Who Sponsored this study?
**GlaxoSmithKline**

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# The antibody response and safety of a new liquid formula of a meningitis (ACWY) vaccine, given to healthy adults


*GSK would like to thank all the people who took part in this clinical study. We think it is important that you know the study results. We hope it helps you understand and feel proud about your important role in medical research.*

# Overview

## Why was this study done?

This study was done to find out if a new liquid formula of a meningitis ACWY vaccine can work as well as the current vaccine formula. The researchers also gathered vaccine side effect information.

## What was studied?

- Body defenses ("antibodies") against 4 types of bacteria that can cause meningitis.
- Possible vaccine side effects.

## Who was in this study?

- 979 healthy adults aged 18-44 years took part in the study. 971 of them completed the study.

## What kind of study was it?

- Controlled: Study participants were assigned to 2 different groups. 1 received the new liquid vaccine. The other received the current vaccine.
- Randomized: Participants had the same chance of being in either of the 2 groups. (like tossing a coin).
- Observer blind study: Study participants and the staff who followed them did not know which vaccine was given.

## Main results

- Antibody levels were similar in the 2 groups of participants.
- Side effects of the 2 vaccines were similar and were all known reactions to the vaccine. They did not raise any new safety concerns.

**NCT number:** NCT03652610
**EudraCT number:** 2017-003692-61

# General information about the research study

## When was the study done?

This study was done between September 2018 and June 2019. Each participant was requested to stay in the study for around 6 months.

## Why was this study done?

The main goal of the study was to find out if a new liquid formula of the MenACWY vaccine can work as well as the currently licensed and available formula. The liquid vaccine formula eliminates the need to reconstitute the dry powder component with the liquid component before administration, thus preventing possible errors in mixing and administering the vaccine.

Meningitis happens when the tissues that cover the brain and spinal cord become inflamed (swollen) because of infection. Meningitis is rare but it can have very serious long-term effects such as deafness, seizures and loss of limbs. Meningitis can even be deadly.

Meningitis is caused by infectious agents, and meningococcus types A, C, W, and Y are among the most common bacterial causes of this disease. The two vaccines in this study are both aimed at protecting against the A, C, W and Y types of meningococcus infections.

# Who took part in this study?

**979 adults from Australia, Belgium, Canada, Germany and Italy**

**18-44 years old when they got the study vaccine**

**614 women (63%)**

**365 men (37%)**

Participants could take part in the study if:

- they were at least 18 years old and healthy

Participants could not take part in the study if they:

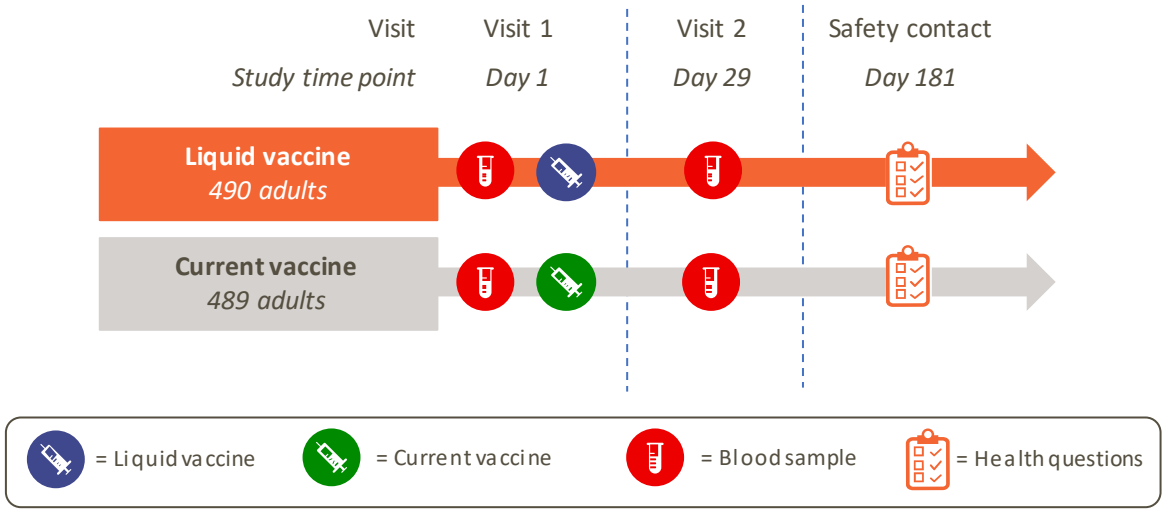
- were allergic to any ingredient in the study vaccines
- had received any meningitis vaccine in the past
- had ever been sick with a meningitis infection

## Which vaccines were studied?

Two versions of the MenACWY vaccine were studied. One was a new, all liquid, formula. The other was the current vaccine. The current vaccine is a dry powder that must be mixed with its liquid component before it can be given. Both vaccines were given by injection in the arm.

## How was the study done?

**Figure 1. Study design**

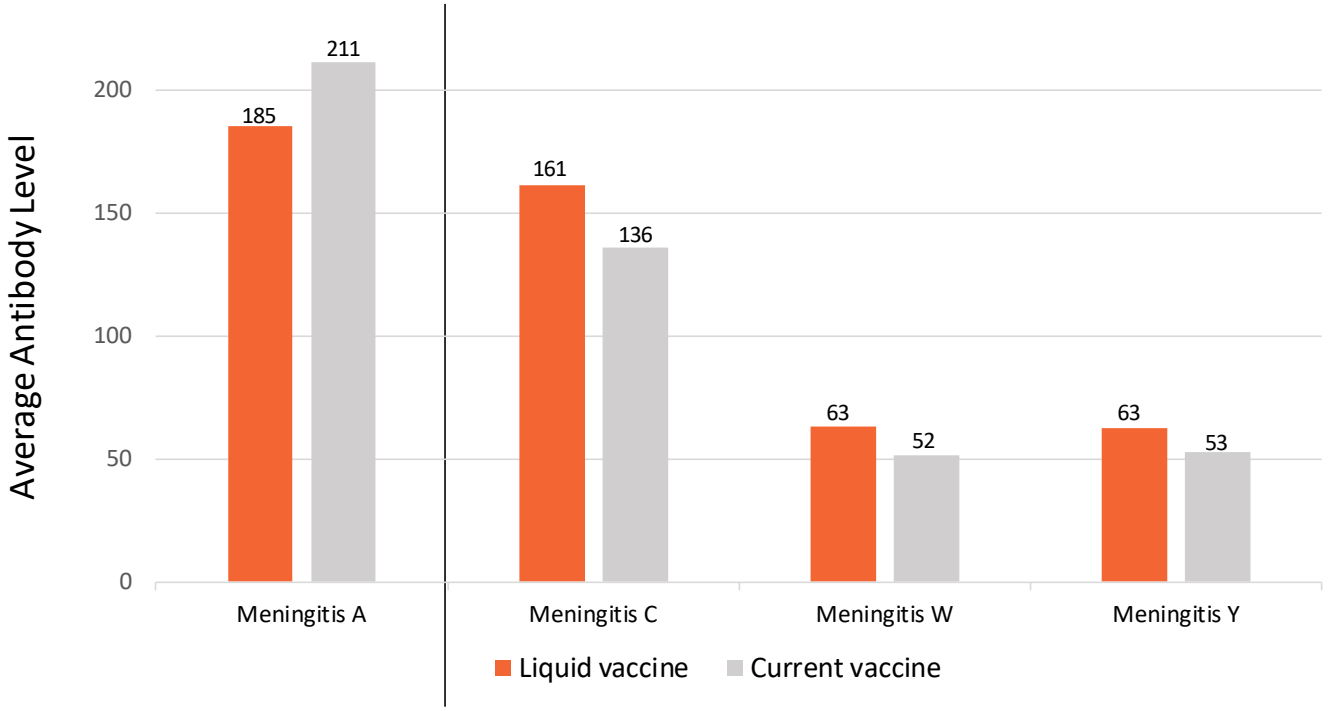



## What were the main results of the study?

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

The researchers compared antibody levels 1 month after vaccination in adults who got the new liquid vaccine formula, with those who got the current vaccine formula. Meningitis A antibody levels were the main point of comparison for the researchers. Antibody levels to all 4 meningitis types are shown in Figure 2 (below). The researchers found that average antibody levels were similar in the 2 groups and would help protect against meningococcus types A, C, W, and Y.

**Figure 2: Antibody levels against Meningitis A, C, W,Y types, 1 month after vaccination**




## What were the side effects?

Unwanted medical events (adverse events) can happen to people when they receive a vaccine. Study doctors record these events. The cause of these adverse events is not always known.

A summary of the events reported in this study may be found in the *clinical results summary*.

If the study doctor thinks that the event was caused by the vaccine, they record it as a possible side effect[1] of the vaccine.

Adverse events judged by the study doctor not to be related to the vaccine are not included in this report.

The researchers found that study participants had similar side effects with both vaccines during the week after vaccination, when most side effects happen (Table 1)[2]. Adverse events were also monitored for up to a month after injection. Serious adverse events requiring hospitalization or considered life threatening were monitored for up to 6 months after vaccine injection. Less than 2% of study participants reported a serious adverse event and none of them were considered caused by the study vaccines. No study participant withdrew from the study because of a vaccine side effect.

[1] *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*

[2] *8 people either dropped out of the study or were lost to follow-up*

**Table 1. Number and percentage of participants reporting side effects up to 7 days after vaccination**

| | Liquid vaccine 489 adults | Current vaccine 487 adults |
|---|---|---|
| *Side effects at the site of injection* | | |
| Pain | 200 (41%) | 182 (37%) |
| Redness | 28 (6%) | 28 (6%) |
| Skin thickening | 25 (5%) | 24 (5%) |
| *Other side effects* | | |
| Chills | 42 (9%) | 40 (8%) |
| Fatigue (tiredness) | 159 (33%) | 159 (33%) |
| Fever (38°C and above) | 7 (1%) | 10 (2%) |
| Headache | 158 (32%) | 165 (34%) |
| Joint pain | 43 (9%) | 46 (9%) |
| Loss of appetite | 31 (6%) | 40 (8%) |
| Muscle pain | 58 (12%) | 58 (12%) |
| Nausea | 49 (10%) | 50 (10%) |

**Some volunteers had more than one side effect*

## How has this study helped patients and researchers?

This study showed that the liquid formula of MenACWY vaccine was as safe as, and worked as well as, MenACWY vaccine current formula. Eliminating the need to reconstitute the vaccine before its injection is expected to ease the vaccine administration.

## Are there plans for further studies?

Another study testing the liquid formula of MenACWY vaccine was ongoing at the time this summary was prepared. Results will be available on the websites of European Medicines Agency and/or the United States National Institutes of Health. Links to this study are provided at the end of this summary.

## Where can I find more information about this study?

**The detailed title of this research study is:**

A phase 2b, randomized, controlled, observer-blind, multi-center, non-inferiority immunogenicity and safety study of two formulations of GSK Biologicals' Meningococcal ACWY conjugate vaccine (GSK3536820A and *Menveo*) administered to healthy adults 18 to 40 years of age.

| Organization | Website | Study Number |
|---|---|---|
| European Medicines Agency | www.clinicaltrialsregister.eu | 2017-003692-61 |
| United States National Institutes of Health (NIH) | www.clinicaltrials.gov | NCT03652610 |

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 XX YYYY 20ZZ. The information in this summary does not include additional information available after this date.



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 below.

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

EudraCT summary:
https://www.clinicaltrialsregister.eu/ctr-search/search?query=2017-003692-61
US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT03652610