Who Sponsored this study ?
GlaxoSmithKline

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How do infants respond to a booster shot of a 6-in-1 vaccine if their mothers got the dTpa vaccine during pregnancy?

GSK would like to thank all the infants 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?

This was a study to see if responses to a booster shot of a 6-in-1 vaccine were similar in infants born to:

- mothers who got a vaccine against diphtheria, tetanus, whooping cough (dTpa) during their pregnancy, and
- mothers who did not get the dTpa vaccine during pregnancy.

What was studied?

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

Who was in this study?

Healthy infants (247 girls and 293 boys) from Australia, Canada, Czechia, Finland, Italy, and Spain took part.

What kind of study was it?

- **Open label:** The same 6-in-1 vaccine was given to all infants, so the study doctors and parents knew which vaccine the infants got.

  Controlled study: infants born to mothers vaccinated during pregnancy (dTpa group) where compared to infants whose mothers were not. (Control group).

Main results

After the booster shot:

- More than 99% of infants in both groups were protected against diphtheria, tetanus, polio, hepatitis B and Hib.
- More than 92% of infants in both groups responded with whooping cough antibodies.
- The side effects in this study were similar in both groups of infants. They were known reactions of the 6-in-1 vaccine, and of short duration.

NCT number: NCT02853929
EudraCT number: 2014-001120-30

General information about the research study

When was the study done?

The study started on 19 September 2016 and ended on 19 March 2019.

Why was this study done?

This study was done to find out if infant's responses to the booster shot of the 6-in-1 vaccine were affected by whether their mothers got the dTpa vaccine during pregnancy. Safety information was collected during the study.

The infants got the booster shot of the 6-in-1 vaccine when they were between 11 and 18 months old. The main goal of the study was to measure antibodies against 6 diseases. These were:

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

The infants also got a commonly used pneumococcal vaccine at the same time as the 6-in-1 vaccine. Antibodies against pneumonia were measured. Those results that were not main study goals can be found in the ***clinical results summary***.

Who took part in this study?

540 healthy infants
from 6 countries

9 months old when the study started

247 girls (46%)

293 boys (54%)

Infants could take part in the study if they:

- were born to mothers who were part of another GSK study
- had received the 6-in-1 vaccine in another GSK study

Infants could not take part in the study if they:

- had received other booster vaccines against diphtheria, tetanus, whooping cough, Hib, pneumococcus, and/or polio
- had a history of these diseases

Which vaccines were studied?

- **6-in-1 vaccine**: A combination vaccine against diphtheria, tetanus, whooping cough, polio, hepatitis B and Hib.
- **Pneumococcal vaccine**: A vaccine against pneumonia.

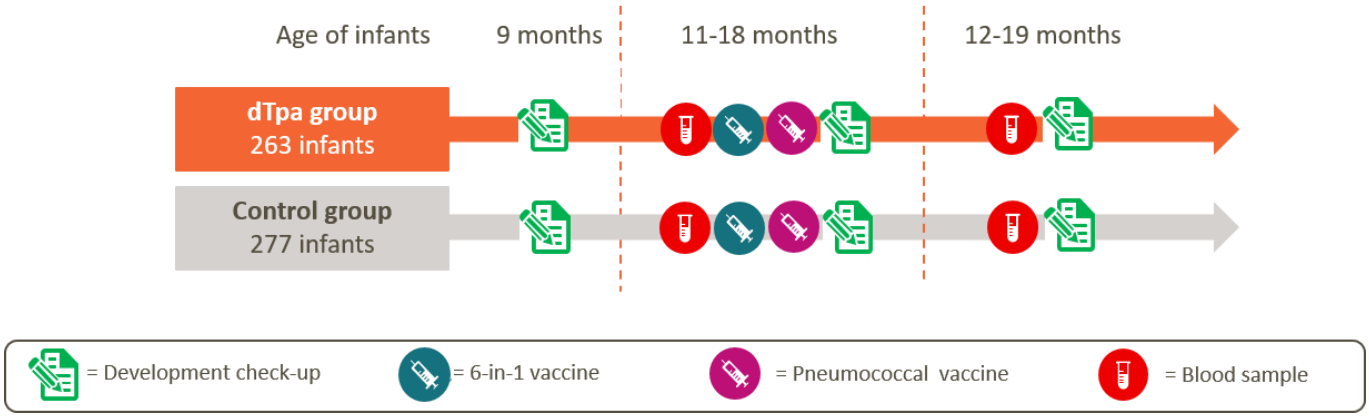
Both vaccines were given by injection into the thigh or arm muscle.

How was the study done?

Blood samples were taken before and 1 month after the booster shot. The blood samples were used to measure the amounts of antibodies.

It took about 9 to 10 months for each infant to complete the study.

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.

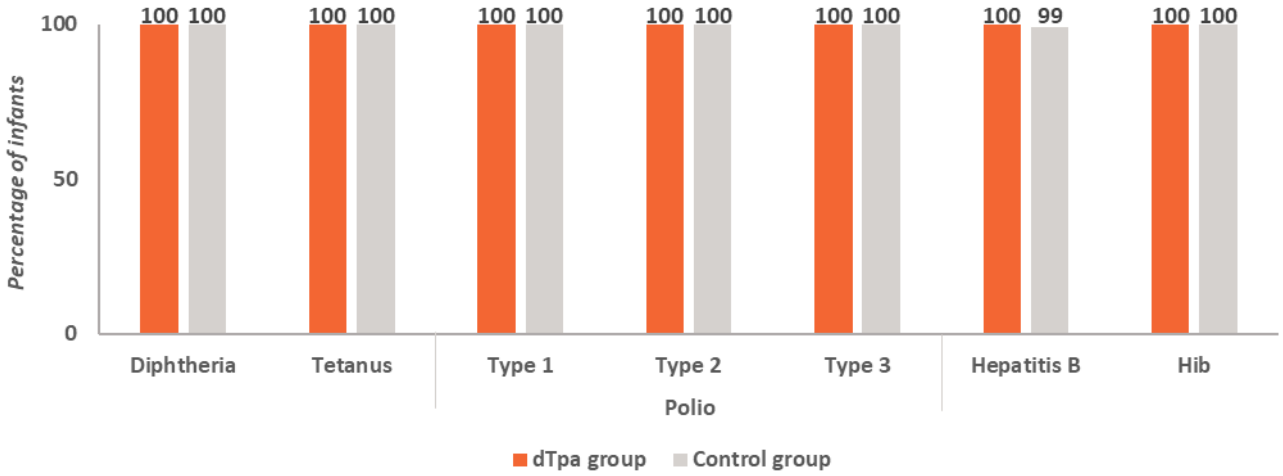
Antibodies against diphtheria, tetanus, hepatitis B, Hib, and polio

Most people are protected against these 5 diseases if the amounts of antibodies in their blood are above certain levels. These are called the **protective antibody levels**.

One month after the booster shot (**Figure 2**):

- All infants in both groups had protective antibody levels against diphtheria, tetanus and polio (Type 1, 2 and 3).
- More than 99% of infants in both groups had protective antibody levels against hepatitis B and Hib.

Figure 2: Infants with protective antibody levels



Antibodies against whooping cough

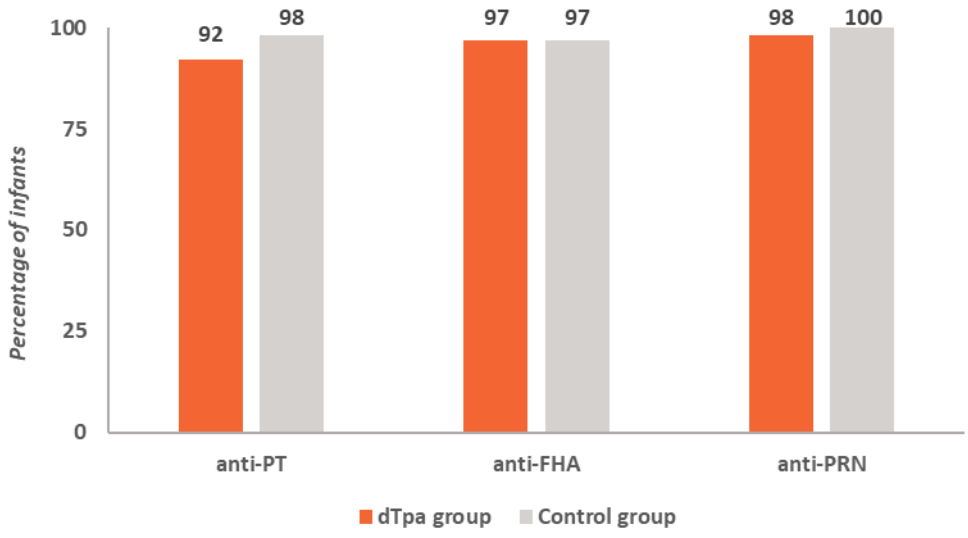
For whooping cough, the protective antibody levels are unknown. So, we measured the amounts of antibodies to see if the infants might be able to fight off whooping cough. This is called a **response**.

We measured 3 kinds of antibodies ('anti-PT', 'anti-FHA' and 'anti-PRN') against whooping cough.

We found that after the booster shot (**Figure 3**):

- more than 92% of infants in the dTpa group, and more than 96% of infants in the control group responded with whooping cough antibodies.

Figure 3: Infants who responded with whooping cough antibodies



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 all 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.

We found that:

- Side effects were similar in both groups, not serious and lasted only a short time.
- The most common side effect at the injection site was redness for both vaccines (**Figure 4**).
- The most common other side effect was irritability for both vaccines (**Figure 5**).

Figure 4: Side effects at the place where the vaccine was given

	6-in-1 vaccine		*Pneumococcal vaccine*	
	dTpa group (257 infants)	**Control group (275 infants)**	**dTpa group (257 infants)**	**Control group (274 infants)**
Pain	119 of 257 (46%)	137 of 275 (50%)	113 of 257 (44%)	124 of 274 (45%)
Redness	126 of 257 (49%)	147 of 275 (54%)	120 of 257 (47%)	132 of 274 (48%)
Swelling	103 of 257 (40%)	106 of 275 (39%)	87 of 257 (34%)	86 of 274 (31%)

Figure 5: Other side effects

	6-in-1 vaccine + Pneumococcal vaccine	
	dTpa group (258 infants)	**Control group (275 infants)**
Drowsiness	100 of 258 (39%)	109 of 275 (40%)
Irritability	140 of 258 (54%)	159 of 275 (58%)
Loss of appetite	84 of 258 (33%)	97 of 275 (35%)
Fever (37.5°C and above)	64 of 258 (25%)	67 of 275 (24%)
Vomiting	4 of 263 (2%)	0

Note: Some infants had more than 1 side effect. The tables list the side effects in at least 1% of infants.

**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.*

How has this study helped patients and researchers?

This study helped researchers, doctors and parents understand that:

- Giving pregnant mothers a dTpa vaccine does not affect the ability of the booster shot of the 6-in-1 vaccine to protect their babies against diphtheria, tetanus, hepatitis B, Hib and polio.
- The whooping cough antibodies transferred from mothers to infants during pregnancy may reduce the infants's ability to make their own antibodies against whooping cough but the importance of this effect is not known.
- The side effects of the 6-in-1 vaccine in infants of vaccinated mothers and mothers who did not get dTpa vaccine during pregnancy are similar. They are known side effects of the vaccine.

Are there plans for further studies?

At the time this summary was prepared, no further studies were planned with the 6-in-1 vaccine in infants born to mothers vaccinated against dTpa during their pregnancy.

Where can I find more information about this study?

The detailed title for this research study is:

A phase IV, open-label, non-randomised, multi-centre study to assess the immunogenicity and safety of a booster dose of *Infanrix hexa* in healthy infants born to mothers vaccinated with *Boostrix* during pregnancy or immediately post-delivery.

Organization	Website	Study Number
European Medicines Agency	www.clinicaltrialsregister.eu	2014-001120-30
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT02853929

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 19 November 2019. 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=2014-001120-30
US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT02853929