



Who sponsored this study?

GlaxoSmithKline

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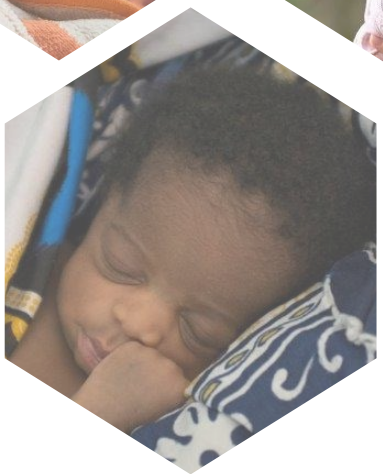
Does a rotavirus vaccine work well with 3 common childhood vaccines?



GSK would like to thank all the babies 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?

The researchers wanted to learn if changing the manufacturing process for a rotavirus vaccine changes how babies respond to 3 common childhood vaccines.

What was studied?

- Babies responses (antibodies) to vaccines against common childhood diseases: diphtheria, tetanus, whooping cough, hepatitis B, polio and diseases caused by *H. influenza* and *pneumococcus* were measured.
- Possible side effects of study vaccines.

Who was in this study?

- 1272 healthy American babies (655 boys and 617 girls)

What kind of study was it?

- Randomized: The babies were placed in 2 groups by chance (like tossing a coin). Each group got 1 of the 2 study vaccines.
- Single blind: The study doctor knew which vaccine the babies received. The babies' parents/guardians did not.
- Controlled: PCV-free group antibody responses were compared to current rotavirus vaccine antibody responses.

Main results

- All antibodies that were measured were similar in both groups of babies.
- The side effects of the 2 rotavirus vaccines were similar. Most side effects were those that are typically associated with vaccination. This study did not raise any safety concerns.

NCT number: NCT03207750
EudraCT number: 2016-003210-27

General information about the research study

When was the study done?

The study started on 14-September-2017 and ended on 01-March-2019.

Why was this study done?

The main goal of the study was to find out if babies respond differently to 3 common childhood vaccines when the manufacturing process is changed to remove porcine circovirus 1 (PCV-1) contaminant from a rotavirus vaccine.

Even though PCV-1 is harmless to humans, GSK decided to develop a PCV-free rotavirus vaccine. Being PCV-free means that no form of PCV can be detected by current tests.

Rotavirus is the most common cause of severe diarrhea in babies and young children. Vaccination helps protect them against rotavirus infection by making "antibodies". They protect the body against the virus.

Who took part in this study?

1272 babies from the **United States**

6 to 12 weeks old when they got their first vaccination

617 girls (49%)

655 boys (51%)

Babies could take part in the study if :

- Parents/guardians agreed they could be part of the study
- They were healthy

Babies could not take part in the study if they:

- Had any of the diseases covered by the vaccines
- Had already gotten the common childhood vaccines used in this study

Which vaccines were studied?

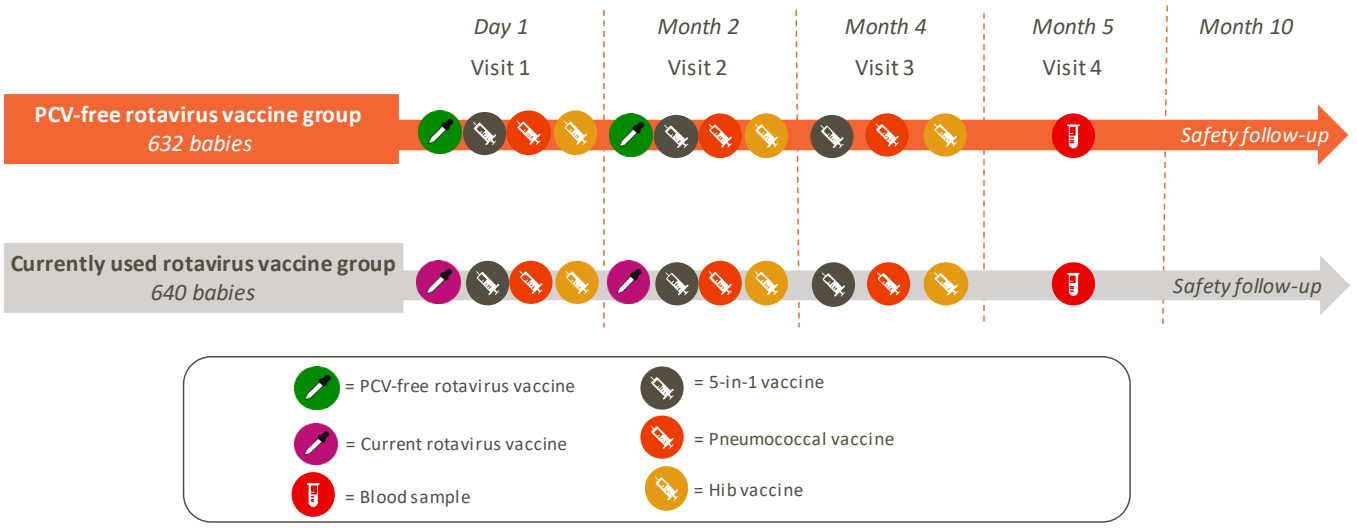
Two rotavirus vaccines were studied. They were given by mouth:

- A PCV-free, rotavirus vaccine
- The current rotavirus vaccine

All the babies in this study also got 3 common childhood vaccines. They were given by a shot in the thigh muscle:

- A 5-in-1 vaccine: A combination vaccine against 5 different diseases (diphtheria, tetanus, whooping cough, hepatitis B, and polio).
- A pneumococcal vaccine: A vaccine against diseases caused by 13 forms of the pneumococcus bacteria.
- A Hib vaccine: A vaccine against diseases caused by *H. influenza* (Hib), including meningitis and pneumonia.

How was the study done?



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.

Researchers compared babies who got the PCV-free rotavirus vaccine with babies who got the currently used rotavirus vaccine. They found:

- 100% of babies in both groups were protected against diphtheria and tetanus.
- More than 99% of the babies in both groups were protected against hepatitis B and polio (types 1, 2, and 3).
- At least 97% of all the babies in both groups had protection against Hib.
- Antibody levels against the 13 forms of pneumococcus bacteria were similar in both groups of babies.
- More than 90% of babies in both groups made antibodies against the 3 whooping cough bacterial toxins we tested.

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 the study doctors think the adverse event was caused by the vaccine, they record it as a possible side effect (adverse reaction). The table below lists the side effects that occurred in more than 1% of babies in both groups.

During the study, 3% of all the babies had another side effect. These side effects are not part of the table because the number of babies who experienced each one was very small.

A summary of all events reported in this study may be found in the clinical results summary.

Side effects of the rotavirus vaccines in more than 1% of babies[1]

	PCV-Free rotavirus vaccine group 632 babies	Current rotavirus vaccine group 640 babies
Irritability/Fussiness	433 (69%)	437 (68%)
Cough/Runny Nose	128 (20%)	117 (18%)
Loss of Appetite	223 (35%)	217 (34%)
Vomiting	93 (15%)	77 (12%)
Fever 38°C and above	72 (11%)	79 (12%)
Diarrhea (Day 1-8)	60 (10%)	42 (7%)
Diarrhea (Day 9-30)	45 (7%)	41 (6%)

[1]In this summary, "side effects*" refer only to those events that the study doctor thinks may have been caused by the rotavirus study vaccines.

How has this study helped patients and researchers?

This study showed that doctors can give either the current or PCV-free rotavirus vaccine to babies, together with the 3 common childhood vaccines used in this study, and expect a similar result. They also learned that the side effects of the two rotavirus vaccines were similar.

Are there plans for further studies?

Other studies of the GSK rotavirus vaccine were ongoing when this summary was written.

**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 IIIA, randomized, single-blind, multi-centric study to evaluate the immunogenicity, reactogenicity and safety of three doses of Pediarix, Hiberix and Prevenar 13 when co-administered with two doses of the PCV-free liquid formulation of GSK Biologicals' oral live attenuated HRV vaccine as compared to the currently licensed lyophilized formulation of the HRV vaccine in healthy infants 6-12 weeks of age.

Clinical studies have unique study numbers. The following unique study numbers are associated with this study.

Organization	Website	Study Number
European Medicines Agency	www.clinicaltrialsregister.eu	2016-003210-27
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT03207750

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 18 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=2016-003210-27
US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT03207750