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 to prescribe to study participants. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Pfizer, Inc.

Medicine(s) Studied: Meningococcal Polysaccharide Groups A, C, W-135, and Y Tetanus Toxoid Conjugate Vaccine (MenACWY-TT), Marketed as Nimenrix®, Compound Number: PF-06866681

Protocol Number: C0921003

Dates of Study: 02 October 2013 to 05 December 2019

Title of this Study: Immunogenicity and Safety Study of 1 and 2 Doses of Meningococcal Vaccine MenACWY-TT in Toddlers, Persistence up to 5 Years After Vaccination and Co-administration With Pfizer's Prevenar 13® Vaccine

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[Supplemental Report (Year 5 hSBA Immunogenicity) to Final Report: A Phase III, Randomised, Open, Controlled, Multicentre, Primary Vaccination Study to Evaluate the Immunogenicity and Persistence of 1 and 2 Doses of Meningococcal Conjugate Vaccine MenACWY-TT in Toddlers (After 1 Month and up to 5 Years) and to Demonstrate Non-Inferiority of Co-Administration of MenACWY-TT and 13-Valent Pneumococcal Conjugate Vaccine Prevenar 13® Versus Separate Administration of the 2 Vaccines]

Date(s) of this Report: 29 September 2021

– Thank You –

If you participated in this study, Pfizer, the Sponsor, would like to thank you and your child 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 child's study site.

Why was this study done?

What is meningococcal disease?

Invasive meningococcal disease is an illness which may cause a serious infection in the blood, as well as swelling around the brain and spinal cord. Meningococcal disease is more common in young children than adults. Children who get this illness are at risk for hearing loss and other disabilities. However, invasive meningococcal disease may be prevented with a vaccine. A vaccine is a type of medicine that helps people fight off germs.

Meningococcal disease is caused by the meningococcus germ. There are different types of this germ. For example, meningococcal type A disease is caused by the meningococcus A germ.

What are MenACWY-TT and 13-Valent Pneumococcal Conjugate Vaccine?

MenACWY-TT (Nimenrix®) is a vaccine approved for the prevention of meningococcal disease. This vaccine targets 4 common types of meningococcus germ: A, C, Y, and W. It is given by injection into the muscle.

Some children in this study also received another vaccine, called 13 Valent Pneumococcal Conjugate Vaccine (Prevenar 13®). Prevenar 13 is often given at the same time as MenACWY-TT. Prevenar 13 targets 13 common types of the pneumococcus germ, which can cause ear infections or other serious infections. It is given by injection into the muscle.

For this study, MenACWY-TT was considered an investigational vaccine, which means that it's still being studied.

What was the purpose of this study?

The main purpose of this study was to learn about the safety and effects of MenACWY-TT in toddler-aged children, when given alone or together with 13-Valent Pneumococcal Conjugate Vaccine.

Researchers wanted to know:

Would children have an immune response against meningococcus germs 1 month after receiving their last dose of MenACWY-TT?

Would children still have an immune response against meningococcus germs 1 year, 3 years, and 5 years after receiving their last dose of MenACWY-TT?

To answer these questions, researchers collected blood samples from the children. The researchers looked for antibodies in the blood against the 4 different types of meningococcus germ. Antibodies are special proteins made by the body that can recognize and help kill germs. This is known as an "immune response". Antibodies may protect children from getting sick when they come into contact with meningococcus germs.

What happened during the study?

How was the study done?

This study compared 4 groups of children to learn more about the effects of MenACWY-TT when given alone or together with 13-Valent Pneumococcal Conjugate Vaccine. Children were assigned to 1 of 4 groups by chance alone.

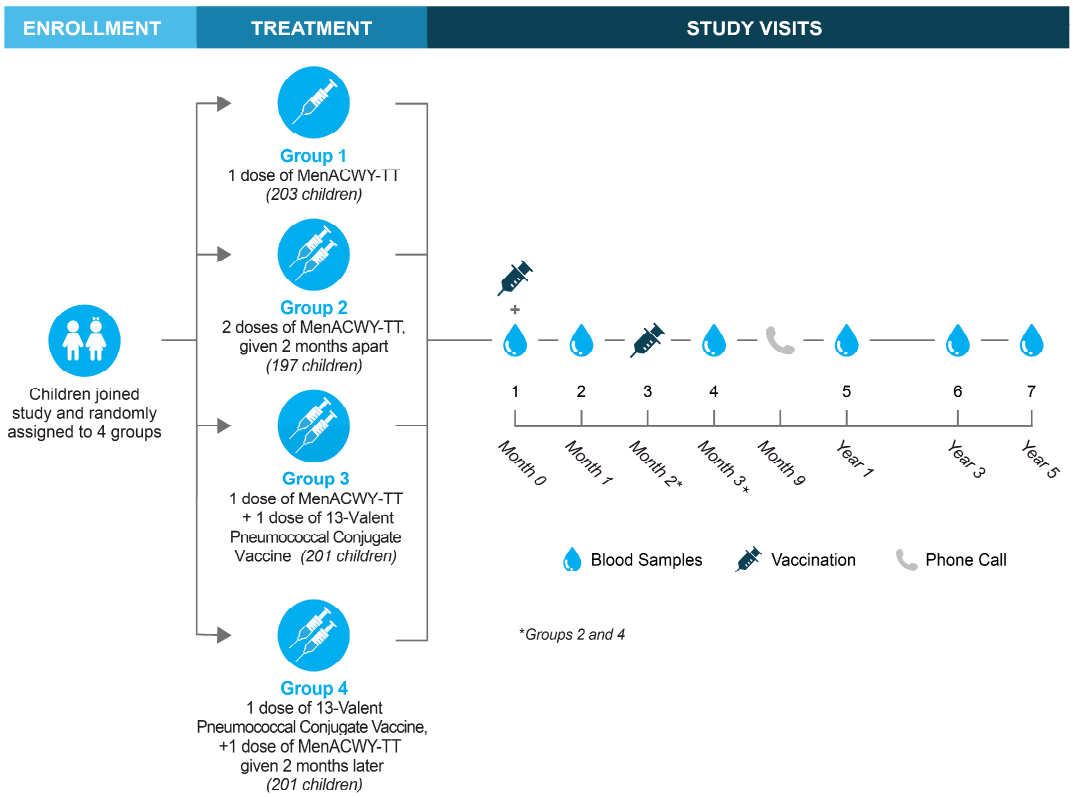
- Group 1: Children received 1 dose of MenACWY-TT (203 participants)
- Group 2: Children received 2 doses of MenACWY-TT, given 2 months apart (197 participants)

- Group 3: Children received 1 dose of MenACWY-TT together with 1 dose of 13-Valent Pneumococcal Conjugate Vaccine (201 participants)
- Group 4: Children received 1 dose of 13-Valent Pneumococcal Conjugate Vaccine, followed by 1 dose of MenACWY-TT given 2 months later (201 participants)

All children were between 12 and 14 months of age when they received their first dose of study vaccine. Children and their parents/guardians were expected to attend 7 in-person study visits and 1 phone visit. The researchers collected blood samples from the children throughout the study. They looked for antibodies in the blood against the 4 different types of meningococcus germ.

This was an "open label" study, which means that the children, their parents/guardians, and the researchers knew which vaccines the children received.

The figure below shows what happened during the study.



Where did this study take place?

The study took place at 54 locations in 6 countries.

When did this study take place?

It began 02 October 2013 and ended 05 December 2019.

Who participated in this study?

Children were checked (screened) by the study doctors to make sure they were a good fit for the study.

This study included children who:

- Were between 12 and 14 months of age when they received their first study vaccine
- 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 had meningococcal disease
- Had been vaccinated with 13-Valent Pneumococcal Conjugate Vaccine and Diphtheria, Tetanus, and Pertussis containing-vaccine (DTP) at least 5 months before joining the study
- Had not received certain other vaccines
- Had never had a severe medical problem or allergic reaction to any of the study vaccine ingredients
- Parents/guardians were informed of the risks and benefits of this study and agreed to participate

Of the 802 children who completed vaccination, 619 (77%) returned for their 5-year follow-up visit. 184 children (23%) left the study early by their parent/guardian's choice or because they passed away for a reason that was not related to study vaccination (2 participants).

- A total of 375 girls (47%) were vaccinated

- A total of 427 boys (53%) were vaccinated
- All children were between the ages of 12 and 14 months when they received their first study vaccine

How long did the study last?

Children were in the study for about 62 months. The entire study took more than 6 years to complete.

This study was completed as planned. When the study ended in December 2019, 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 children have an immune response against meningococcus germs 1 month after receiving their last dose of MenACWY-TT?

One month after their last dose of MenACWY-TT, most children (at least 93%) in all 4 vaccine groups produced strong immune responses against meningococcus germs.

Did children still have an immune response against meningococcus germs 1 year, 3 years, and 5 years after receiving their last dose of MenACWY-TT?

In general, children still had immune responses against meningococcus germs 1 year, 3 years, and 5 years after receiving their last dose of MenACWY-TT. The number of children who still had immune responses against meningococcus germs 1 year, 3 years, and 5 years after receiving their last dose of MenACWY-TT was similar in all 4 vaccine groups.

This does not mean that everyone in this study had these results. These are just some of the main findings of this study. Other studies may have different results.

What medical problems did participants have during the study?

The researchers recorded 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 vaccine groups in many studies, doctors try to understand what effects a study vaccine might have on a participant.

How many participants had medical problems within 30 days of receiving study vaccine?

The following percentage of participants had medical problems within 30 days of receiving the first dose of study vaccine:

- Group 1 (1 dose of MenACWY-TT): 42% (86 out of 203 participants)
- Group 2 (2 doses of MenACWY-TT, given 2 months apart): 46% (91 out of 197 participants)
- Group 3: (1 dose of MenACWY-TT together with 1 dose of 13-Valent Pneumococcal Conjugate Vaccine): 43% (86 out of 201 participants)
- Group 4 (1 dose of 13-Valent Pneumococcal Conjugate Vaccine, followed by 1 dose of MenACWY-TT given 2 months later): 42% (85 out of 201 participants)

One participant left the study because of a medical problem that was not considered to be related to the study vaccines.

Below are instructions on how to read Tables 1 and 2.

Instructions for Understanding Tables 1 and 2.

- The **1st** column of the table lists medical problems that were commonly reported during the study. All medical problems reported by at least 5% of participants are listed.
- The **2nd through 5th** columns tell how many of the participants in each group reported each medical problem. Next to this number is the percentage of the participants in each group who reported the medical problem.
- Example: Using these instructions, in Table 1 you can see that 7 out of the 203 (3%) participants in Group 1 reported diarrhea, and 7 out of the 197 (4%) participants dosed in Group 2 reported diarrhea.

Table 1. Commonly reported medical problems within 30 days after first vaccination (at least 5% in any group)

Medical Problem	Group 1 (203 Participants)	Group 2 (197 Participants)	Group 3 (201 Participants)	Group 4 (201 Participants)
Diarrhea	7 out of 203 participants (3%)	7 out of 197 participants (4%)	9 out of 201 participants (5%)	10 out of 201 participants (5%)
Teething	7 out of 203 participants (3%)	6 out of 197 participants (3%)	12 out of 201 participants (6%)	14 out of 201 participants (7%)
Vomiting	6 out of 203 participants (3%)	12 out of 197 participants (6%)	4 out of 201 participants (2%)	5 out of 201 participants (3%)

Table 1. Commonly reported medical problems within 30 days after first vaccination (at least 5% in any group)

Medical Problem	Group 1 (203 Participants)	Group 2 (197 Participants)	Group 3 (201 Participants)	Group 4 (201 Participants)
Fever	11 out of 203 participants (5%)	17 out of 197 participants (9%)	12 out of 201 participants (6%)	7 out of 201 participants (4%)
Common cold	8 out of 203 participants (4%)	13 out of 197 participants (7%)	10 out of 201 participants (5%)	7 out of 201 participants (4%)
Infection of the nose, throat, and upper airways	9 out of 203 participants (4%)	13 out of 197 participants (7%)	10 out of 201 participants (5%)	12 out of 201 participants (6%)
Cough	13 out of 203 participants (6%)	11 out of 197 participants (6%)	8 out of 201 participants (4%)	7 out of 201 participants (4%)

The following percentage of participants had medical problems within 30 days of receiving the second dose of study vaccine:

- Group 3: (1 dose of MenACWY-TT together with 1 dose of 13-Valent Pneumococcal Conjugate Vaccine): 35% (68 out of 197 participants)
- Group 4 (1 dose of 13-Valent Pneumococcal Conjugate Vaccine, followed by 1 dose of MenACWY-TT given 2 months later): 30% (61 out of 201 participants)

Table 2. Commonly reported medical problems within 30 days after second vaccination (at least 5% in any group)

Medical Problem	Group 3 (197 Participants)	Group 4 (201 Participants)
Diarrhea	8 out of 197 participants (4%)	10 out of 201 participants (5%)
Infection of the nose, throat, and upper airways	12 out of 197 participants (6%)	9 out of 201 participants (5%)

Did participants have any serious medical problems?

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

How many participants had serious medical problems during this study?

The following percentage of participants had serious medical problems. For the first 9 months of the study, all serious medical problems were recorded. After the first 9 months, only serious medical problems that were related to taking the study vaccine, to pneumococcal disease, to participating in the study, or that caused the participant to leave the study early were recorded.

- Group 1 (1 dose of MenACWY-TT): 6% (12 out of 203 participants)
- Group 2 (2 doses of MenACWY-TT, given 2 months apart): 6% (11 out of 197 participants)
- Group 3 (1 dose of MenACWY-TT together with 1 dose of 13-Valent Pneumococcal Conjugate Vaccine): 6% (13 out of 201 participants)

- Group 4 (1 dose of 13-Valent Pneumococcal Conjugate Vaccine, followed by 1 dose of MenACWY-TT given 2 months later): 8% (16 out of 201 participants)

Infections were the most common serious medical problem in this study. Four serious medical problems were considered by the study doctors to be related to taking the study vaccines.

Two participants died during this study. Neither death was considered by the study doctors to be related to the study vaccines.

How many participants had newly diagnosed chronic medical problems that happened within 9 months of receiving study vaccines?

The following percentage of participants had newly diagnosed chronic medical problems that happened with 9 months of receiving study vaccines (food allergy, asthma, skin irritation, or eczema).

- Group 1 (1 dose of MenACWY-TT): 1% (2 out of 203 participants)
- Group 2 (2 doses of MenACWY-TT, given 2 months apart): 2% (3 out of 197 participants)
- Group 3: (1 dose of MenACWY-TT together with 1 dose of 13-Valent Pneumococcal Conjugate Vaccine: 1% (1 out of 201 participants)
- Group 4 (1 dose of 13-Valent Pneumococcal Conjugate Vaccine, followed by 1 dose of MenACWY-TT given 2 months later): 3% (5 out of 201 participants)

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 child's study site.

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

www.clinicaltrials.gov	Use the study identifier **NCT01939158**
www.clinicaltrialsregister.eu	Use the study identifier **2013-001083-28**

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

Again, if your child participated in this study, **thank you** for volunteering. We do research to try to find the best ways to help study participants, and you helped us to do that!