Who Sponsored this study?

**GlaxoSmithKline**

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# A clinical study to help establish the shelf life of a new liquid formula of a meningitis (ACWY) vaccine


*GSK would like to thank all the adults and children and their parents, 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 compared the responses to and safety of a currently available meningitis vaccine with a new, fully liquid, form of the same vaccine to help establish the shelf life of the new vaccine.

## What was studied?

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

## Who was in this study?

1707 healthy males and females between the ages of 10 and 40 years enrolled in the study. 1690 of them received one of the study vaccines.

## What kind of study was it?

- Randomized – Study volunteers were assigned to a study group by chance (like tossing a coin).
- Controlled – the new liquid vaccine was compared to the current vaccine formula.
- Observer blind – neither the participants or the staff who followed them knew which vaccine was given.

## Main results

- Antibody levels in the groups who received the vaccines stored for 24 and 30 months were similar to those who received the currently available vaccine.
- Side effects of the vaccines in this study were similar in all groups. They did not raise any safety concerns.

**NCT number:** NCT03433482
**EudraCT number:** 2017-003456-23

# General information about the research study

### When was the study done?

This study was done between August 30, 2018 and December 17, 2019. Each participant was asked to stay in the study for about 6 months.

### Why was this study done?

This study compared the safety and antibody levels developed after injection of a new, fully liquid meningitis vaccine with that of the currently licensed vaccine. The new vaccine comes in a single vial and was kept under proper storage conditions for either 24 or 30 months before being given to study volunteers.

Meningitis happens when the tissues that cover the brain and spinal cord (called “meninges”) 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 an infection. 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 meningitis types A, C, W and Y.

# Who took part in this study?

**1690 participants from Brazil, Estonia, Finland, France, Mexico, Russia, South Africa, Spain and Turkey were vaccinated**

**10 to 40 years old when vaccinated**

**961 females joined the study (57%)**

**729 males joined the study (43%)**

People could take part in the study if they:

- were between 10 and 40 years old and healthy at first vaccination

People 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, unless Meningitis C vaccine was received when younger than 2 years old
- had ever been sick with a meningitis infection

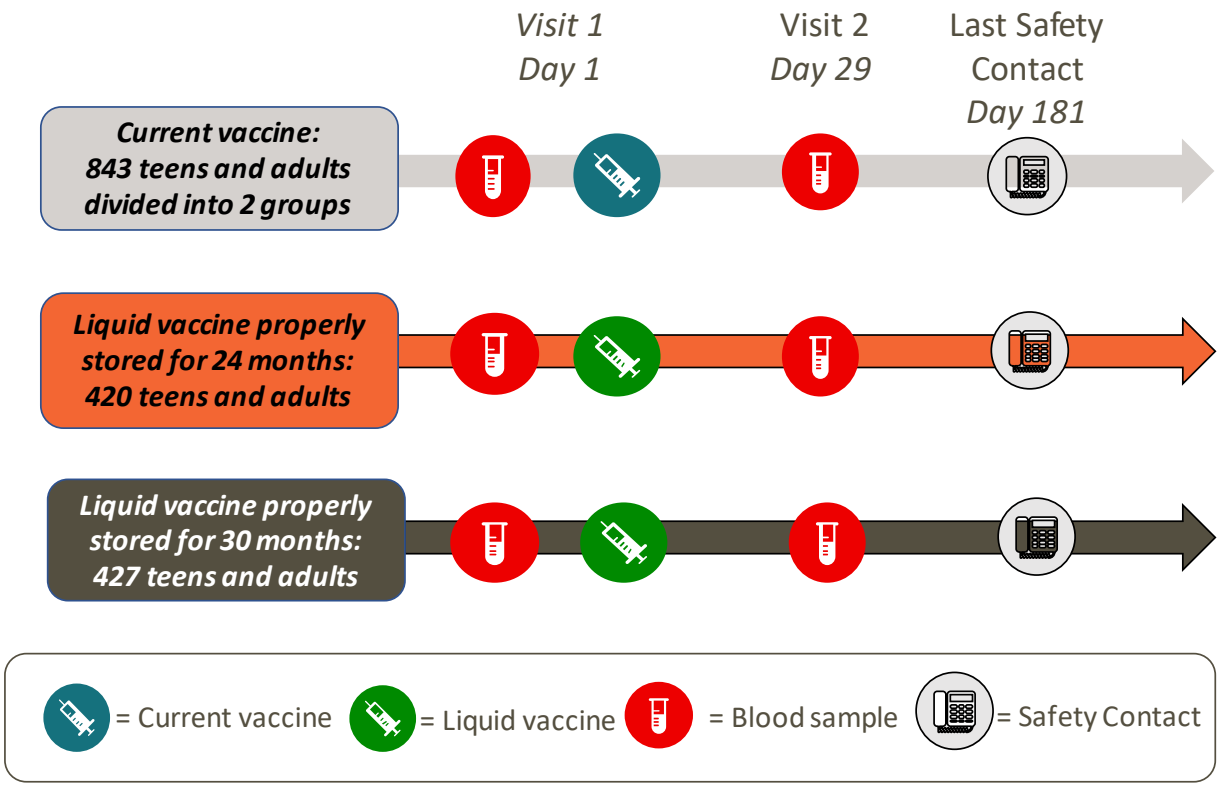
# Which vaccines were studied?

A new fully liquid version of the meningitis ACWY vaccine was compared to the curent approved version of the same vaccine.

The current vaccine comes in 2 vials. One has a dry powder that must be mixed with the liquid in the second vial before it can be given. Both vaccines were given by injection in the arm.

## How was the study done?

**Figure 1. Study design**



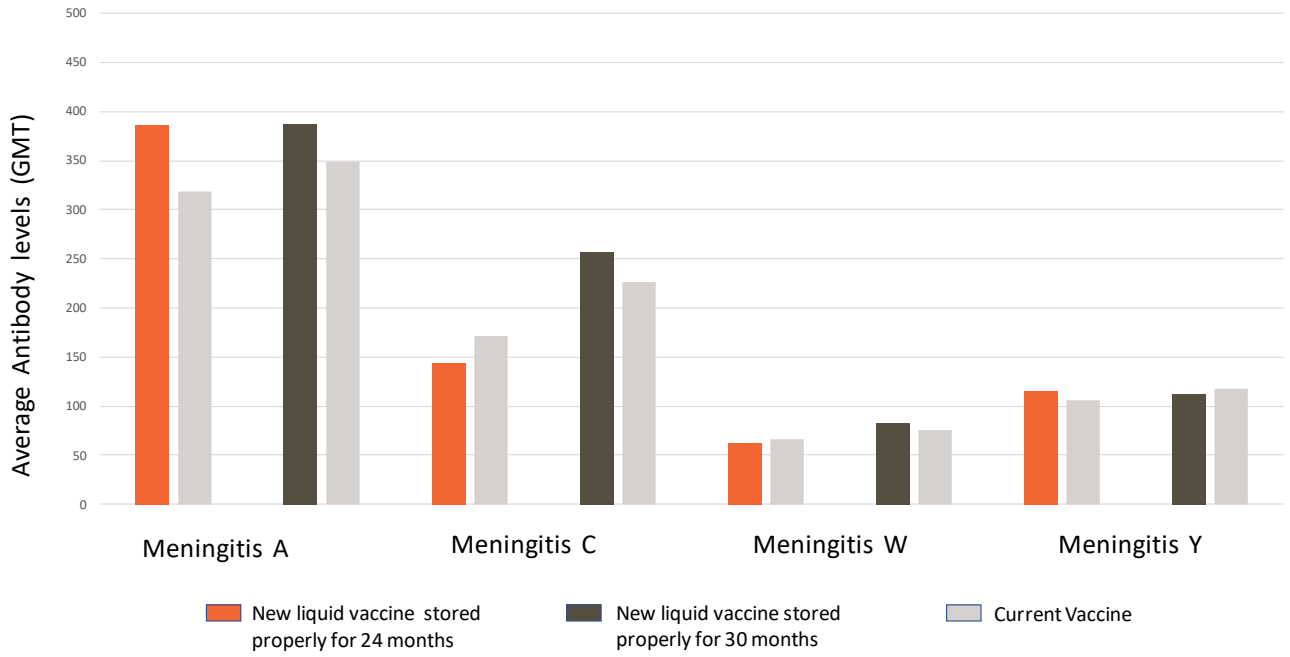

## What were the main results of the study?

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

The researchers compared participants who got the current vaccine with those who got the new liquid vaccine that had been kept under proper storage conditions for 24 or 30 months. They found that average antibody levels were similar in all groups.

Antibody levels against the 4 types of meningitis in both vaccines are shown in Figure 2 (below). They were measured 1 month after the people in this study had received their vaccine dose.

**Figure 2: Antibody levels against Meningitis A, C, W, and 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, it is recorded as a possible side effect[1].

Adverse events judged by the study doctors to not be related to a study 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. This is when most vaccine side effects happen (Table 1).

Side effects 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 1% of study participants reported a serious adverse event. None of them were considered to be 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*

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

| | Liquid vaccine stored properly for 24 months 420 volunteers | Liquid vaccine stored properly for 30 months 427 volunteers | Current vaccine** 843 teens and adults divided into 2 groups |
|---|---|---|---|
| | *Side effects at the site of injection* | | |
| Pain | 189 (45%) | 202 (47%) | 373 (44%) |
| Redness | 48 (11%) | 58 (14%) | 91 (11%) |
| Skin thickening | 50 (12%) | 54 (13%) | 90 (11%) |
| | *Other side effects* | | |
| Chills | 75 (18%) | 78 (18%) | 135 (16%) |
| Fatigue (tiredness) | 174 (41%) | 149 (35%) | 322 (38%) |
| Fever (38°C and above) | 15 (4%) | 15 (4%) | 30 (4%) |
| Headache | 164 (39%) | 169 (40%) | 308 (37%) |
| Joint pain | 45 (11%) | 49 (11%) | 90 (11%) |
| Loss of appetite | 53 (13%) | 63 (15%) | 88 (10%) |
| Muscle aches | 60 (14%) | 58 (14%) | 124 (15%) |
| Nausea | 54 (13%) | 42 (10%) | 94 (11%) |

**Some volunteers had more than one side effect*
*** Includes all study participants who received the current vaccine*

## How has this study helped patients and researchers?

This study showed that the fully liquid meningitis vaccine kept under proper storage conditions for either 24 or 30 months worked as well as the current meningitis vaccine.

Eliminating the need to mix 2 vials - the powder and liquid parts of the vaccine - before injection is expected to make giving this vaccine easier.

The results of this study will be used to help establish the shelf life of the new, fully liquid, vaccine.

## Are there plans for further studies?

No other studies are currently planned to further test the new fully liquid formula of the meningitis ACWY vaccine.

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

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

A phase 2b, randomized, controlled, observer-blind, multi-center study to evaluate safety and immunogenicity of different formulations of GSK Biologicals' Meningococcal ACWY conjugate vaccine (GSK3536820A and *Menveo*) administered to healthy adolescents and young adults 10 to 40 years of age.

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 | 2017-003456-23 |
| United States National Institutes of Health (NIH) | www.clinicaltrials.gov | NCT03433482 |

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 29 January, 2021. 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=2017-003456-23
US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT03433482?term=2017-003456-23&draw=2&rank=1