



Who Sponsored this study ?
GlaxoSmithKline

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A study of how Russians from age 4 to 65+ years respond to a 3-in-1 combined vaccine against diphtheria, tetanus, and whooping cough






GSK would like to thank all the adults, adolescents 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 was done to support the registration of a 3-in-1 vaccine in Russia. The 3-in-1 vaccine works against diphtheria, tetanus, and pertussis (whooping cough).

What was studied?

- The researchers studied how many people built an antibody defense after vaccination. The antibodies they studied were against diphtheria, tetanus, and whooping cough (pertussis).
- Vaccine safety was also studied.

Who was in this study?

447 Russian children and adults:

111 children aged 4-9 years;

111 adolescents aged 10-17 years;

113 adults aged 18-64 years;

112 older adults aged 65 and older.

What kind of study was it?

- This was an 'open label' study. 'Open label' means that the study staff and and the people in the study knew what vaccine was given.

Main results

- One month after vaccination, at least 99% of all people in the study were protected against diphtheria and tetanus.
- At least 97% of all people in the study had positive antibody levels against whooping cough (pertussis) a month after vaccination.

NCT number: NCT03311659
EudraCT number: 2015-003405-42

General information about the research study

When was the study done?

The study was done between January 26, 2018 and August 31, 2018.

Why was this study done?

Your body can fight off most germs without help. Sometimes it takes time to be able to fight the germs. That is when the germs can make you sick. Vaccines work by making your body think it has seen the germ before and is ready to fight it. After a vaccine shot, you make body defenses (antibodies) against disease causing bacteria and viruses.

This study was done to find out whether older children and adults who are getting the 3-in-1 vaccine shot would make natural defenses (antibodies) against all 3 diseases after a single shot of the study vaccine.

Russian babies are regularly get this vaccine at the age of 3 months. But, older children, adolescents and adults are not routinely vaccinated. This leaves many people unprotected. Unprotected people can catch and spread these diseases. Vaccinating older children and adults may result in fewer people being infected.

Researchers also wanted to find out how much antibody the study subjects made. And, they wanted to learn about possible vaccine side effects including any short-term reactions.

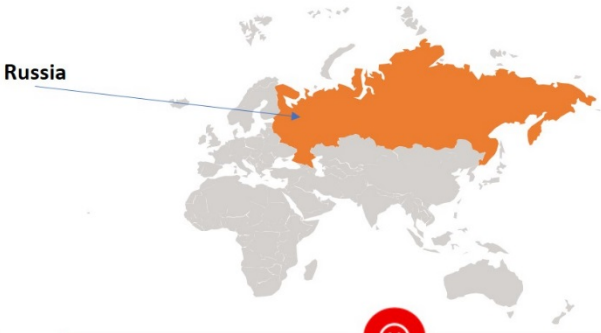
Who took part in this study?

111 Children- age 4-9 years

111 Adolescents- age 10-17 years

113 Adults- age 18-64 years

112 Older Adults- age 65+ years



People could take part in this study IF they were:

- healthy and aged 4 years or older
- children who had received all recommended vaccinations up to age 3 years

People could not take part in this study IF they were:

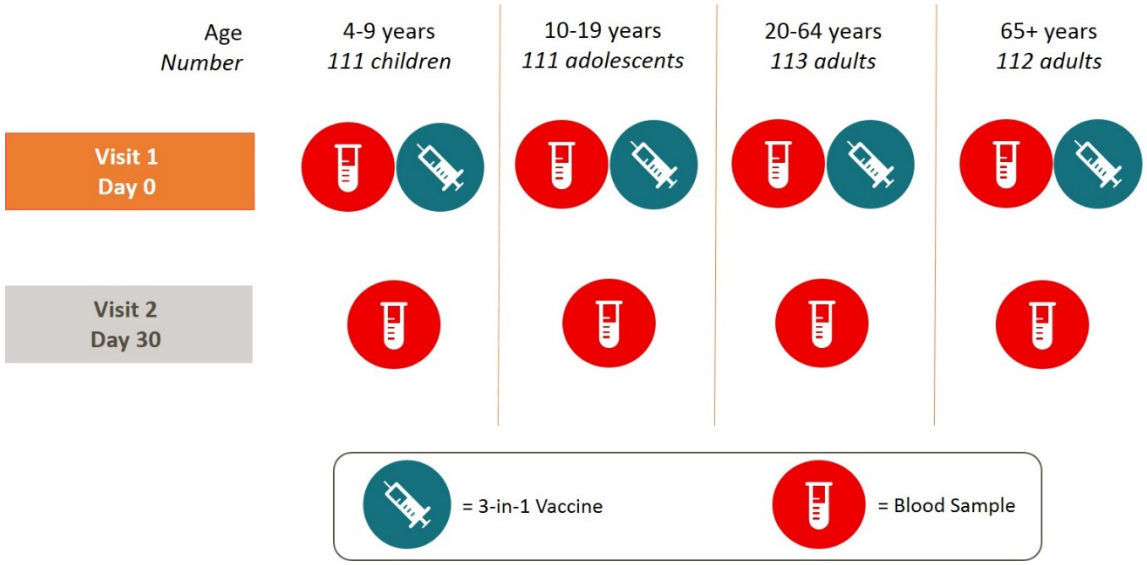
- 6 or 7 years old and had already received the dTap booster shot recommended at that age
- age 8 or older who had diphtheria, tetanus or whooping cough anytime within the 5 years before the study started
- taking any prohibited medicines or drugs or any other vaccine
- women of childbearing potential who were pregnant, planned to get pregnant or breastfeed

Which vaccines were studied?

The vaccine in this study was a 3-in-1 vaccine against diphtheria, tetanus, and pertussis (whooping cough). Everyone in the study got a single shot of the vaccine in their arm.

How was the study done?

Every person in the study got one shot of the 3-in-1 vaccine. Blood samples were taken before vaccination and at another visit one month later to measure the body defenses made after the vaccine shot. Each person was in the study for 1 month.



What were the main results of the study?

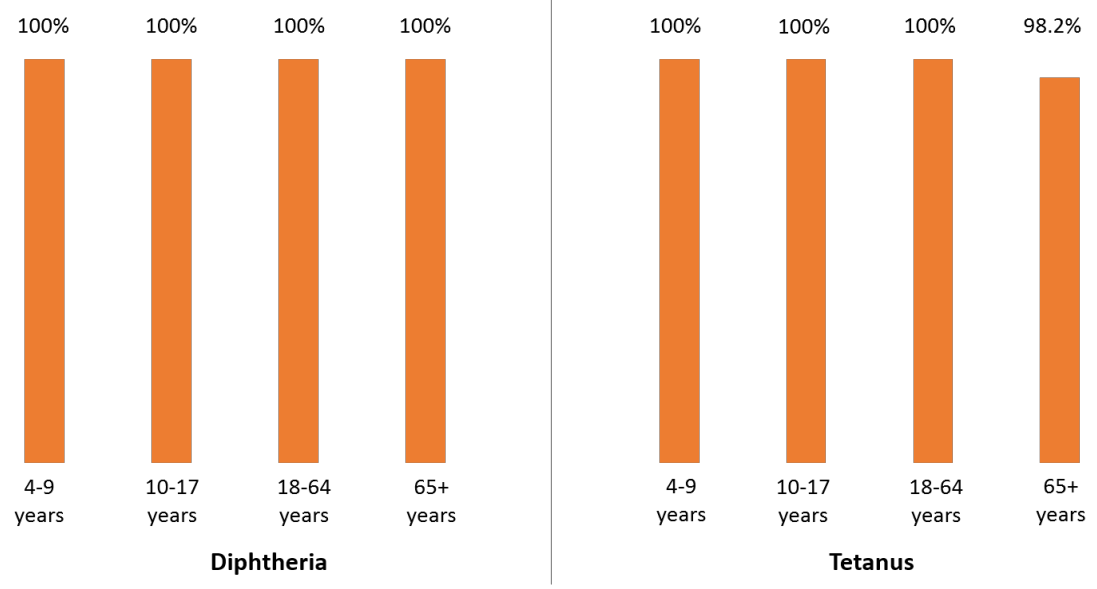
This report focuses on the results of the main goals of the study. All results may be found in the clinical results summary.

Diphtheria and tetanus

Most people in this study are protected against diphtheria and tetanus if they have antibodies in their blood that reach what are called **protective antibody levels**.

One month after vaccination, more than 99% of all the people in this study had antibodies in their blood against diphtheria and tetanus that reach protective levels (Figure 1).

Figure 1. Percentage of people in the study who were protected against diphtheria and tetanus, 1 month after 3-in-1 vaccine



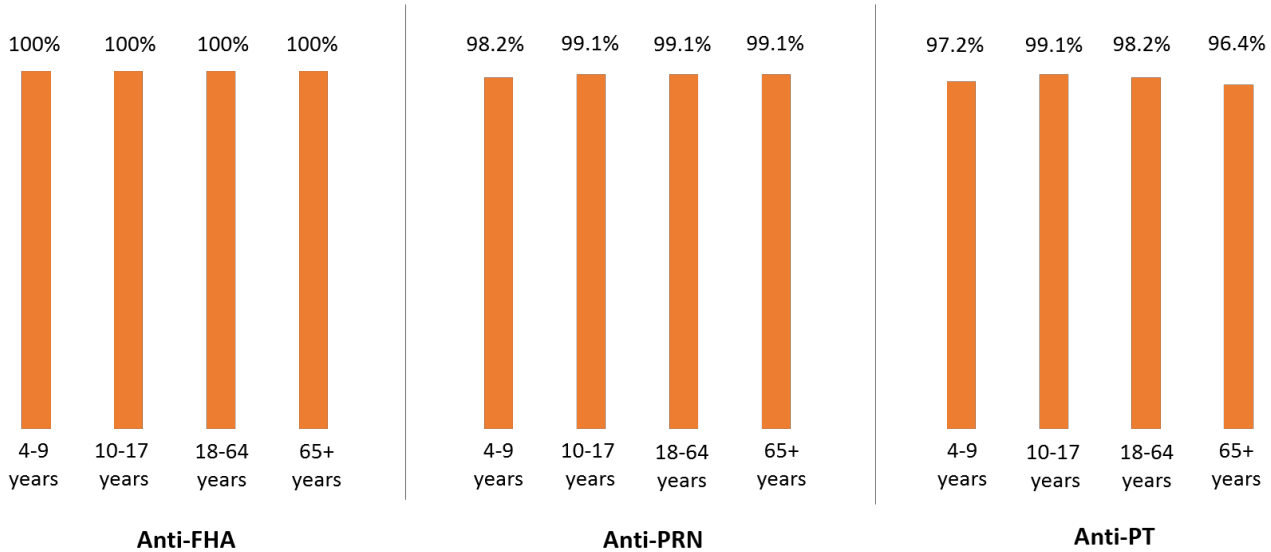
Whooping Cough

Whooping cough is different from the 2 other diseases in this vaccine because scientists do not know exactly what level of antibody is protective. The level at which most people can fight off whooping cough is called the **positive antibody level.**

In this study, more than 96% of the people had positive antibody levels for whooping cough one month after vaccination. (Figure 2). Antibodies against 3 different parts of the germ causing whooping cough were measured.

These parts are known as FHA, PRN, and PT. The antibodies directed against them are known as anti-FHA, anti-PRN, and anti-PT.

Figure 2. Percentage of people in the study with positive antibody levels against whooping cough, 1 month after the 3-in-1 vaccine



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 if they were caused by the vaccine or not. A summary of all events reported in this study may be found in the ***clinical results summary***.

If the study doctors think that the unwanted event was caused by the vaccine, they record it as a possible side effect.

In general, side effects in this study were mostly not serious and lasted only a short time. Most side effects were those that are typically associated with vaccination. Possible side effects had to be recorded in a diary every day, within 4 days of vaccination. Only 1 other side effect happened to more than 1 person in any age group: itching at the site of the shot. Please see Table 1 for details.

Table 1. Side effects reported by more than 1 person in any age group

	18 Young Children Age 4-5 years	93 Children Age 6-9 years	111 Adolescents Age 10-17 years	113 Adults Age 18-64 years	112 Older Adults Age 65 years +
Side effects in the upper arm within 4 days of vaccination					
Pain	13 (72.2%)	56 (60.2%)	68 (61.3%)	76 (67.3 %)	71 (63.4 %)
Redness	15 (83.3%)	61 (65.6%)	62 (55.9%)	33 (29.2%)	36 (32.1 %)
Swelling	15 (83.3 %)	58 (62.4%)	54 (48. %)	25 (22.1 %)	22 (19.6 %)
Itching	0	2 (2.1%)	0	0	0
Other side effects within 4 days of vaccination					
Irritability Fussiness	4 (22.2%)	NA	NA	NA	NA
Appetite loss/GI Upset	3 (16.7%)	6 (6.5%)	3 (2.7%)	6 (5.3%)	0
Drowsiness/Fatigue	1 (5.6)	23 (24.7%)	29 (26.1%)	22 (19.4 %)	18 (16 %)
Headache	NA	15 (16.1%)	29 (26.1%)	21 (18.5 %)	16 (14.2 %)
Fever (38°C and above)	0	3 (3.2 %)	5 (4.5%)	1 (0.9%)	1 (0.9%)

NA: Side effect not reported in this age group

How has this study helped patients and researchers?

This study helped researchers learn more about how the 3-in-1 vaccine works in Russians from age 4 to 65 years and older. They also learned how well it is tolerated. The results of this study will support registration of the study product to vaccinate Russians aged 4 and older.

**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.*

Are there plans for further studies?

This vaccine is being studied to find out how it works in pregnant women. The objective is to see if vaccinating women while pregnant can protect newborns before the babies can themselves be vaccinated.

Where can I find more information about this study?

The detailed title for this research study is:

A phase III, open-label, single-group, multi-centre study to assess the immunogenicity, safety and reactogenicity of GSK Biologicals' combined reduced antigen content diphtheria, tetanus, and acellular pertussis (dTpa) vaccine, *Boostrix*, administered as a booster dose in healthy Russian subjects aged four years and older

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	2015-003405-42
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT03311659

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 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.

This document was developed and approved by GSK on 16 October 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/search?query=2015-003405-42
US NIH/clinicaltrials.gov: https://clinicaltrials.gov/ct2/show/NCT03311659