem after Vaccination 1.
- A total of 134 out of the 695 (19.3%) participants in Group B (sequential administration) who received Vaccination 1 had at least 1 medical problem after Vaccination 1.
- A total of 117 out of the 689 (17.0%) participants in Group A (coadministration) who received Vaccination 2 had at least 1 medical problem after Vaccination 2.
- A total of 115 out of the 691 (16.6%) participants in Group B (sequential administration) who received Vaccination 2 had at least 1 medical problem after Vaccination 2.

A total of 10 participants left the study because of medical problems. The most common medical problems – those reported by 4 or more participants (0.6%) in Group A or Group B after each vaccination – 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 by 4 or more participants (0.6%) after each vaccination are listed.
- The **2nd** column tells how many of the 703 participants in Group A (coadministration) reported each medical problem after Vaccination 1. Next to this number is the percentage of the 703 participants in Group A who reported the medical problem after Vaccination 1.
- The **3rd** column tells how many of the 695 participants in Group B (sequential administration) reported each medical problem after Vaccination 1. Next to this number is the percentage of the 695 participants in Group B who reported the medical problem after Vaccination 1.
- The **4th** column tells how many of the 689 participants in Group A who reported each medical problem after Vaccination 2. Next to this number is the percentage of the 689 participants in the Group A who reported the medical problem after Vaccination 2.
- The **5th** column tells how many of the 691 participants in Group B reported each medical problem after Vaccination 2. Next to this number is the percentage of the 691 participants in Group B who reported the medical problem after Vaccination 2.

- Using these instructions, you can see that 2 out of the 703 (0.3%) participants in Group A reported diarrhea (loose stools) after Vaccination 1. A total of 1 out of the 695 (0.1%) participants in Group B reported diarrhea (loose stools) after Vaccination 1.

Table 1. Commonly reported medical problems by study participants

Medical Problem	Group A Vaccination 1 (703 Participants)	Group B Vaccination 1 (695 Participants)	Group A Vaccination 2 (689 Participants)	Group B Vaccination 2 (691 Participants)
Diarrhea (loose stools)	2 out of 703 participants (0.3%)	1 out of 695 participants (0.1%)	2 out of 689 participants (0.3%)	5 out of 691 participants (0.7%)
Infection affecting the larger airways	0	0	5 out of 689 participants (0.7%)	3 out of 691 participants (0.4%)
COVID-19	36 out of 703 participants (5.1%)	27 out of 695 participants (3.9%)	30 out of 689 participants (4.4%)	20 out of 691 participants (2.9%)

Table 1. Commonly reported medical problems by study participants

Medical Problem	Group A Vaccination 1 (703 Participants)	Group B Vaccination 1 (695 Participants)	Group A Vaccination 2 (689 Participants)	Group B Vaccination 2 (691 Participants)
Infection of the airways	2 out of 703 participants (0.3%)	1 out of 695 participants (0.1%)	1 out of 689 participants (0.1%)	4 out of 691 participants (0.6%)
Nose or throat infection	16 out of 703 participants (2.3%)	23 out of 695 participants (3.3%)	13 out of 689 participants (1.9%)	15 out of 691 participants (2.2%)
Nose, or throat infection caused by a virus	9 out of 703 participants (1.3%)	2 out of 695 participants (0.3%)	4 out of 689 participants (0.6%)	3 out of 691 participants (0.4%)
Fall	3 out of 703 participants (0.4%)	3 out of 695 participants (0.4%)	4 out of 689 participants (0.6%)	5 out of 691 participants (0.7%)
Back pain	4 out of 703 participants (0.6%)	2 out of 695 participants (0.3%)	1 out of 689 participants (0.1%)	2 out of 691 participants (0.3%)

Table 1. Commonly reported medical problems by study participants				
Medical Problem	Group A Vaccination 1 (703 Participants)	Group B Vaccination 1 (695 Participants)	Group A Vaccination 2 (689 Participants)	Group B Vaccination 2 (691 Participants)
Headache	5 out of 703 participants (0.7%)	3 out of 695 participants (0.4%)	3 out of 689 participants (0.4%)	2 out of 691 participants (0.3%)
Cough	6 out of 703 participants (0.9%)	0	1 out of 689 participants (0.1%)	1 out of 691 participants (0.1%)

COVID-19 = coronavirus disease 2019

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.

A total of 14 participants had serious medical problems within 1 month after Vaccination 1.

- Eight out of 703 participants (1.1%) in Group A (coadministration) had serious medical problems.

- Six out of 695 participants (0.9%) in Group B (sequential administration) had serious medical problems.

A total of 7 participants had serious medical problems within 1 month after Vaccination 2.

- Two out of 689 participants (0.3%) in Group A (coadministration) had serious medical problems.
- Five out of 691 participants (0.7%) in Group B (sequential administration) had serious medical problems.

One participant died during the study. Researchers do not believe that the death or any of the serious medical problems reported by participants were related to investigational study vaccines.

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 C3671006

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

www.clinicaltrials.gov	Use the study identifier **NCT05301322**

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!