Who Sponsored this study ?
GlaxoSmithKline

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CAN A 5-IN-1 VACCINE REDUCE THE INJECTIONS NEEDED TO PROTECT RUSSIAN BABIES AGAINST 5 CHILDHOOD DISEASES?

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?

We wanted to see if we can use a 5-in-1 vaccine to reduce the number of injections Russian babies need to vaccinate them against 5 childhood diseases: diphtheria, tetanus, whooping cough, polio, and diseases caused by *Haemophilus influenzae* type b (Hib).

What was studied?

- Body defenses (called "**antibodies**") against diphtheria, tetanus, whooping cough, polio, and Hib.
- Possible side effects of the vaccine.

Who was in this study?

124 boys and 111 girls from Russia took part in this study. They were 3 to 4 months old at the time of the first vaccination.

What kind of study was it?

Open label: The same vaccine was given to all babies, so the study doctors and parents knew which vaccine the babies got.

Main results

After 3 injections of the 5-in-1 vaccine:

- All babies had protective antibody levels against diphtheria and tetanus.
- Almost all babies had protective antibody levels against Hib and polio.
- Whooping cough antibodies were present in almost all babies.

The side effects reported in this study were known side effects of the 5-in-1 vaccine. The results did not raise any new safety concerns.

NCT number: NCT02858440
EudraCT number: 2013-005577-43

General information about the research study

When was the study done?

The study started on 13 September 2016 and ended on 13 November 2018.

Why was this study done?

We did this study to see if we can reduce the number of injections Russian babies need to vaccinate them against 5 childhood diseases.

Babies can easily get infected with bacteria and viruses, because the body's defense systems are still developing. Vaccines help the body make defenses, called "**antibodies**", which can protect against infections.

Combination vaccines can help protect against many infections in one go. GSK makes a 5-in-1 combination vaccine that helps to protect babies against 5 childhood diseases:

- diphtheria
- tetanus
- whooping cough (pertussis)
- polio, and
- diseases caused by *Haemophilus influenzae* (Hib), including meningitis and pneumonia.

This 5-in-1 vaccine can be safely given to babies from the age of 2 months. It is available in many countries, but not in Russia.

In Russia, babies need more than one vaccine to vaccinate them against these 5 diseases. With the 5-in-1 vaccine, it may be possible to vaccinate them with a single vaccine instead of separate vaccines.

The **main goal** of the study was to measure antibodies against the 5 diseases after 3 injections of the 5-in-1 vaccine in Russian babies.

Babies were also given an extra injection (**booster**) at 18 months of age. Antibodies were also measured after the booster injection. As this was not the main goal of the study, the results are not reported here, but can be found in the ***clinical results summary***.

Who took part in this study?

235 babies from Russia

3 to 4 months old when they got the first vaccination

111 girls (47%)
124 boys (53%)

Babies could take part in the study if they

- were healthy
- born at full term (9 months of pregnancy)

Babies could not take part in the study if they

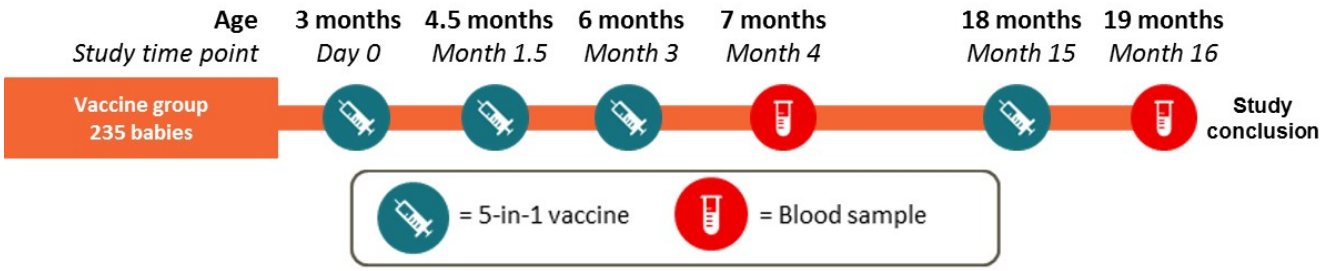
- had already been vaccinated against diphtheria, tetanus, pertussis, polio and Hib
- had a history of these diseases

Which vaccines were studied?

We studied a 5-in-1 vaccine against diphtheria, tetanus, whooping cough, polio and Hib diseases. The vaccine was given by injection into the thigh muscle.

How was the study done?

Figure 1: Study design



All babies got 3 injections of the 5-in-1 vaccine over 3 months (**primary vaccination**), and a booster about 1 year later. Blood samples were taken one month after both the primary vaccination and the booster vaccination (**Figure 1**). The blood samples were used to measure the amounts of antibodies.

Study doctors also collected information about the safety of the vaccine.

What were the main results of the study?

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

Antibodies against diphtheria, tetanus, whooping cough, polio, and Hib diseases

Researchers have found that most people are protected against diphtheria, tetanus, Hib and polio (types 1, 2 and 3) if the average amounts of antibodies in their blood are above certain levels, called **protective antibody levels**.

Researchers still have to find protective antibody levels for whooping cough. Most people may be protected from this disease if the average amounts of antibodies in their blood are above certain levels, called **positive antibody levels**.

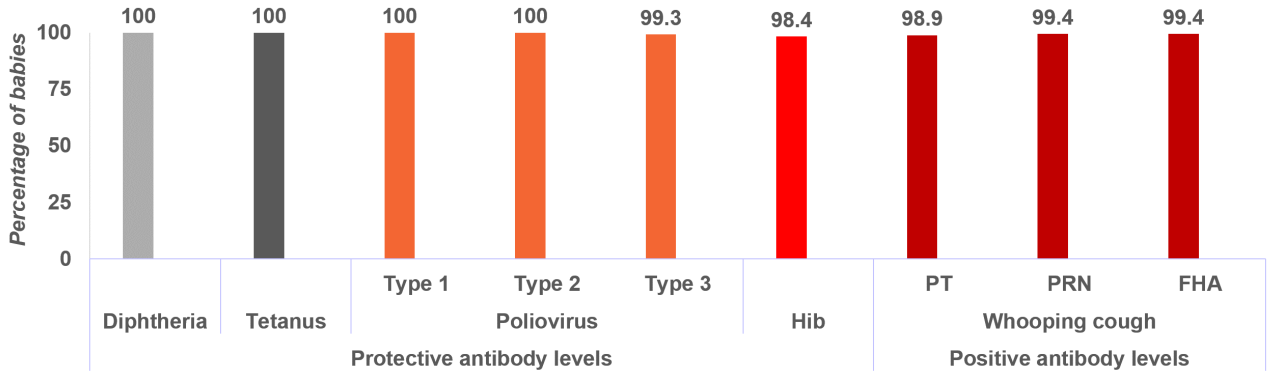
Figure 2 shows the main results of the study.

After primary vaccination:

- All babies had protective antibody levels against diphtheria and tetanus.
- More than 98% of babies had protective antibody levels against polio (types 1, 2 and 3) and Hib.
- More than 98% of babies had positive antibody levels for 3 types of antibodies against whooping cough (called ‘anti-PT’, ‘anti-FHA’ and ‘anti-PRN’).

All babies had protective or positive antibody levels for all 5 diseases after the booster dose. These results can be found in the ***clinical results summary.***

Figure 2: Percentage of babies with protective or positive levels of antibodies



What were the side effects?

Unwanted medical events (adverse events) can happen to people when they receive a vaccine. Study doctors record these events. A summary of all adverse 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 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.

Figure 3 shows the side effects reported in this study.

Irritability or fussiness were the most common side effects of the vaccine. All side effects reported in this study were common side effects of the 5-in-1 vaccine and of short duration.

The side effects reported in the study did not raise any new safety concerns.

Figure 3: Side effects reported for at least 2 babies in the study

	Side effects at the place of injection	
	After primary	After booster
Redness	122 of 232 (52.6%)	101 of 225 (44.9%)
Swelling	83 of 232 (35.8%)	73 of 225 (32.4%)
Pain	77 of 232 (33.2%)	71 of 225 (31.6%)

**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*

	Other side effects	
	After primary	After booster
Irritability/Fussiness	150 of 232 (64.7%)	88 of 225 (39.1%)
Sleepiness	122 of 232 (52.6%)	54 of 225 (24.0%)
Loss of appetite	74 of 232 (31.9%)	40 of 225 (17.8%)
Fever	53 of 232 (22.8%)	26 of 225 (11.6%)

Note: some babies had more than 1 side effect

How has this study helped patients and researchers?

This study showed that the 5-in-1 vaccine can reduce the number of injections needed to protect Russian babies against 5 childhood diseases. These results can be submitted to the Russian health authority for approval of the vaccine. If this vaccine is approved in Russia, doctors will be able to vaccinate babies with a single vaccine instead of separate vaccines.

This summary only shows results from 1 study. Other studies may find different results.

Are there plans for further studies?

At the time of preparation of this summary, no further studies were planned with the 5-in-1 vaccine in Russian babies.

Where can I find more information about this study?

The detailed title for this research study is:

A phase III, open-label study to assess the immunogenicity and reactogenicity of GSK Biologicals' DTPa-IPV/Hib vaccine administered as a three-dose primary vaccination course at 3, 4.5 and 6 months of age and a booster dose at 18 months of age in healthy infants in Russia.

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	2013-005577-43
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT02858440

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 3 June 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/2013-005577-43/results
US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT02858440?term=116194&rank=1