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.

Vaccine Studied: PF-07831695

Protocol Number: C4801002

Dates of Study: 08 November 2023 to 27 May 2024

Title of this Study: A Study in Healthy Toddlers to Look at the Safety and Immune Response of a Candidate Against Pneumococcal Bacteria

[A Phase 2, Randomized, Open-Label Trial to Describe the Safety and Immunogenicity of a Monovalent Pneumococcal Conjugate Candidate Administered as a 2-Dose Series in Healthy Toddlers 11 Through 15 Months of Age Who Previously Received the PCV10 Primary Series]

Date of this Report: 25 November 2024

– Thank You –

If your child participated in this study, Pfizer, the Sponsor, would like to thank you for your child's 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 pneumococcal disease?

Pneumococcal (noo-muh-KOK-uhl) disease is an infection caused by a germ called Streptococcus pneumoniae, also known as S pneumoniae. In some people, this germ may be found in the nose without causing any symptoms. It can also spread to different parts of the body and lead to lung or blood infections, or a very serious condition such as infection of the lining of the brain. These infections may become severe and may even cause death.

Vaccines are used to help prevent the risk of serious diseases caused by this germ. Currently, multiple vaccines are approved to prevent diseases caused by different types (strains) of this germ. While these available vaccines have reduced some of the impact of pneumococcal diseases, a specific type of this germ still causes a lot of the diseases in infants and children.

What is Monovalent Pneumococcal Conjugate Candidate?

Currently, there are two Pfizer licensed pneumococcal vaccines; they are Prevnar 13 (13vPnC) and Prevnar 20 (20vPnC). These vaccines contain components to help protect against multiple types of S pneumoniae. 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.

A monovalent pneumococcal conjugate (mPnC) candidate is designed to help protect against one specific type of S pneumoniae.

What was the purpose of this study?

The main purpose of this study was to learn about the safety of the two doses of the mPnC candidate in healthy toddlers. Researchers did this by checking for any “local reactions”, “systemic events”, or medical problems after the participants received the candidate or an mPnC control.

The mPnC control contains only one part of a currently approved pneumococcal vaccine, designed to help protect against the same specific type of S pneumoniae as the mPnC candidate.

Both the candidate and the control were given as an injection into the muscle at each injection visit.

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. A **systemic event** includes symptoms like fever, drowsiness or increased sleep, decreased appetite, or irritability.

Researchers wanted to know:

- **Did the participants have redness, swelling, or pain at the injection site within 7 days after each injection?**
- **Did the participants have fever, drowsiness or increased sleep, decreased appetite, or irritability within 7 days after each injection?**
- **What medical problems did participants have during the study?**
- **Did the participants have any serious medical problems during the study?**

What happened during the study?

How was the study done?

Researchers gave the mPnC candidate to a group of study participants to learn about its safety. They also looked at the safety of the mPnC control.

This study planned to include healthy toddlers between 11 and 15 months of age, who previously received 2 doses of PCV10 (10-valent pneumococcal conjugate) vaccine as a routine immunization schedule. The study was explained to the caregivers, who could choose whether they wanted their toddler to be part of the study.

The participants were equally divided into 2 groups by chance alone. This is known as “randomization”. Randomization is done to fairly compare the groups.

In this study, the caregivers of the participants (toddlers) and the researchers knew which injection each participant received. This is known as an open-label study.

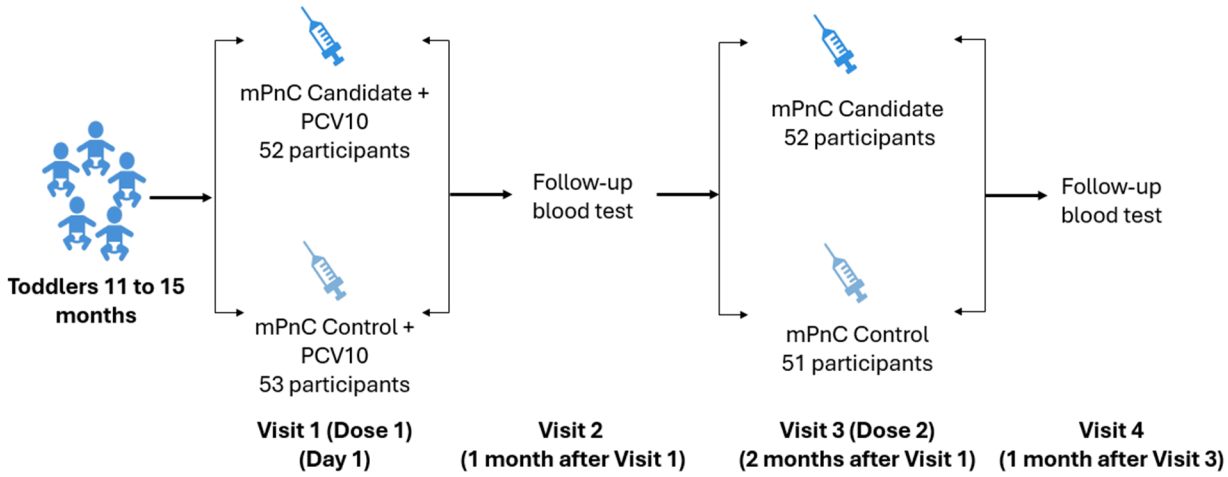
One group received the mPnC candidate, the other group received the mPnC control. Participants received either the mPnC candidate or the mPnC control as a single injection into their left thigh during 2 different visits, 2 months apart. Both groups also received a single injection of PCV10 (given in the right thigh) at the first visit as shown in Figure 1.

The researchers observed the participants for any immediate medical issues in the office for 30 minutes after each injection.

The participants’ caregivers were provided with an electronic diary in which they recorded any redness, swelling, or pain at the injection site for 7 days. They also recorded whether the toddler had fever, drowsiness or increased sleep, decreased appetite, or irritability. The use of fever or pain medication within 7 days after receiving each injection was also recorded.

Researchers monitored the safety and health of study participants throughout the study.

Figure 1: What happened during the study



Where did this study take place?

The Sponsor ran this study at 11 locations in 2 countries in Europe.

When did this study take place?

It began 08 November 2023 and ended 27 May 2024.

Who participated in this study?

The study included 105 healthy toddlers who had already received 2 infant doses of pneumococcal conjugate vaccine (PCV10) as per the vaccine schedule for infants.

- A total of 53 toddler boys participated.
- A total of 52 toddler girls participated.
- All participants were between the age of 11 and 13 months.

Participants were to receive 2 doses of the injection under study. Of the 105 participants who started the study, 103 finished the study.
Two participants did not receive Dose 2 of the mPnC control.

Two participants left before the end of the study, one stopped meeting the eligibility criteria and one left due to 'other reason' (change in life situation).

How long did the study last?

Study participants were in the study for 3 months. The entire study took around 7 months to complete.

When the study ended in May 2024, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

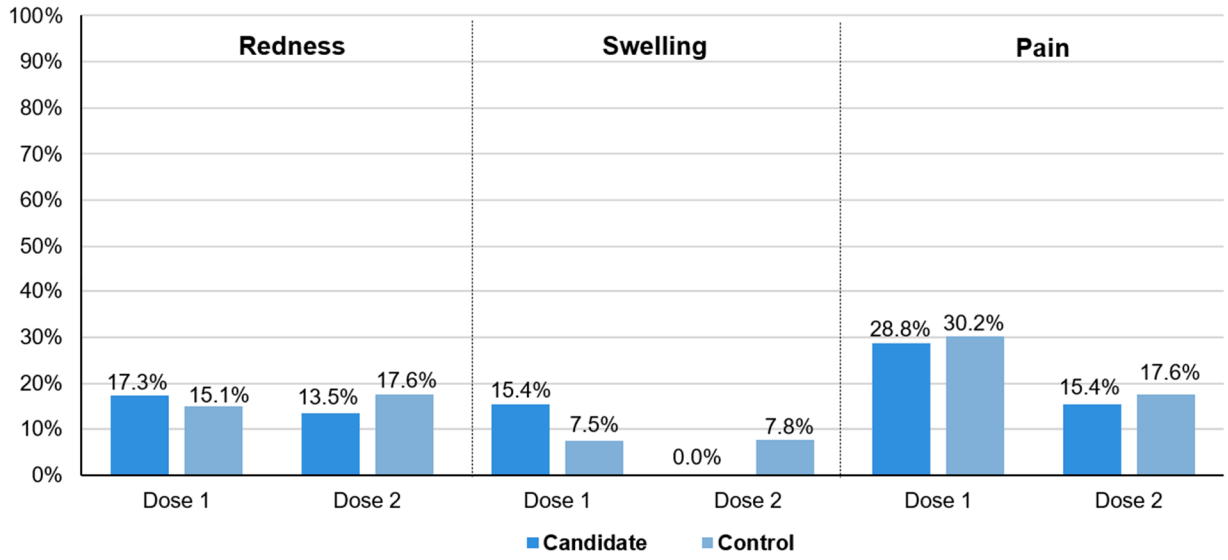
What were the results of the study?

Did the participants have redness, swelling, or pain at the injection site within 7 days after each injection?

After Dose 1, pain at the injection site was the most commonly reported local reaction among study participants in both groups.

After Dose 2, pain and redness at the injection site were the most commonly reported local reaction among study participants in both groups as shown in Figure 2.

Figure 2: Percentage of participants with redness, swelling or pain after each injection

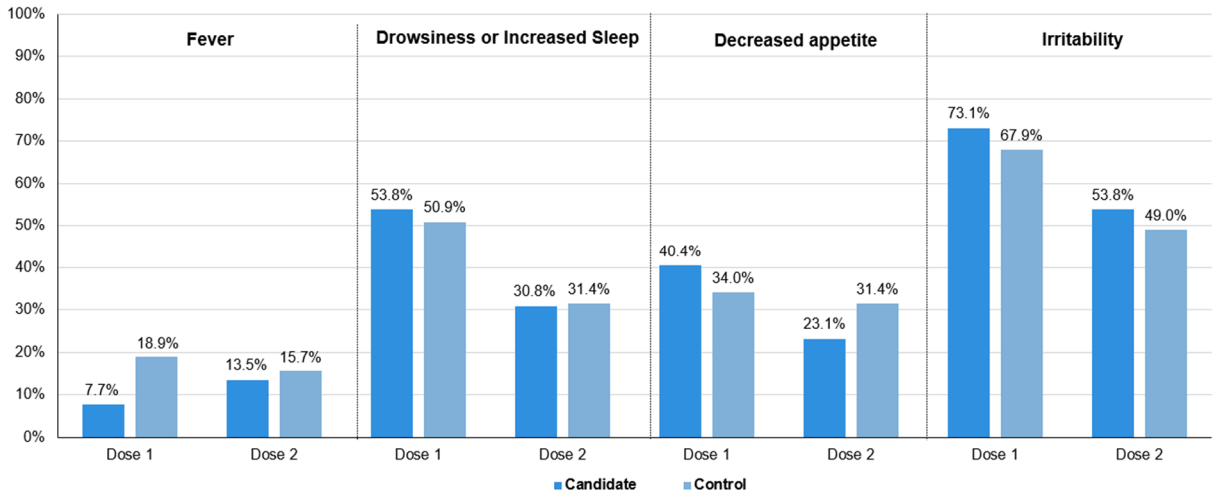


The percentages of participants who reported redness, swelling, and pain at the injection site were generally similar, or lower, after Dose 2 compared with Dose 1.

Did the participants have fever, drowsiness or increased sleep, decreased appetite, or irritability within 7 days after each injection?

Irritability was the most commonly reported event among study participants in both groups, after Dose 1 and Dose 2, as shown in Figure 3 on the next page.

Figure 3: Percentage of participants with fever, drowsiness or increased sleep, decreased appetite, or irritability after each injection



The percentages of participants who reported these events were generally lower after Dose 2 compared with Dose 1 in both groups except for fever, which was reported by more participants after Dose 2 in mPnC candidate group.

The above results do 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 treatment or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors try to understand what effects a study medication might have on a participant.

In this study, 44 out of 52 (84.6%) participants who received the mPnC candidate, and 40 out of 53 (75.5%) participants who received mPnC control, had at least 1 medical problem. The medical problems reported in the study were consistent with common childhood conditions. No participants left the study because of medical problems. The most common medical problems – those reported by more than 5% of 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 more than 5% of participants are listed.
- The **2nd** column tells how many of the 52 participants who received the mPnC candidate reported each medical problem. Next to this number is the percentage of the 52 participants who received the mPnC candidate reported the medical problem.
- The **3rd** column tells how many of the 53 participants who received the mPnC control reported each medical problem. Next to this number is the percentage of the 53 participants who received the mPnC control reported the medical problem.
- Using these instructions, you can see that 24 out of the 52 (46.2%) participants receiving mPnC candidate reported infection in the nose or throat. A total of 22 out of the 53 (41.5%) participants receiving mPnC control reported infection in the nose or throat.

Table 1. Commonly reported medical problems by study participants		
Medical Problem	**mPnC Candidate (52 Participants)**	**mPnC Control (53 Participants)**
Infection in the nose or throat	24 out of 52 participants (46.2%)	22 out of 53 participants (41.5%)
Infection in the stomach and intestines	14 out of 52 participants (26.9%)	12 out of 53 participants (22.6%)
Inflammation of the nose and throat	8 out of 52 participants (15.4%)	5 out of 53 participants (9.4%)
Diarrhea	7 out of 52 participants (13.5%)	2 out of 53 participants (3.8%)
Infection of the middle ear	5 out of 52 participants (9.6%)	4 out of 53 participants (7.5%)
Stuffy and runny nose	4 out of 52 participants (7.7%)	3 out of 53 participants (5.7%)
Vomiting	3 out of 52 participants (5.8%)	0 out of 53 participants (0%)

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 (1) participant (1.9%, or 1 out of 52 participants) who received the mPnC candidate had a serious medical problem. One (1) participant (1.9%, or 1 out of 53 participants) who received the mPnC control had a serious medical problem. Both medical problems reported below required hospital care:

- One participant in the mPnC candidate group had a viral infection.
- One participant in the mPnC control group had inflammation of the airways in the lungs.

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 **C4801002**

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

www.clinicaltrials.gov	Use the study identifier **NCT06116591**
www.euclinicaltrials.eu	Use the study identifier **2023-505154-18-00**

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 your child 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!