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 intervention 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: PF-07831695

Protocol Number: C4801001

Dates of Study: 15 August 2022 to 07 October 2022

Title of this Study: A Study to Look at the Safety and the Immune Response to Candidates Against Pneumococcus Bacteria

[A Phase 1, Randomized, Open-Label Trial to Evaluate the Safety and Immunogenicity of Pneumococcal Conjugate Formulations in Healthy Adults 18 Through 49 Years of Age]

Date(s) of this Report: 28 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 Streptococcus pneumoniae?

Streptococcus pneumoniae (also known as S. pneumoniae) is a germ and a leading cause of serious diseases, including infection of the lungs (pneumonia), infection of the lining of the brain (meningitis), and infection of the blood (bacteremia) and continues to be a public health concern. Vaccines are used to help prevent serious disease caused by this germ.

What is the candidate?

The candidate is a potential component that may be used to prevent infection against S. pneumoniae. Currently, there are two Pfizer licensed pneumococcal vaccines; they are Prevnar 13 (13vPnC) and Prevnar 20 (20vPnC) which contains components to help protect against the germ. It is given via an injection into your muscle, often in the upper arm. After a person gets a vaccine, the body's response includes making antibodies. Antibodies fight infections and help prevent diseases. This is called an immune response.

What was the purpose of this study?

The purpose of this study was to learn how different formulations of a pneumococcal conjugate (candidates) differ in their immune response (number of antibodies - protective proteins that remove germs from body made). Researchers wanted to know about the body's immune response to each candidate and they also looked at the safety of the candidate. They did this by looking to see if there were any local reactions, systemic events, or medical problems after the candidate was given. A local reaction is when there is redness, swelling, or pain at the injection site. The injection site is the skin area where the needle was inserted. A

systemic event is when there are symptoms like fever, tiredness, headache, muscle pain and joint pain.

Researchers wanted to know:

- **Did participants have any local reactions or systemic events after the study intervention?**
- **What medical problems did participants have during the study?**
- **Did study participants have any serious medical problems during the study?**

What happened during the study?

How was the study done?

This was an “open-label” study, which means that the participants and the researchers knew which study intervention the participants received.

Participants between the 18 to 49 years of age were invited to join the study. Each participant received single dose of a study candidate or control and was assigned by chance to 1 of the 9 groups: 6 groups received 1 of 6 different variations of candidate and 3 groups received candidate control, 13vPnC, or PCV15 as given below:

- Candidate-1 (dose volume: 0.25 mL)
- Candidate-2 (dose volume: 0.5 mL)
- Candidate-3 (dose volume: 0.25 mL)
- Candidate-4 (dose volume: 0.5 mL)

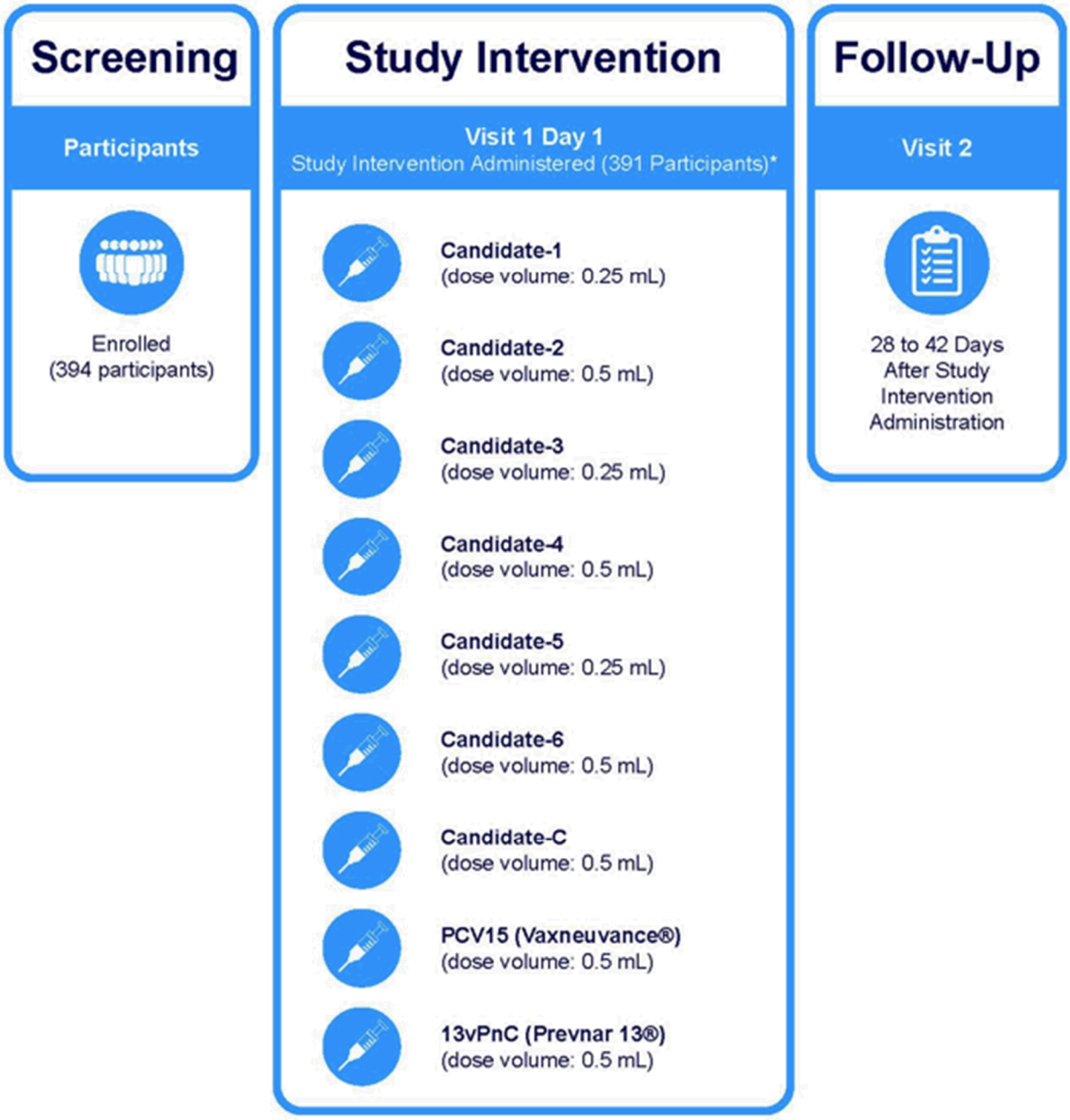
- Candidate-5 (dose volume: 0.25 mL)
- Candidate-6 (dose volume: 0.5 mL)
- Candidate-C (dose volume: 0.5 mL)
- PCV15 (Vaxneuvance®) (dose volume: 0.5 mL)
- 13vPnC (Prevnar 13®) (dose volume: 0.5 mL)

Different variations of the candidates were administered, including PCV15 (a pneumococcal vaccine that is currently licensed in the United States), and 13vPnC on a group of study participants to find out if study participants had any medical problems or side effects.

Researchers also tested the effect of the candidate on the immune response. They did this by collecting blood samples from all participants before giving study intervention and at follow-up visit approximately 1 month later at Visit 2 as shown in Figure 1.

Figure 1 below shows what happened during the study.

Figure 1: Study Design



Where did this study take place?

The Sponsor ran this study at 17 locations in the USA.

When did this study take place?

It began 15 August 2022 and ended 07 October 2022.

Who participated in this study?

The study included healthy participants who met the inclusion/exclusion criteria for things such as age, condition type, severity, and prior treatments.

- A total of 164 men participated
- A total of 230 women participated.
- All participants were between the ages of 18 and 49.

Among the 394 participants who were assigned to receive the candidate or the control, 391 received the study intervention, and 3 did not receive the study intervention.

Of the 394 participants enrolled, 386 finished. 8 did not finish the study because:

- They were lost to follow-up (4 participants);
- They withdrew by their choice, or the doctors decided it was best for the participants to stop being in the study (2 participants); or
- They were enrolled into the study too late (2 participants).

How long did the study last?

Study participants were in the study for 1 month (28 to 42 days after receiving the study intervention). The entire study took 2 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 have any local reactions or systemic events after the study intervention?

Participants recorded any effect that the study intervention might have had at the site of injection. This included local reactions like redness, swelling, and pain. They also recorded any systemic events. Systemic events included things like fever, tiredness, headache, muscle pain and joint pain.

The researchers also collected information on medical problems that the participants had within 30 days of study intervention. These medical problems are discussed in the next section of this document.

Did the participants have any local reactions within 7 days of the study intervention?

Pain at injection site was the most commonly reported local reaction among study participants in all groups. This ranged from 5 (12.2%) participants in candidate-1 group to 20 (44.4%) participants in Candidate-5 group, and 6 (13.3%) participants in the Candidate-C control group. Pain at the injection site was also most commonly reported in the PCV15 and 13vPnC groups: 29 (67.4%) participants and 29 (63.0%) participants respectively.

Did the participants have any systemic events within 7 days of the study intervention?

Tiredness (fatigue) and headache were the most commonly reported systemic events among study participants in all candidate groups.

Fatigue ranged from 13 (31.7%) participants in Candidate-1 group to 20 (47.6%) participants in Candidate-2 group and 16 (35.6%) participants in the Candidate-C control group. Fatigue was reported in 23 (53.5%) participants in PCV15 and 21 (45.7%) participants in 13vPnC groups.

Headache ranged from 12 (26.1%) participants in Candidate-6, to 18 (43.9%) participants given in Candidate-1 group, and 10 (22.2%) participants in the Candidate-C group. Headache was reported in 15 (34.9%) participants in PCV15 and 11 (23.9%) participants in 13vPnC groups.

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 intervention (for example, caused by an unknown underlying disease or by chance). Or, medical problems could have been caused by a study intervention or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across different groups in many studies, doctors can better understand what effects a study candidate/control vaccine might have on a participant.

A total of 13 out of 391 (3.32%) participants in this study had at least 1 medical problem. No participants left the study because of medical problems. The most common medical problems are described below.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists all medical problems that were reported during the study.
- The **2nd** column tells how many of the 257 participants who were given different variations of the candidate (excluding the control) reported each medical problem. Next to this number is the percentage of those who reported the medical problem among the 257 participants taking different variations of the candidate.
- The **3rd** column tells how many of the 134 participants who were given one of the existing vaccines or the candidate control reported each medical problem. Next to this number is the percentage of those who reported the medical problem among the 134 participants who were given one of the existing vaccines or the candidate control.
- Using these instructions, you can see that 2 out of the 257 (0.78%) participants who were given variations of the candidate (excluding the control) reported COVID-19. A total of 2 out of the 134 (1.5%) participants who were given one of the existing vaccines or the Candidate control reported COVID-19.

Table 1. Commonly reported medical problems by study participants		
Medical Problem	Study Candidate (257 Participants)	Candidate Control + PCV15 + 13vPnC (Comparator) (134 Participants)
COVID-19	2 out of 257 participants (0.78%)	2 out of 134 participants (1.5%)
Redness, swelling or pain	1 out of 257 participants (0.39%)	0 participants
Flu	1 out of 257 participants (0.39%)	0 participants
Upper airway infection	1 out of 257 participants (0.39%)	0 participants
Fall	1 out of 257 participants (0.39%)	0 participants
Broken leg	1 out of 257 participants (0.39%)	0 participants
Joint pain	1 out of 257 participants (0.39%)	0 participants
Back pain	1 out of 257 participants (0.39%)	0 participants
Anxiety	1 out of 257 participants (0.39%)	0 participants
Itching	1 out of 257 participants (0.39%)	0 participants

Table 1. Commonly reported medical problems by study participants		
Medical Problem	Study Candidate (257 Participants)	Candidate Control + PCV15 + 13vPnC (Comparator) (134 Participants)
Rash	1 out of 257 participants (0.39%)	0 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.

One participant (0.26%, or 1 out of 391 participants) had serious medical problems.

- One participant in the Candidate-5 group had cellulitis (an infection of the skin and nearby tissue). Researchers do not believe this was related to study interventions.

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 C4801001

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

www.clinicaltrials.gov	Use the study identifier **NCT05489328**

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