CLINICAL TRIAL 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 medicine 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: Respiratory Syncytial Virus Stabilized Prefusion F Subunit Vaccine (RSVpreF), Compound Number: PF-06928316

Protocol Number: C3671004

Dates of Trial: 01 October 2019 to 11 December 2019

Title of this Trial: A Study of A RSV Vaccine When Given Together With Tdap in Healthy Nonpregnant Women Aged Between 18 and 49 Years

[Final Report: A Phase 2b, Placebo-Controlled, Randomized, Observer-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of a Respiratory Syncytial Virus (RSV) Vaccine When Administered Concomitantly With Tetanus, Diphtheria, and Acellular Pertussis Vaccine (Tdap) in Healthy Nonpregnant Women 18 Through 49 Years of Age]

Date of this Report: 19 November 2020

– Thank You –

Pfizer, the Sponsor, would like to thank you for your participation in this clinical trial and provide you a summary of results representing everyone who participated. If you have any questions about the study or results, please contact the doctor or staff at your study site.

WHY WAS THIS STUDY DONE?

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 very serious in infants and young children.

This study is about a vaccine called the "respiratory syncytial virus stabilized prefusion F subunit 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.

After a vaccine is injected into a person's body, the body responds to help fight infections and prevent diseases. The response to vaccines includes making "antibodies", which are proteins that fight infections and help to prevent diseases. This is part of the body's "immune response".

The Sponsor of this study is developing RSVpreF for use in pregnant women. During pregnancy, vaccinated mothers may pass on antibodies to their baby. So, RSVpreF may be able to help to prevent infections caused by RSV in infants if it is given to the mother while she is pregnant.

RSVpreF is an investigational vaccine, which means that it has not been approved for general use and it is not yet known if it will protect against disease caused by RSV.

The study participants may have received RSVpreF, Tdap vaccine (a vaccine against diseases called tetanus, diphtheria, and pertussis), and/or placebo. A placebo looks like the study vaccine but not does contain any active ingredients. The purpose of this study was to learn about the safety of RSVpreF when given alone or together with Tdap, and to learn whether giving RSVpreF and Tdap together changes how well either vaccine works.

Researchers asked these main questions:

- One month after vaccination, did participants who received Tdap and RSVpreF have a comparable level of Tdap antibodies to those who received Tdap and placebo?
- One month after vaccination, did participants who received Tdap and RSVpreF have a comparable level of RSV antibodies to those who received RSVpreF and placebo?

To answer these questions, the researchers measured the amount of antibodies in participants' blood 1 month after being vaccinated.

To learn about the safety of RSVpreF when given together with Tdap or placebo, researchers asked these questions:

- What percentage of participants had "local reactions" (redness, swelling, or pain at the injection site) within 7 days after vaccination?
- What percentage of participants had "systemic events" (fever, headache, tiredness, muscle pain, joint pain, nausea, vomiting, or diarrhea) within 7 days after vaccination?
- What percentage of participants had medical problems within 1 month after vaccination?
- What percentage of participants had serious medical problems or medical problems that required treatment from a doctor during the study?

WHAT HAPPENED DURING THE STUDY?

This study compared 5 groups of participants to learn about the safety of RSVpreF when given alone and together with Tdap in healthy, nonpregnant women, and to learn whether giving RSVpreF and Tdap together changes how either vaccine works.

Participants were checked (screened) to make sure they were a good fit for the study. This study included adult women who:

- Were between the ages of 18 and 49 years
- Were not pregnant or breastfeeding

- Were considered to be healthy or with stable chronic disease by the study doctors
- Did not have a disease or take medicine that would be associated with a weakened immune system
- Had never received any vaccine for RSV
- Had not received a DTaP or Td (tetanus and diphtheria) vaccine within 5 years
- Had never had an allergic reaction to any of the ingredients in the study vaccines

This was a "randomized" study, which means that participants were assigned to 1 of 5 groups based on chance alone. Randomization is done to make the groups similar so that differences in immune response or safety are most likely due to the different vaccines people received.

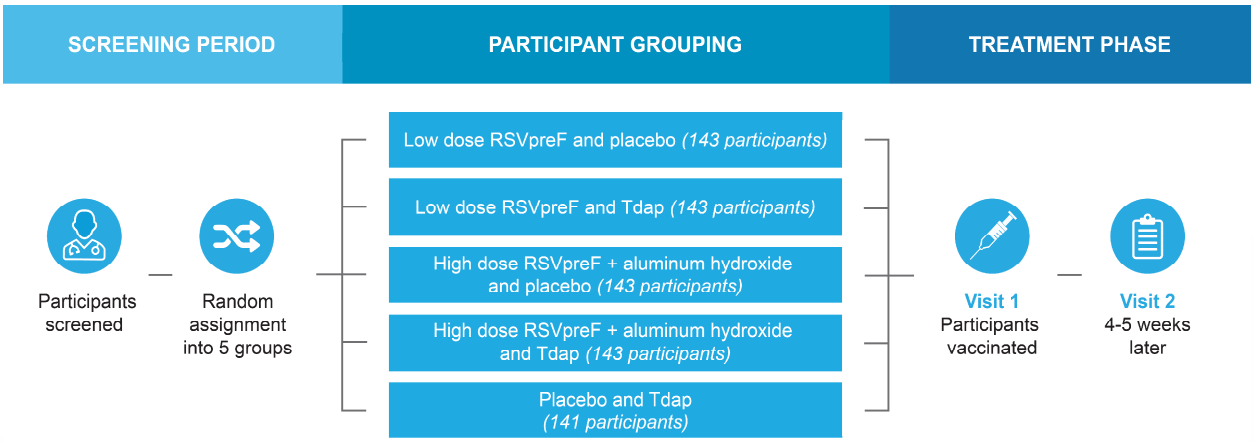
This study was also "double-blinded". This means that participants and study staff members assessing safety did not know who was given which injection. This was done to make sure that the study results were not influenced in any way.

The vaccine combinations were given as 2 injections at the same time (one in each arm). Some of the RSVpreF vaccines also contained aluminum hydroxide, an ingredient that is commonly included in vaccines to help make the immune response stronger. The combinations included:

- Low dose RSVpreF and placebo (143 participants)
- Low dose RSVpreF and Tdap (143 participants)
- High dose RSVpreF + aluminum hydroxide and placebo (143 participants)
- High dose RSVpreF + aluminum hydroxide and Tdap (143 participants)
- Placebo and Tdap (141 participants)

Participants were expected to participate in 2 study visits. At the first visit, blood samples were collected, and the participants received the injections. The second visit was done about 1 month after the first visit. Blood samples were collected, and participants were checked for any medical problems.

The figure on the following page shows what happened during the study.



While participants were in this study for about 4 to 5 weeks, the entire study took about 2 months to complete since not all participants entered the study at the same time. The Sponsor ran this study at 16 locations in the United States. It began 01 October 2019 and ended 11 December 2019. All participants were women between the ages of 18 and 49 years.

Of the 713 participants who joined the study, 709 (99%) received study injections. A total of 695 participants (97%) completed both study visits, while 14 participants (2%) did not complete both visits and left the study early by their choice.

Throughout the course of the study, the Sponsor reviewed the data. When the study ended in December 2019 and after antibody testing was completed, the Sponsor then created a report of the results. This is a summary of that report.

WHAT WERE THE RESULTS OF THE STUDY?

One month after vaccination, did participants who received Tdap and RSVpreF have a comparable level of Tdap antibodies to those who received Tdap and placebo?

To answer this question, the researchers measured the amount of antibodies in participants' blood 1 month after vaccination. They looked to see if the amount of antibodies that the body produced against tetanus, diphtheria, and pertussis were

comparable in participants who received Tdap and RSVpreF, and in those who received Tdap and placebo.

The researchers found that antibody levels against tetanus and diphtheria were comparable in participants who received Tdap and RSVpreF, and in those who received Tdap and placebo. However, antibody levels against pertussis were not comparable and were lower in participants who received Tdap and RSVpreF than in those who received Tdap and placebo. Based on these results, the researchers have decided that the results are not likely the result of chance.

One month after vaccination, did participants who received RSVpreF and Tdap have a comparable level of RSV antibodies to those who received RSVpreF and placebo?

To answer this question, the researchers measured the amount of antibodies in participants' blood 1 month after vaccination. They looked to see if the amount of antibodies that the body produced against RSV was comparable in participants who received RSVpreF and Tdap, and in those who received RSVpreF and placebo.

The researchers found that RSV antibody levels were comparable in participants who received RSVpreF and Tdap, and in those who received RSVpreF and placebo. Based on these results, the researchers have decided that the results are not likely the result of chance.

This does not mean that everyone in this study had these results. Other studies may produce different results, as well. These are just some of the main findings of the study, and more information may be available at the websites listed at the end of this summary.

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 study vaccine or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By looking at medical problems across many treatment groups in many studies, doctors try to understand what the side effects of an experimental drug (in this case experimental vaccine) might be.

What percentage of participants had local reactions within 7 days after vaccination?

Redness, swelling, or pain at the injection site are known as "local reactions". The table on the following page shows the percentage of participants with local reactions within 7 days after vaccination.

Participants With Local Reactions Within 7 Days After Vaccination					
	Low dose RSVpreF and placebo (141 Participants)	Low dose RSVpreF and Tdap (141 Participants)	High dose RSVpreF + aluminum hydroxide and placebo (141 Participants)	High dose RSVpreF + aluminum hydroxide and Tdap (143 Participants)	Placebo and Tdap (139 Participants)
Pain at injection site	57 (40%)	63 (45%)	94 (67%)	89 (62%)	36 (26%)
Redness at injection site	10 (7%)	6 (4%)	7 (5%)	8 (6%)	1 (1%)
Swelling at injection site	10 (7%)	8 (6%)	6 (4%)	10 (7%)	2 (1%)
Any local reaction	59 (42%)	64 (45%)	95 (67%)	90 (63%)	36 (26%)

What percentage of participants had systemic events within 7 days after vaccination?

Fever, headache, tiredness, muscle pain, joint pain, nausea, vomiting, and diarrhea are known as "systemic events". The table on the following page shows the number of participants with systemic events within 7 days after vaccination.

Participants With Systemic Events Within 7 Days After Vaccination					
	Low dose RSVpreF and placebo (141 Participants)	Low dose RSVpreF and Tdap (141 Participants)	High dose RSVpreF + aluminum hydroxide and placebo (141 Participants)	High dose RSVpreF + aluminum hydroxide and Tdap (143 Participants)	Placebo and Tdap (139 Participants)
Fever	11 (8%)	9 (6%)	9 (6%)	11 (8%)	7 (5%)
Tiredness	60 (43%)	68 (48%)	63 (45%)	67 (47%)	61 (44%)
Headache	50 (36%)	59 (42%)	65 (46%)	59 (41%)	51 (37%)
Nausea	32 (23%)	24 (17%)	22 (16%)	28 (20%)	30 (22%)
Muscle pain	49 (35%)	70 (50%)	68 (48%)	76 (53%)	48 (35%)
Joint pain	21 (15%)	25 (18%)	24 (17%)	25 (18%)	16 (12%)
Vomiting	5 (4%)	7 (5%)	3 (2%)	3 (2%)	6 (4%)
Diarrhea	22 (16%)	27 (19%)	17 (12%)	24 (17%)	21 (15%)
Any systemic event	94 (67%)	109 (77%)	99 (70%)	104 (73%)	96 (69%)

What percentage of participants had medical problems within 1 month after vaccination?

55 out of 709 vaccinated participants (8%) had at least 1 new or worsening medical problem within 1 month after vaccination, including:

- Low dose RSVpreF and placebo: 8 out of 141 participants (6%)
- Low dose RSVpreF and Tdap: 11 out of 141 participants (8%)

- High dose RSVpreF + aluminum hydroxide and placebo: 8 out of 142 participants (6%)
- High dose RSVpreF + aluminum hydroxide and Tdap: 15 out of 144 participants (10%)
- Placebo and Tdap: 13 out of 141 participants (9%)

A total of 6 participants (1%) had a medical problem that the study doctor considered to be related to study vaccines. Most of the related medical problems were mild to moderate in severity, with short duration.

The table below shows the most common medical problems that happened within 1 month after study vaccination.

Most Common Medical Problems Within 1 Month After Vaccination (2 or More Participants in Any Group)

Medical Problem	Low dose RSVpreF and placebo (141 Participants)	Low dose RSVpreF and Tdap (141 Participants)	High dose RSVpreF + aluminum hydroxide and placebo (142 Participants)	High dose RSVpreF + aluminum hydroxide and Tdap (144 Participants)	Placebo and Tdap (141 Participants)
Tiredness	0 (0%)	3 (2%)	0 (0%)	1 (1%)	1 (1%)
Common cold	0 (0%)	1 (1%)	1 (1%)	0 (0%)	2 (1%)
Infection of the nose, throat, and upper airways	0 (0%)	0 (0%)	2 (1%)	2 (1%)	4 (3%)
Headache	0 (0%)	1 (1%)	0 (0%)	2 (1%)	0 (0%)

Migraine headache	**0 (0%)**	**0 (0%)**	**0 (0%)**	**2 (1%)**	**1 (1%)**
Throat pain	**2 (1%)**	**0 (0%)**	**1 (1%)**	**0 (0%)**	**0 (0%)**

WERE THERE ANY SERIOUS MEDICAL PROBLEMS?

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

What percentage of participants had serious medical problems or medical problems that required treatment from a doctor during the study?

1 participant (less than 1%) had a serious medical problem during the study, which was not considered to be related to the study vaccines. This participant was in the high dose RSVpreF + aluminum hydroxide and placebo group. No participants died or left the study because of a medical problem.

A total of 7 participants (1%) required treatment from a doctor for a medical problem during the study that was unrelated to the 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.clinicaltrials.gov Use the study identifier **NCT04071158**

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients. Further clinical trials with RSVpreF are ongoing.

Again, **thank you** for volunteering. We do research to try to find the best ways to help patients, and you helped us to do that!