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 vaccine works, how it works, and if it is safe for people to get. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Pfizer Inc.

Vaccine(s) Studied: Meningococcal ABCWY vaccine (called MenABCWY or PF-06886992)

Protocol Number: C3511004

Dates of Study: 17 June 2020 to 05 January 2024

Title of this Study: A study of MenABCWY vaccine in healthy adolescents – to find out if it was safe and produced antibody responses against a germ called *Neisseria meningitidis*

[A Phase 2b, Randomized, Observer-Blinded Trial to Describe the Safety, Tolerability, and Immunogenicity of MenABCWY Administered on 2 Different Dosing Schedules in Healthy Participants ⩾11 to <15 Years of Age]

Date(s) of this Report: 11 December 2024

– Thank You –

If you or your child participated in this study, Pfizer, the Sponsor, would like to thank you for you or your child's participation.

This summary will describe the study results. If you or your child have any questions about the study or the results, please contact the doctor or staff at you or your child's study site.

Why was this study done?

What is meningococcal disease?

Neisseria meningitidis (or *N. meningitidis*) is a kind of germ (bacteria). Meningococcus is its other name. There are different types of this germ. For example, meningococcal type A disease is caused by the meningococcus A germ. Meningococcus A, B, C, W, and Y are the most common types.

Neisseria meningitidis can cause infections of the blood, as well as inflammation around the brain and spinal cord. People who get this illness are at risk for brain damage, loss of limbs, hearing loss, and other disabilities.

What is a vaccine and an antibody?

A vaccine can help prevent an infection or a disease. It works by helping the body fight off germs.

Antibodies are proteins that fight infections and help prevent diseases. After a person gets a vaccine, the body's response includes making antibodies. This is called an antibody response.

What is MenABCWY vaccine?

Meningococcal ABCWY vaccine (men-in-jo-kok-uhl A-B-C-W-Y) or MenABCWY, is an injectable study vaccine, which was not approved for general use at the time when this study started. Before the study ended, the MenABCWY vaccine was approved for use in the United States for people 10 to 25 years of age.

The MenABCWY vaccine is a combination of 2 other vaccines that are already used for the prevention of meningococcal disease:

- Nimenrix®, which is used to prevent disease caused by meningococcus types A, C, W, and Y
- Trumenba®, which is used to prevent disease caused by meningococcus type B

MenABCWY combines protection against meningococcus types A, B, C, W, and Y into 1 vaccine.

What was the purpose of this study?

This study aimed to find out if the MenABCWY vaccine, when 2 doses were given 1 year or 3 years apart, was safe in healthy adolescents and if it produced antibody responses against *N. meningitidis*. These periods of time between MenABCWY vaccine doses were longer compared to previous studies, which looked at 2 doses given 6 months apart.

Researchers wanted to know:

Did participants, who received the MenABCWY vaccine, have an antibody response against meningococcal type B germs?

What medical problems did participants have after receiving the MenABCWY vaccine?

Did participants have medical problems, after receiving the MenABCWY vaccine, that were not serious but required them to visit their doctor or go to a hospital?

Were participants diagnosed with a new long-term disease or medical condition after receiving the MenABCWY vaccine?

Did participants have medical problems immediately after receiving the MenABCWY vaccine?

Did participants miss days from school or work due to medical problems after receiving the MenABCWY vaccine?

Did participants have any serious medical problems after receiving the MenABCWY vaccine?

What happened during the study?

How was the study done?

Researchers tested the MenABCWY vaccine on 2 groups of healthy adolescents who joined the study. Participants who were assigned into Group 1 were given 2 doses of the MenABCWY vaccine 1 year apart. Participants who were assigned into Group 2 were given 2 doses of the MenABCWY vaccine 3 years apart. Study participants were assigned to each group by chance alone.

Before all participants completed 13 months of the study, the researchers, participants and their parents or guardians did not know which group they were assigned to. Only the person preparing the vaccine for injection knew whether the participant was receiving the study vaccine or the placebo. This is known as an "observer-blinded" study. In order to keep the study blinded, participants in Group 2 received a placebo (saline) vaccine 1 year after the 1st dose of MenABCWY. A placebo does not have any medicine in it. After all participants completed 13 months of the study, the researchers, participants and their parents or guardians were told which group they were assigned to.

During the study, the participants visited the study site 6 times:

- In Group 1, there were 2 vaccination visits and 4 follow-up visits. Blood samples were collected at the 1st vaccination visit and at each of the 4 follow-up visits. Researchers contacted the participants' parents or guardians once by telephone to check the participant(s) health and asked them how they were feeling.
- In Group 2, there were 3 vaccination visits and 3 follow-up visits. Blood samples were collected at the 1st vaccination visit and at each of the 3 follow-up visits. Researchers contacted the participants'

parents or guardians twice by telephone to check the participant(s) health and asked them how they were feeling.

A diagram showing what happened in this study is provided in Figure 1 and Figure 2.

Figure 1. Study Plan (Group 1)

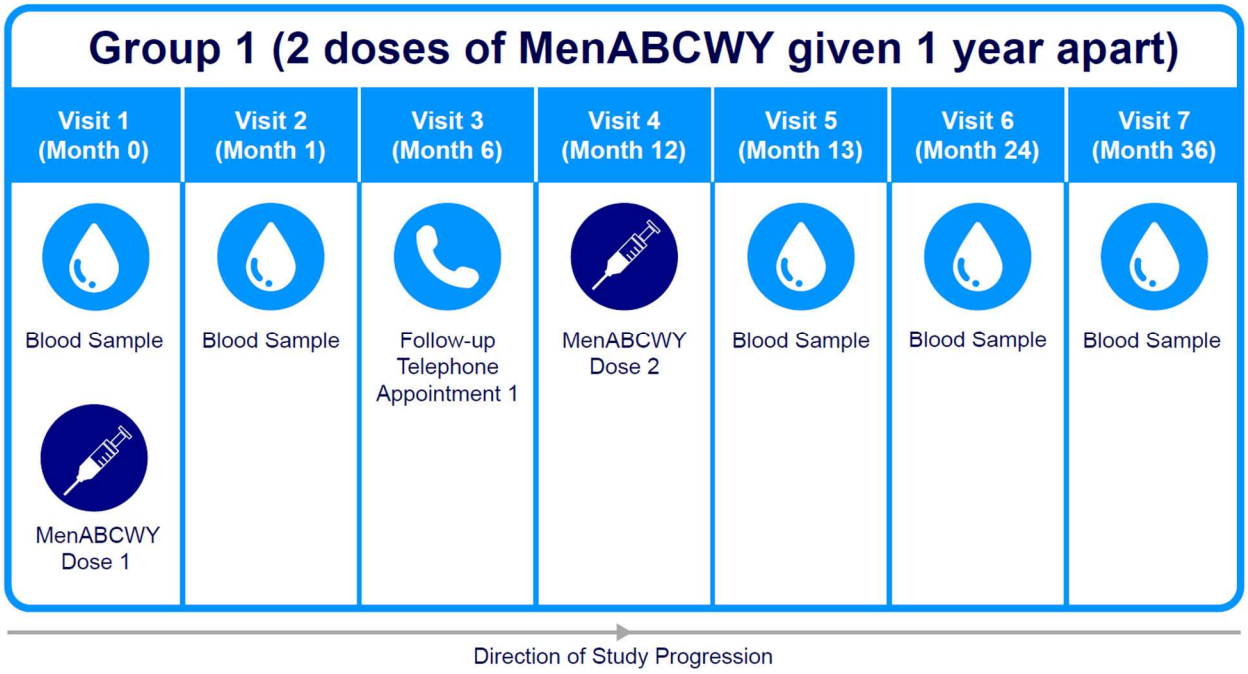
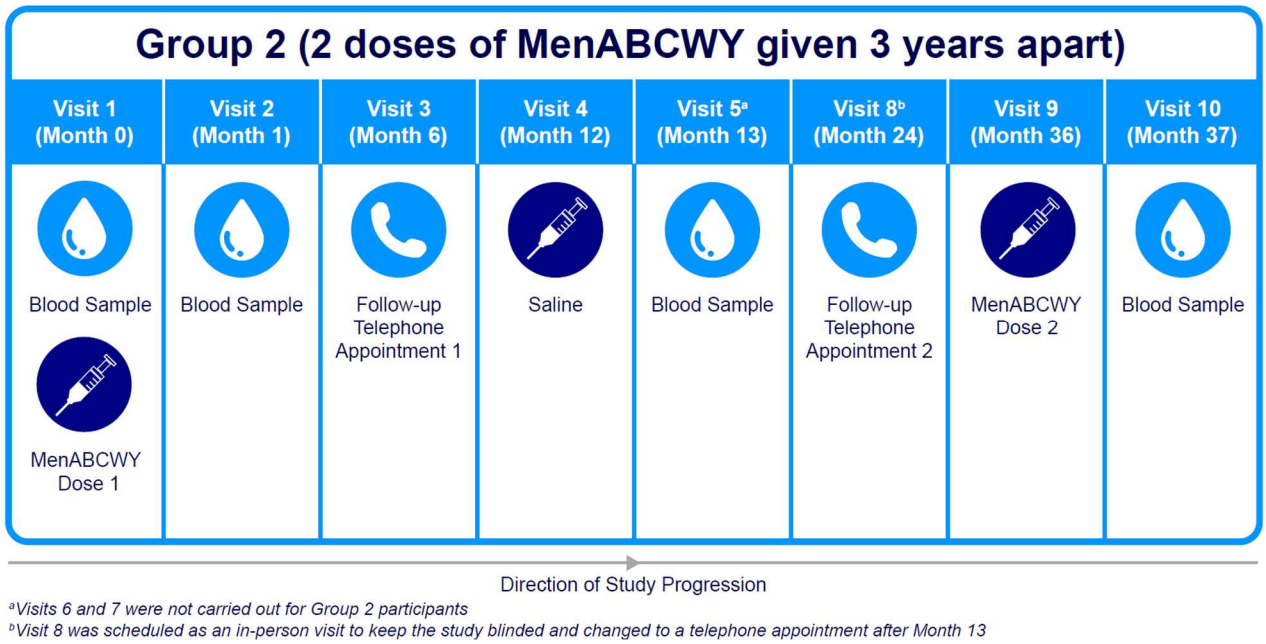


Figure 2. Study Plan (Group 2)



[a]*Visits 6 and 7 were not carried out for Group 2 participants*
[b]*Visit 8 was scheduled as an in-person visit to keep the study blinded and changed to a telephone appointment after Month 13*

Where did this study take place?

The Sponsor ran this study at 21 locations in the United States.

When did this study take place?

It began 17 June 2020 and ended 05 January 2024.

Who participated in this study?

The study included healthy participants who had not received any meningococcal vaccines before they joined the study.

- A total of 163 boys and 131 girls participated
- All participants were between the ages of 11 and 14 years when they started the study

Of the 309 participants who started the study, 121 participants in Group 1 and 103 participants in Group 2 received 2 doses of MenABCWY.

A total of 96 participants did not finish the study. The most common reason was that the participant stopped going to study visits and could not be contacted by the study staff.

How long did the study last?

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

When the study ended in January 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?

Researchers wanted to know if participants had an antibody response to meningococcal type B germs. To do this, the researchers collected blood samples from participants before and after receiving the study vaccine and they measured the amount of antibody for meningococcal type B germs. The researchers then calculated how many participants had antibody for meningococcal type B germs that was at or above a certain level. This level is often used in studies like this to look at the antibody response.

Researchers also wanted to know about the safety of the study vaccine. To do this, the researchers asked questions to participants' parents or guardians about the participants' health during each follow-up visit.

The researchers also wanted to know if the participants had any medical problems during the study. Medical problems are discussed in the next section of this document.

Did participants, who received the MenABCWY vaccine, have an antibody response against meningococcal type B germs?

Researchers looked at how many participants had an antibody response to meningococcal type B germs. They measured the antibody response before the 1st dose of MenABCWY. They also measured the antibody response 1 month after receiving the 2nd dose of MenABCWY.

One (1) month after the 2nd dose of MenABCWY, at least 96.6% of participants in Group 1 and all participants (100%) in Group 2 had an antibody response.

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 after receiving the MenABCWY vaccine?

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 vaccine the participant was receiving. 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.

Researchers wanted to know if the participants had any medical problems within 30 days after receiving each dose of the MenABCWY vaccine.

Within 30 days after the 1st dose of MenABCWY, 42 out of 146 participants (28.8%) in Group 1 and 41 out of 148 participants (27.7%) in Group 2 had at least 1 medical problem.

Within 30 days after the 2nd dose of MenABCWY, 19 out of 121 participants (15.7%) in Group 1 and 20 out of 103 participants (19.4%) in Group 2 had at least 1 medical problem.

Two (2) participants in Group 1 and 6 participants in Group 2 left the study because of medical problems. Researchers believe that none of these medical problems were related to the study vaccine.

The most common medical problems – those reported by more than 5% of participants in either group – are described below and 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 30 days after the 1st dose of MenABCWY. All medical problems reported by more than 5% of participants in either group are listed.
- The **2nd** column tells how many of the 146 participants reported each medical problem in Group 1. Next to this number is the percentage of the 146 participants who reported the medical problem 30 days after the 1st dose of MenABCWY.
- The **3rd** column tells how many of the 148 participants reported each medical problem in Group 2. Next to this number is the percentage of the 148 participants who reported

the medical problem 30 days after the 1st dose of MenABCWY.

- Using these instructions, you can see that 13 out of the 146 participants (8.9%), in Group 1, reported pain at injection site 30 days after the 1st dose of MenABCWY. A total of 11 out of the 148 participants (7.4%), in Group 2, reported pain at injection site 30 days after the 1st dose of MenABCWY.

Table 1. Commonly reported medical problems by study participants 30 days after the 1st dose of MenABCWY

Medical Problem	Group 1 (146 Participants)	Group 2 (148 Participants)
Pain at injection site	13 out of 146 participants (8.9%)	11 out of 148 participants (7.4%)
Fever	8 out of 146 participants (5.5%)	7 out of 148 participants (4.7%)
Headache	9 out of 146 participants (6.2%)	6 out of 148 participants (4.1%)

After the 2nd dose of MenABCWY, the most commonly reported medical problem was pain in the vaccinated area which was reported for 3 out of 121 participants (2.5%) in Group 1 and 8 out of 103 participants (7.8%) in Group 2.

Did participants have medical problems, after receiving the MenABCWY vaccine, that were not serious but required them to visit their doctor or go to a hospital?

The researchers recorded medical problems, that were not serious but required participants to see a doctor or visit a hospital, after receiving the study vaccine.

Within 6 months after the 1st dose of MenABCWY, these types of problems were reported for 34 out of 146 participants (23.3%) in Group 1 and 29 out of 148 participants (19.6%) in Group 2.

Within 6 months after the 2nd dose of MenABCWY, 16 out of 121 participants (13.2%) in Group 1 reported medical problems that required them to visit their doctor or go to a hospital.

Within 1 month after the 2nd dose of MenABCWY, 4 out of 103 participants (3.9%) in Group 2 reported medical problems that required them to visit their doctor or go to a hospital.

Within 6 months after the 1st dose of MenABCWY, 2 participants reported medical problems that required them to visit their doctor or go to a hospital that were considered related to the study vaccine by the researchers. Both participants recovered from these medical problems:

- One (1) out of 146 participants (0.7%) in Group 1 reported medical problems of a rapid heartbeat, being sick (vomiting), body pain, and headache on the day of vaccination.
- One (1) out of 148 participants (0.7%) in Group 2 reported a medical problem of an overwhelming urge to move their legs 4 months and 2 weeks and 4 days after vaccination.

Were participants diagnosed with a new long-term disease or medical condition after receiving the MenABCWY vaccine?

Within 6 months after the 1st dose of MenABCWY, new long-term diseases or medical conditions were reported for 2 out of 146 participants (1.4%) in Group 1 and 1 out of 148 participants (0.7%) in Group 2.

Researchers believed that these new long-term diseases or medical conditions were not related to the study vaccine.

After the 2nd dose of MenABCWY, no participants in either group reported a new long-term disease or medical condition.

Did participants have medical problems immediately after receiving the MenABCWY vaccine?

Immediately after receiving the 1st dose of MenABCWY:

- One (1) out of 146 participants (0.7%) in Group 1 reported a medical problem of pain at the injection site.
- One (1) out of 148 participants (0.7%) in Group 2 reported a medical problem of headache.

Immediately after receiving the 2nd dose of MenABCWY:

- No participants in Group 1 reported medical problems.
- Three (3) out of 103 participants (2.9%) in Group 2 reported medical problems of pain at the injection site.

These medical problems were not considered serious.

Did participants miss days from school or work due to medical problems after receiving the MenABCWY vaccine?

Within 6 months after the 1st dose of MenABCWY, 12 out of 146 participants (8.2%) in Group 1 and 12 out of 148 participants (8.1%) in Group 2 missed days of school or work due to a medical problem.

Within 6 months after the 2nd dose of MenABCWY, 10 out of 121 participants (8.3%) in Group 1 missed days of school or work due to a medical problem.

Within 1 month after the 2nd dose of MenABCWY, 2 out of 103 participants (1.9%) in Group 2 missed days of school or work due to a medical problem.

Did participants have any serious medical problems after receiving the MenABCWY vaccine?

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

Researchers recorded serious medical problems that occurred after each dose of MenABCWY.

Within 6 months after the 1st dose of MenABCWY, serious medical problems were reported for 1 out of 146 participants (0.7%) in Group 1 and no participants in Group 2.

Within 6 months after the 2nd dose of MenABCWY, serious medical problems were reported for 1 out of 121 participants (0.8%) in Group 1.

Within 1 month after the 2nd dose of MenABCWY, no participants in Group 2 reported serious medical problems.

Researchers believed that the serious medical problems were not related to the study vaccine.

No participants died during the study.

Where can I learn more about this study?

If you or your child 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 C3511004

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

www.clinicaltrials.gov	Use the study identifier **NCT04440176**

Please remember that researchers look at the results of many studies to find out which vaccines can work and are safe for people.

Again, if you or 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!