



Who sponsored this study?
GlaxoSmithKline

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A study of a vaccine against meningitis A, C, W and Y in healthy South Korean babies






GSK would like to thank all the children who took part in this clinical study and their parents. 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?

Researchers wanted to study the body defenses and vaccine safety one year after South Korean babies got vaccinations against 4 types of bacteria that cause meningitis.

What was studied?

- Body defenses (called “antibodies”) against 4 types of bacteria that cause meningitis.
- Possible side effects of the vaccine.

Who was in this study?

128 healthy South Korean babies (59 girls and 69 boys) took part in the study.

What kind of study was it?

- Open-label: All babies got the same vaccine. The study doctors and parents knew which vaccine the babies got.
- Phase 4 study: The study vaccine was approved for use before this study started.

Main results

- The babies in this study had good antibody levels 1 year after their vaccinations.
- Side effects reported in this study were all known reactions to the vaccine. They generally lasted only a few days.

NCT number: NCT02446691
EudraCT number: 2014-005392-90

General information about the research study

When was the study done?

The study started in July 2015 and ended in December 2017.

Why was this study done?

This study was done to learn more about:

- The levels of antibodies 1 year after vaccinations against 4 types of bacteria that cause meningitis.
- The side effects of the vaccine.

Meningitis is rare but it can have very serious long-term effects such as deafness, seizures and loss of an arm or leg. Meningitis can even be deadly.

Meningococcus A, C, W, and Y are 4 types of bacteria that cause meningitis. Meningococcal ACWY vaccines can help protect against meningitis caused by these bacteria.

The main purpose of the study was to see if there were good levels of antibodies 1 year after the study vaccinations and assess vaccine safety. Only the main results are presented here. All results may be found in the ***clinical results summary.***

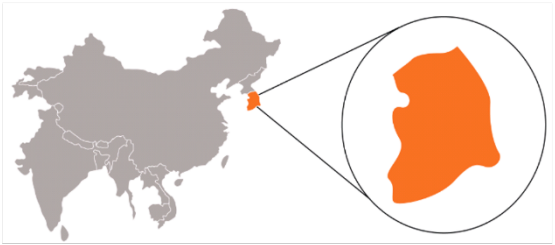
Who took part in this study?

128 babies from South Korea

55 to 89 days old when they got the first vaccination

59 girls (46%)

69 boys (54%)



South Korea

Babies could take part in the study if:

- they were in good health
- their parents gave permission for them to be in the study

Babies could not take part in the study if:

- they got any other meningitis vaccine
- they were previously sick because of a meningococcal infection

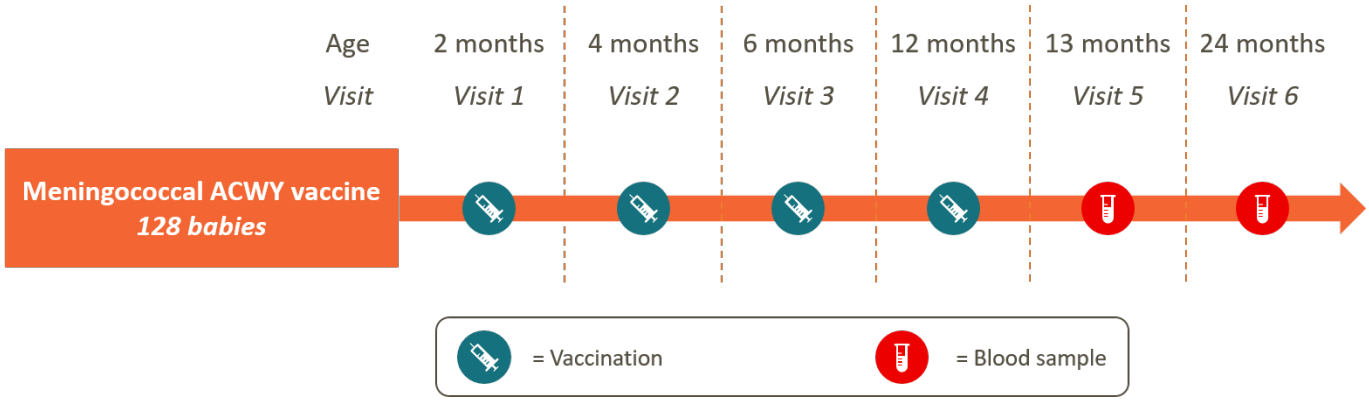
Which vaccines were studied?

A meningococcal ACWY vaccine was studied. The vaccine was given mostly in the thigh, but also in the upper arm.

How was the study done?

The study was done as described in the figure below. Researchers got information about possible vaccine side effects from the babies' parents after every injection.

Study design



What were the main results of the study?Apr

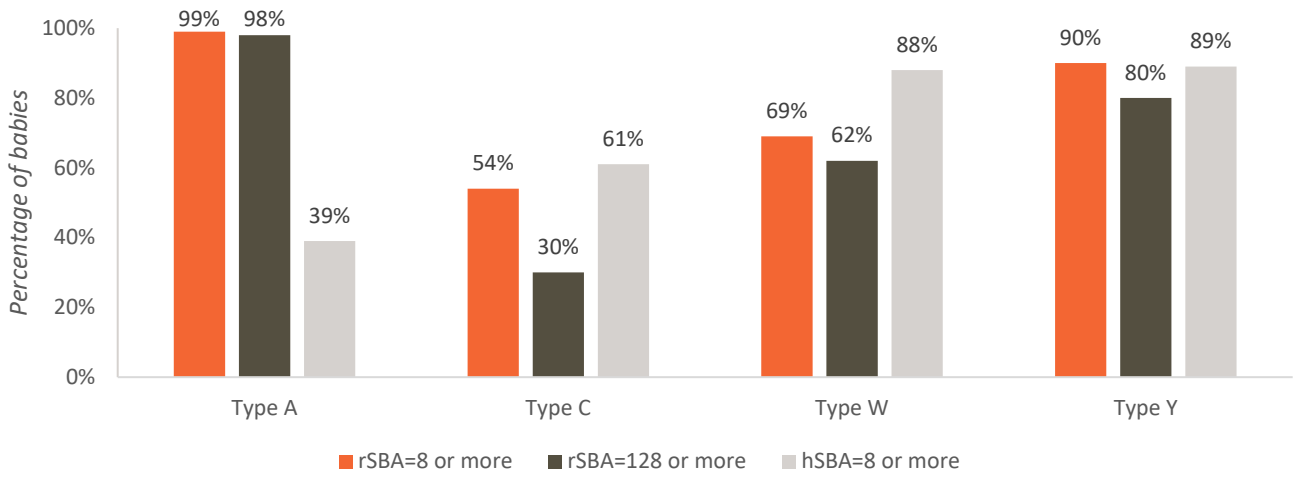
This report provides the main results of the study and the possible side effects. All results may be found in the clinical results summary.

Antibodies 1 year after vaccinations

We measured levels of bacteria-killing antibodies in the blood of babies who received the vaccine to see if it is working. A level of 8 is considered enough to protect most people. Levels can be assessed with tests using rabbit or human proteins. Rabbit proteins have been widely used for these tests because they are easier to get.

We used both rabbit and human proteins to see how many people had a level of 8 after vaccination. We also wanted to find out how many people had antibody levels of 128 by using the rabbit protein. Levels of 128 are often used as an additional measure for assessing how well meningitis vaccines work.

Figure 1. Babies with enough antibodies to kill meningitis bacteria 1 year after vaccinations



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 events reported during the study may be found in the ***clinical results summary.***

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

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

The side effects in this study are known reactions to the meningitis vaccine (Figure 2). They were generally mild or moderate and lasted only a few days.

Figure 2. Number and percentage of babies with side effects*

	Injection 1 Age 2 months 128 babies	Injection 2 Age 4 months 128 babies	Injection 3 Age 6 months 127 babies	Injection 4 Age 12 months 124 babies
Side effects where the injection was given				
Soreness	17 (13%)	21 (16%)	14 (11%)	20 (16%)
Skin thickening	4 (3%)	9 (7%)	3 (2%)	6 (5%)
Redness	4 (3%)	6 (5%)	1 (1%)	6 (5%)
Other side effects				
Irritability/Fussiness	58 (45%)	49 (38%)	47 (37%)	45 (36%)
Sleepiness	52 (41%)	31 (24%)	28 (22%)	20 (16%)
Change in eating habits	29 (23%)	21 (16%)	21 (17%)	24 (19%)
Vomiting	26 (20%)	20 (16%)	15 (12%)	5 (4%)
Diarrhoea	15 (12%)	13 (10%)	15 (12%)	17 (14%)
Fever (38°C and above)	4 (3%)	10 (8%)	6 (5%)	15 (12%)

**Some babies had more than one side effect*

How has this study helped patients and researchers?

This study showed that the body defences against meningitis A, C, W, Y in South Korean babies remained good at 1 year after the vaccinations. The use of the vaccine did not raise any health concerns.

Are there plans for further studies?

There may be studies to further evaluate this vaccine.

The results of any future studies will be available on the websites of the European Medicines Agency and/or the United States National Institutes of Health (see links at the end of this document).

* *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.*

Where can I find more information about this study?

The detailed title for this research study is:

A Phase IV, Open-Label, Multi-Centre Study to Evaluate the Safety and the 1-year Persistence of Antibody Response Among Children Who Received 4 Doses of the GSK MenACWY Conjugate Vaccine at 2, 4, 6 and 12 Months of Age in South Korea.

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	2014-005392-90
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT02446691

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 21 April 2020. 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=2014-005392-90
US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT02446691