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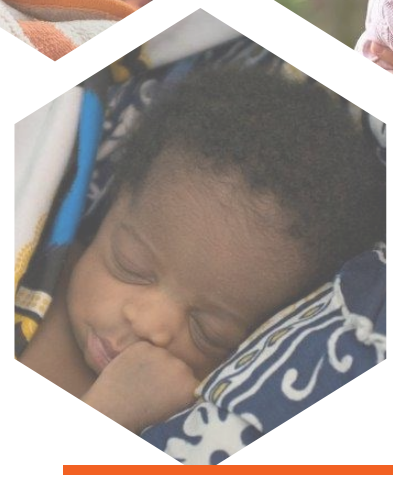
DOES A 6-IN-1 VACCINE PROTECT HEALTHY BABIES IN THE SAME WAY AS A 5-IN-1 VACCINE PLUS AN EXTRA VACCINE SHOT?



GSK would like to thank all the babies who were part of this clinical study and their parents/guardians. 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 conducted?

The study was conducted to see if a vaccine available in many parts of the world could also be used to protect US babies against 6 childhood diseases.

What was studied?

- Body defenses (antibodies) against whooping cough, diphtheria, tetanus, hepatitis B, polio and *Haemophilus influenzae type B* (Hib).
- Possible vaccine side effects.

Who was in this study?

309 healthy baby boys and 276 healthy baby girls, from the United States. All babies were 2 to 3 months old when they received the first study vaccine.

What kind of study was it?

- Randomized: Babies were assigned to vaccination groups by chance (like tossing a coin).
- Open label: Both the study staff and parents/guardians of the babies knew which vaccines were given to the babies.

Main results

- There were no important differences in whooping cough antibody levels between the babies who got either 1 or 2 vaccines against the 6 diseases.
- All babies were protected against diphtheria, tetanus, hepatitis B and polio after the 6-in-1 vaccinations. Nearly all babies (94.8%) were protected against Hib, regardless of which Hib vaccine they received.
- There were no important differences in side effects between the groups in this study. No health concerns were raised.

NCT number: NCT02207413
EudraCT number: 2014-000955-10

General information about the research study

When was the study done?

The study started on 16 April 2014 and ended on 13 November 2015.

Why was this study done?

This study was done to see if it is possible to reduce the number of injections needed to protect babies in the US against 6 childhood diseases. Now, US babies receive 2 vaccines, rather than 1, against these 6 diseases:

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

These diseases can lead to permanent damage or even death. US authorities recommend vaccination against all of them.

The 6-in-1 vaccine used in this study has been available in many countries throughout the world for several years, but not in the US.

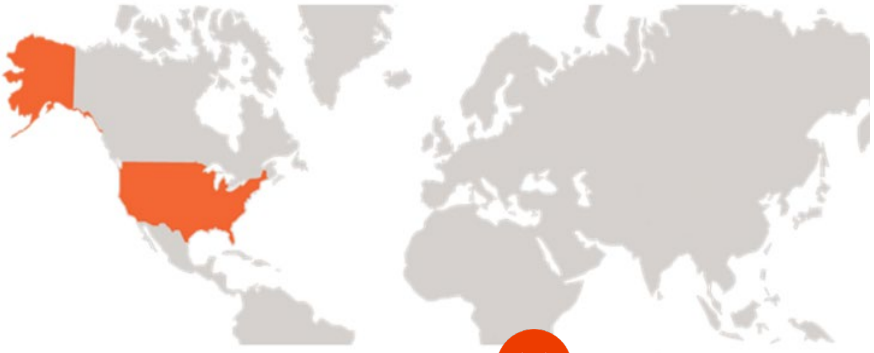
Who took part in this study?

585 babies **from the** United States

Age 6 to 12 weeks old **when first vaccinated**

276 baby girls **(47%)**

309 baby boys **(53%)**



Babies could take part in the study if they:

- Were between 6 and 12 weeks of age at first vaccination
- Born at full-term (9 months)
- Were healthy

Babies could not take part in the study if they:

- Had been vaccinated against diphtheria, tetanus, whooping cough, Hib, rotavirus, pneumococcus, and/or poliovirus
- Received two or more hepatitis B vaccinations within 30 days of the start of the study

Which vaccines were studied?

The following vaccines were studied:

- 6-in-1 vaccine against whooping cough, diphtheria, tetanus, polio, hepatitis B and Hib
- 5-in-1 vaccine against whooping cough, diphtheria, tetanus, polio and Hib
- 5-in-1 vaccine against whooping cough, diphtheria, tetanus, polio and hepatitis B
- 3-in-1 vaccine against whooping cough, diphtheria, tetanus
- Two different Hib vaccines
- hepatitis B vaccine

All babies in this study also got 2 other childhood vaccines, a human rotavirus vaccine and a pneumococcal vaccine. Their responses to these routine vaccines were not part of this study.

How was the study done?

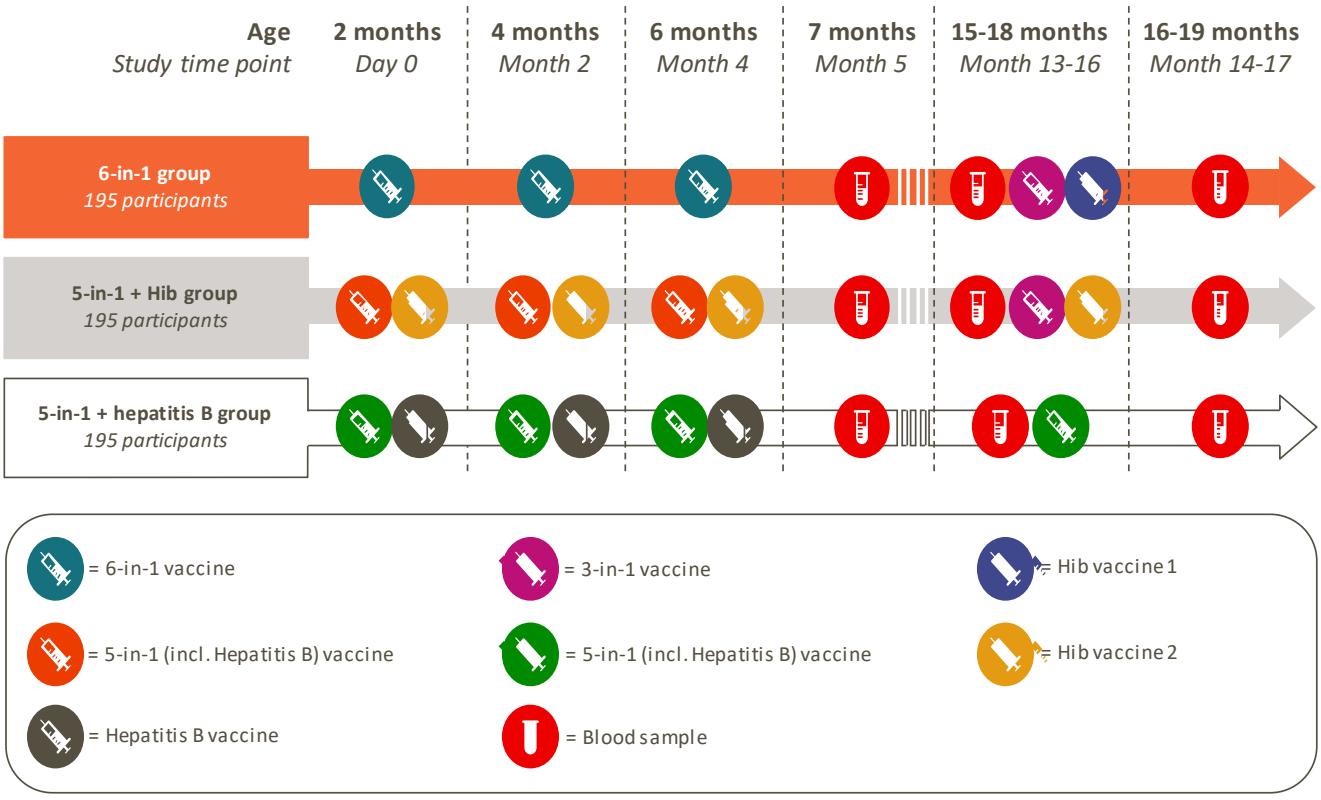
Babies were assigned to 1 of 3 groups. Each group received a different set of vaccines; all were vaccinated against the 6 childhood diseases. (Table 1).

Table 1: Vaccines given to each study group

	Primary vaccination 2, 4 and 6 months of age		Booster vaccination 15 to 18 months of age	
	Vaccine 1	**Vaccine 2**	**Vaccine 1**	**Vaccine 2**
One shot group	6-in-1	-	3-in-1	Hib
Two shot group (a)	5-in-1 (including hepatitis B)	Hib	3-in-1	Hib
Two shot group (b)	5-in-1 (including Hib)	hepatitis B	5-in-1 (including Hib)	-

The Study Overview (**Figure 1)** shows when the vaccines were given and when blood samples were taken in the 3 study groups. Blood samples were used to measure amounts of antibodies against all 6 diseases. Study staff collected information from parents/guardians about possible vaccine side effects.

Figure 1 Study overview

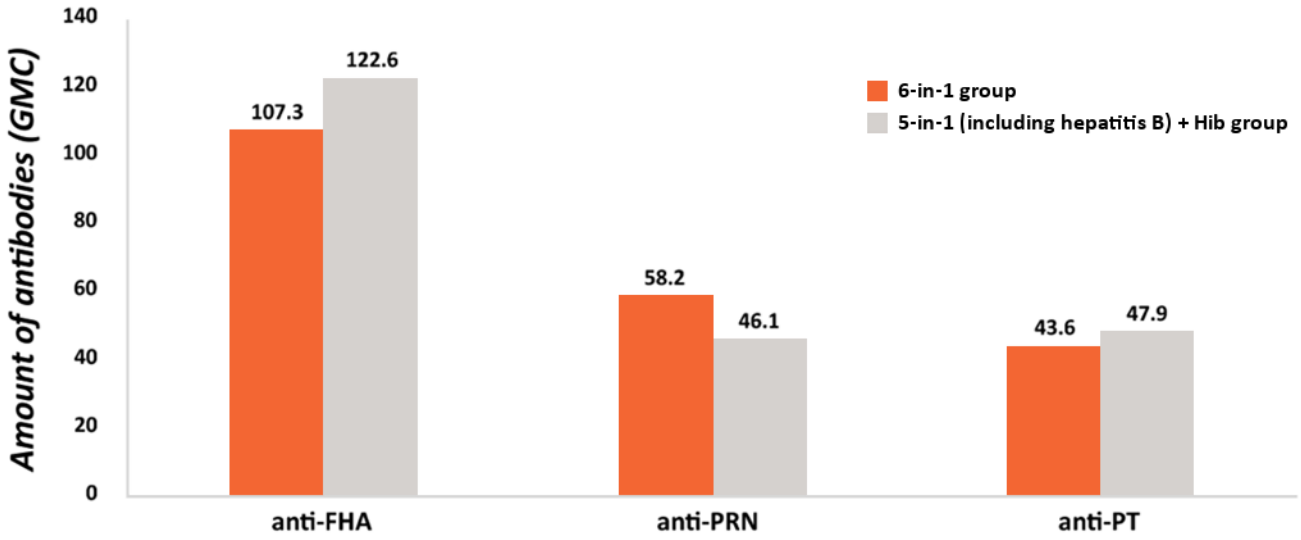


What were the main results of the study? *

There were no important differences in the amounts of whooping cough antibodies between the 2 vaccine groups, after the first 3 (primary) vaccinations.

Figure 2 shows the three different types of whooping cough antibodies (called 'anti-FHA', 'anti-PRN' and 'anti-PT') measured in the blood samples. In this figure, the antibody response to the 6-in-1 vaccine is compared with the antibody response to the 5-in-1 vaccine (including hepatitis B) + Hib. These vaccines are both made by the same manufacturer.

Figure 2 Whooping cough antibodies



Geometric mean concentration (GMC) is a measure of the average amount of antibodies in blood.

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

The results for antibodies against the other 5 diseases may be found in the clinical results summary and were not the main focus of this study. However, in the 6-in-1 vaccine group it should be noted that:

- After the primary vaccination
  - All babies were protected against diphtheria, tetanus, polio, and hepatitis B.
  - Nearly all babies (94.8%) were protected against Hib.
  - After the booster vaccination
  - All babies were protected against Hib.

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 can be found in the **clinical results summary.**

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

A side effect is called 'serious' if it:

- is a threat to life, or
- leads to permanent damage, or
- requires a hospital stay, or
- is fatal

There were 3 serious side effects in the 6-in-1 vaccine group. An 8-week-old girl was very tired (lethargic) but got better on her own in one day. A 10-week-old girl had 2 serious side effects. She had an increased white blood cell count and shallow breathing. She was admitted to the hospital and was better within 2 days.

There were no serious side effects in the 5-in-1 groups.

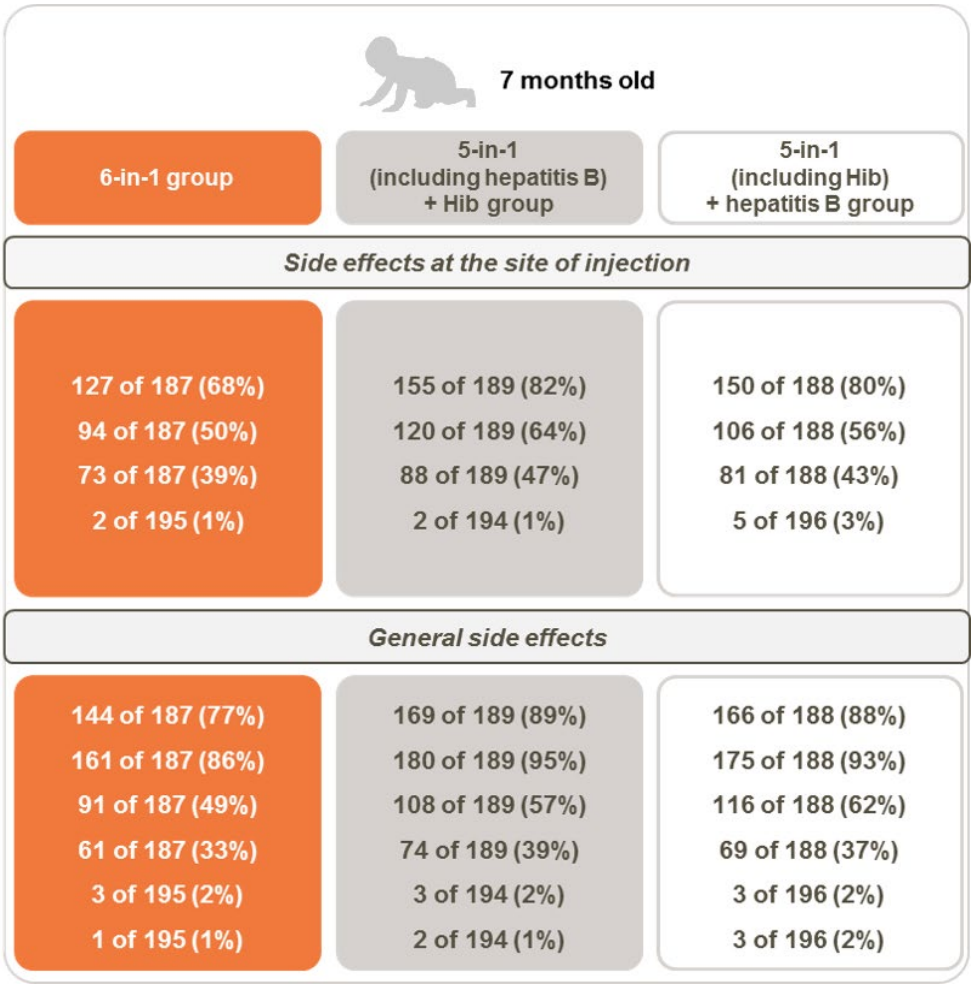
Figures 3a and 3b show side effects at the thigh muscle where the vaccine was injected and general side effects (occurring elsewhere).

Pain in the thigh at the point of injection was the most common side effect after both the primary and booster vaccinations in all groups.

Irritability or fussiness was the most common general side effect after both the primary and booster vaccination in all groups.

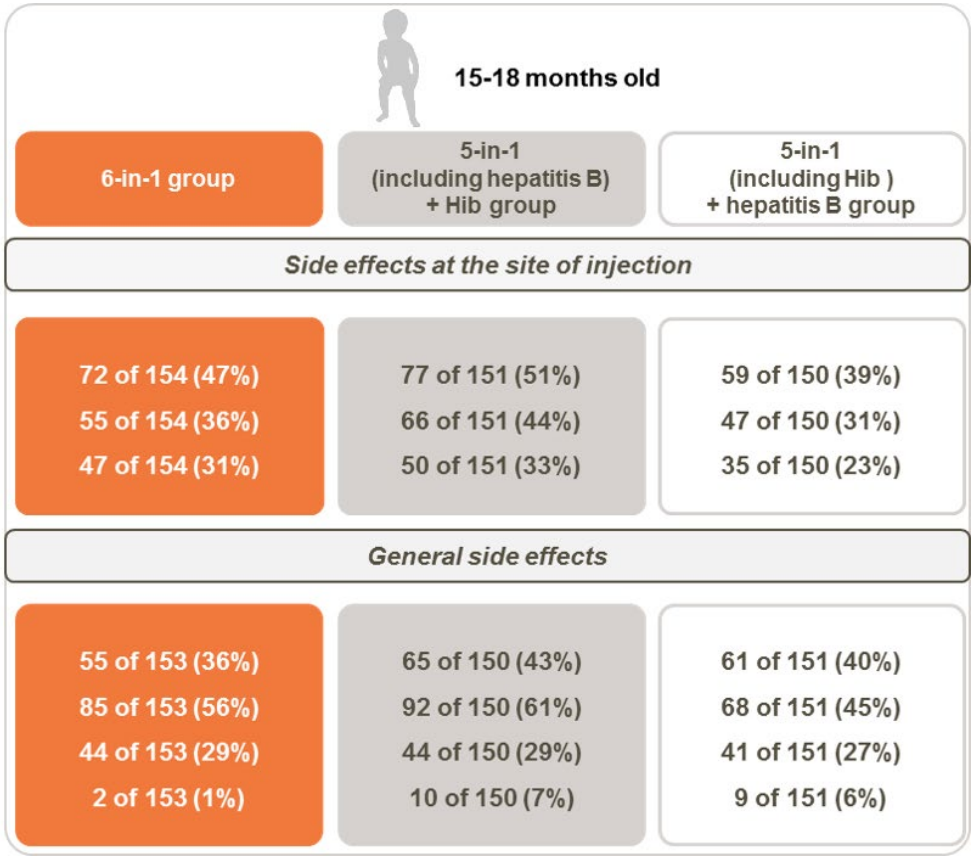
This study did not raise any safety concerns.

Figure 3a: Side effects after the primary vaccination at age 7 months*



* shows side effects that were reported for more than 1% of babies

Figure 3b: Side effects after the booster vaccination between age 15 and 18 months*



* shows side effects that were reported for more than 1% of babies

How has this study helped patients and researchers?

The study showed the number of shots babies get to vaccinate them against childhood diseases can be safely reduced by using the 6-in-1 vaccine instead of the 5-in-1 vaccine plus extra vaccine shots. The amount of antibody against whooping cough was similar in the babies who got the 6-in-1 vaccine and the babies who got the 5-in-1 including hepatitis B vaccine.

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

Are there plans for further studies?

Vaccine quality will be studied. Vaccine safety and the immune system response to the other antigens in the 6-in-1 vaccine besides whooping cough will also be studied.

Where can I find more information about this study?

The detailed title for this research study is:

A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' *Infanrix hexa* vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with *Prevnar* and *Rotarix* with a booster dose of GSK Biologicals' *Infanrix* and *Hiberix* vaccines at 15-18 months 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	2013-004304-19
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 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 September 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/2013-004304-19/results
US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT02096263?term=116194&rank=1