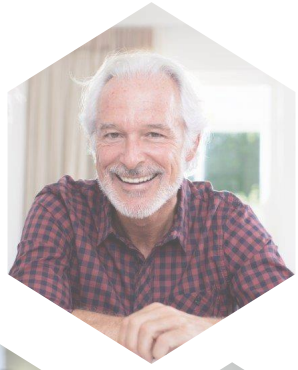




Who Sponsored this study?
GlaxoSmithKline

Clinical Support Help Desk
- http:/www.clinicalsupporth.gsk.com
- GSKClinicalSupportHD@gsk.com

A STUDY OF THE BODY'S RESPONSE TO A BOOSTER DOSE OF A MENINGITIS VACCINE (MENACWY-CRM)






This document provides a short summary of this study for a general audience. You can find more information in scientific summaries of the study. Links to those summaries are provided at the end of this document.

Overview

Why was this study conducted?

This study was done to see how an additional (booster) dose of a meningitis vaccine (MenACWY-CRM) "boosts" the immune system 4 to 6 years after a previous meningitis A, C, W, Y vaccination.

What was studied?

- Body defenses (called "antibodies") against 4 types of bacteria that can cause meningitis.
- Potential side effects of the MenACWY-CRM vaccine.

Who was in this study?

368 women and 333 men from the United States and Puerto Rico took part in this study. They were 15 to 55 years old at the start of the study. All 701 participants got the study vaccine (MenACWY-CRM).

What kind of study was it?

- Non-randomized: the participants were not assigned to different vaccination groups by chance. In this study participants were assigned to different vaccination groups based on previous vaccinations they received.
- Open-label: both the study doctor and the participants knew which vaccine they got. Only one vaccine was given in this study.

Main results

- The MenACWY-CRM vaccine increased the amounts of antibodies against meningococcal bacteria types A, C, W, and Y, 4 to 6 years after receiving the same or a similar vaccine.
- The side effects reported in this study did not raise any new safety concerns.

NCT number: NCT02986854
EudraCT number: 2016-003186-25

General information about the research study

When was the study done?

The study started in December 2016 and ended in December 2017.

Why was this study done?

The brain and spinal cord are covered by tissues called the meninges. When these tissues get inflamed (swell) this is called meningitis. Meningitis is a rare but serious disease that can lead to death or have very serious long-term effects like deafness, seizures and loss of limbs.

Meningitis is caused, among others, by a family of germs called the "meningococcus". There are several types of these bacteria. The most common types are called A, B, C, W, and Y. The MenACWY-CRM vaccine was developed to protect against types A, C, W, and Y.

A vaccine helps the body make defenses called "antibodies" that can help protect against a disease. The antibody levels can drop over time. This drop can make those vaccinated vulnerable to infection again. An additional dose (booster) can then help to "boost" the body's defense system.

This study tested if the MenACWY-CRM vaccine can boost the immune system 4-6 years after a previous dose of the same or a similar vaccine (MenACWY-D).

In this study the MenACWY-CRM vaccine was also given to a group who had not previously received a meningitis vaccine. The response to the vaccine in this group was not the main goal of this study and therefore only the safety results are presented in this summary. The full results in this group can be found in the clinical results summary.

Who took part in this study?

701 participants were vaccinated

15 to 55 years old

368 women (52%)

333 men (48%)

People could take part in the study if they:

- ✓ Were in good health
- ✓ Previously got either MenACWY-CRM vaccine, MenACWY-D vaccine, or no previous meningitis vaccine, depending on the study group

People could not take part in the study if they:

- x Got other vaccines shortly before the study started
- x Were pregnant or breast feeding
- x Experienced confirmed or suspected disease caused by meningococcal bacteria

Which vaccines were studied?

The vaccine given to participants in this study was the MenACWY-CRM vaccine. It was given by injection into the upper arm.

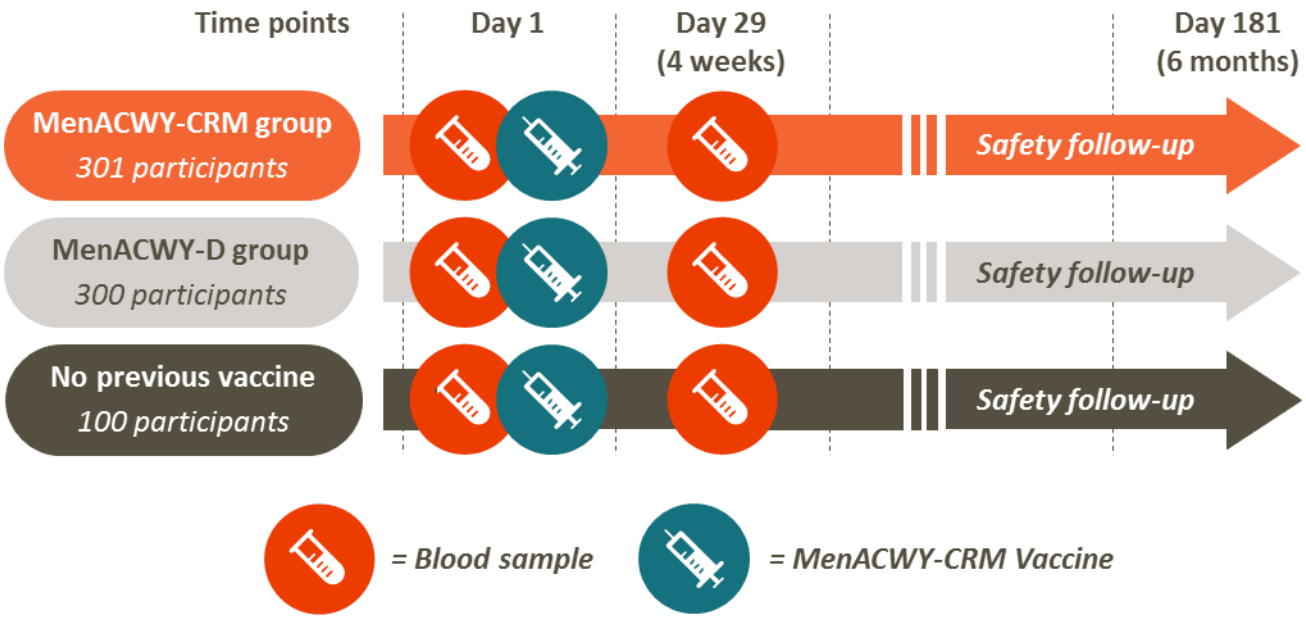
Participants previously got either:

- The same vaccine: **MenACWY-CRM** (MenACWY-CRM group).
- A similar vaccine: **MenACWY-D** (MenACWY-D group). This vaccine was also developed to protect against meningococcal bacteria A, C, W, and Y.
- No meningitis vaccine (No previous vaccine group).

How was the study done?

All participants got one dose of MenACWY-CRM vaccine. A blood sample was taken just before vaccination and approximately 1 month after the vaccination to measure the amounts of antibodies (Figure 1). The participants were followed for 6 months after the vaccination for potential side effects.

Figure 1 Study design



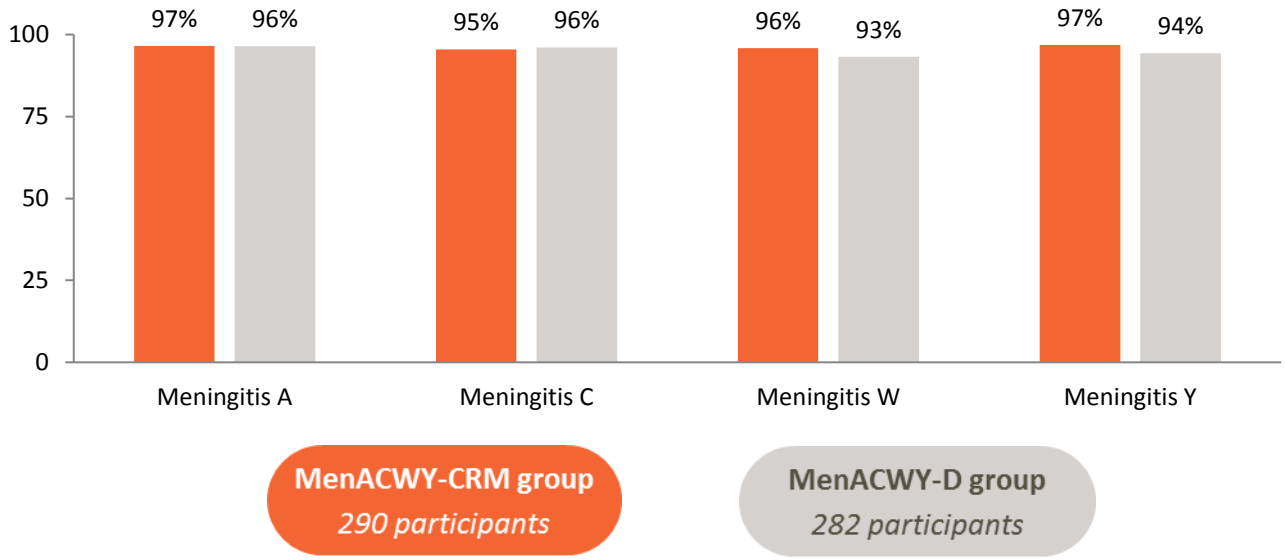
What were the main results of the study?

*This report focuses on the results of the main goals of the study. All results may be found in the **clinical results summary**.*

The response to the booster dose of MenACWY-CRM was considered strong enough if the amount of antibodies after vaccination was 4 times higher than before.

Almost all people who had been previously vaccinated had a strong enough response to boost the immune system (Figure 2).

Figure 2 Percentage of participants with strong enough response to booster dose



Note: the total number of participants in each group is not the same as the total number of participants who were vaccinated. This is because for some participants blood samples were not available or not taken at the correct timepoint.

What were the side effects?

Unwanted medical events (adverse events) can happen to people when they receive a vaccine. Study doctors record all these events. A summary of all events reported may be found in the clinical results summary.

If the study doctor thinks that the event was caused by vaccine, they record this as a possible side effect (adverse reaction).

In this summary, "side effects*" refer to those events that the study doctor thinks may have been caused by the study vaccine.

Side effects at the place of injection

Participants most often reported "pain" at the place of injection in all groups (Table 1).

General side effects

Table 2 shows general side effects reported by more than 1 in 100 (1%) participants in any group.

"Tiredness", "headache" and "muscle pain" were most often reported in all groups.

**The use of the term side effects in this summary may be different to that in the Informed Consent or other documents related to the vaccine.*

Table 1 **Numbers and percentages of participants with side effects at the place of the injection**

Side Effect	MenACWY-CRM group	MenACWY-D group	No previous vaccine
Pain	114 of 292 (39%)	96 of 296 (32%)	40 of 97 (41%)
Swelling	15 of 286 (5%)	9 of 286 (3%)	8 of 92 (9%)
Redness	12 of 286 (4%)	8 of 287 (3%)	10 of 92 (11%)

Note: the total number of participants in each group is not the same for all side effects. This is because some participants did not provide any information ("yes" or "no") for one side effect, but did provide it for another side effect.

Table 2 **Numbers and percentages of participants with general side effects**

Side Effect	MenACWY-CRM group	MenACWY-D group	No previous vaccine
Tiredness	**113 of 295 (38%)**	110 of 296 (37%)	19 of 97 (20%)
Headache	**100 of 294 (34%)**	82 of 295 (28%)	21 of 97 (22%)
Muscle pain	**55 of 294 (19%)**	54 of 296 (18%)	15 of 97 (15%)
Feeling sick	**48 of 294 (16%)**	44 of 294 (15%)	13 of 97 (13%)
Joint pain	**44 of 294 (15%)**	38 of 295 (13%)	13 of 96 (14%)
Loss of appetite	**37 of 294 (13%)**	46 of 296 (16%)	6 of 97 (6%)
Shivering	**34 of 294 (12%)**	35 of 295 (12%)	10 of 97 (10%)
Fever (38°C and above)	**2 of 296 (1%)**	5 of 296 (2%)	0 of 97

Note: the total number of participants in each group is not the same for all side effects. This is because some participants did not provide any information ("yes" or "no") for one side effect, but did provide it for another side effect.

How has this study helped patients and researchers?

The results from this study will be submitted to regulatory agencies for evaluation and, if approved, may enable doctors to administer a booster dose of MenACWY-CRM to people who have received a meningitis A, C, W, Y vaccine before.

Are there plans for further studies?

There may be studies to further evaluate the MenACWY-CRM vaccine. The results of any future studies will be available on the websites of the European Medicines Agency and/or the Unites States National Institutes of Health (see links at the end of this document).

Where can I find more information about this study?

The detailed title for this research study is:
A Phase 3b, Controlled, Open-Label, Multi-Center Study to Evaluate Safety and Immunogenicity of a Single Dose of GlaxoSmithKline's Meningococcal ACWY Conjugate Vaccine (*Menveo*), Administered to Healthy Individuals 15 through 55 years of age, approximately 4-6 years after primary ACWY vaccination.

Clinical studies have unique study numbers. Below are the unique study numbers associated with this study.

Organization	Website	Study Number
European Medicines Agency	www.clinicaltrialsregister.eu	2016-003186-25
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT02986854

Your doctor can help you understand more about this study and the results. You should not make changes to your care based on the results of this or any single study.

This document was developed and approved by GSK on 12 March 2019. The information in this summary does not include additional information available after this date.

For readers of this document in text form, the websites associated with the hyperlinks above are:

EudraCT summary:
https://www.clinicaltrialsregister.eu/ctr-search/trial/2016-003186-25/results

US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT02986854