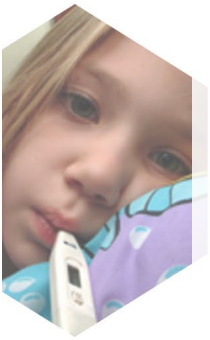


Who sponsored this study?

GlaxoSmithKline

Clinical Support Help Desk

- http://www.clinicalsupporthd.gsk.com
- GSKClinicalSupportHD@gsk.com
- Telephone: +1-438-899-8201

A study on the safety of a Rotavirus vaccine in babies

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?

GSK's rotavirus vaccine is available for use in many countries. Some years ago, researchers found low amounts of fragments of porcine circovirus 1 (PCV-1), an animal virus, in the GSK vaccine. Although health authorities decided that PCV-1 was not a threat to public health and to vaccinated babies and children, GSK decided to develop a PCV-free rotavirus vaccine. The main goal of this study was to assess safety of the PCV-free rotavirus vaccine.

What was studied?

- Possible vaccine side effects.

Who was in this study?

693 girls and 658 boys from 5 countries took part in the study. They were 6 to 12 weeks old when they got their first vaccination.

What kind of study was it?

- Randomized: Babies who joined this study were assigned to a study group by chance (like tossing a coin).
- Observer-blind: neither the babies' parents or guardians nor the medical staff responsible for evaluation of the study results knew which vaccine the babies got.

Main results

- This study did not raise any safety concerns about the PCV-free Rotavirus vaccine.
- One baby withdrew from the study because of a vaccine side effect. Less than 1% of study participants reported a serious medical event. This study did not raise any safety concerns.

NCT number: NCT03954743
EudraCT number: 2018-001986-18

General information about the research study

When was the study done?

The study started in July 2019 and ended in November 2020.

Why was this study done?

Rotaviruses affect the gut. These viruses can spread through oral transmission and result in severe watery diarrhea, vomiting, fever and/or abdominal pain. Vaccines can help protect against rotaviruses. Vaccines contain parts of these viruses that cannot cause infection. These parts help the body make defenses, known as antibodies, against those rotaviruses.

GSK's rotavirus vaccine is available for use in many countries. Some years ago, researchers found low amounts of fragments of porcine circovirus 1 (PCV-1), an animal virus, in the GSK vaccine. Although health authorities decided that PCV-1 was not a threat to public health and to vaccinated babies and children, GSK decided to develop a PCV-free rotavirus vaccine. The main goal of this study was to assess safety of the PCV-free rotavirus vaccine.

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

Who took part in this study?

1351 babies from **5 countries**.

6 to 12 weeks old when they got their first vaccination.

693 girls (51%)

658 boys (49%)

Babies could take part in the study if they:

- were in good health
- were allowed by their parents to participate to the study

Babies could not take part in the study if they:

- previously received a Rotavirus vaccine
- had birth defects or a weak immune system
- previously got sick from a condition of the gut where the gut folds into itself (intussusception).

Which vaccines were studied?

PCV-free Rotavirus vaccine: a vaccine that has been developed to protect against rotaviruses. This vaccine did not contain the PCV-1 fragments and was given orally.

Currently used Rotavirus vaccine: a vaccine that had previously been developed to protect against rotaviruses. This vaccine contained small amounts of PCV-1 fragments and was given orally.

How was the study done?

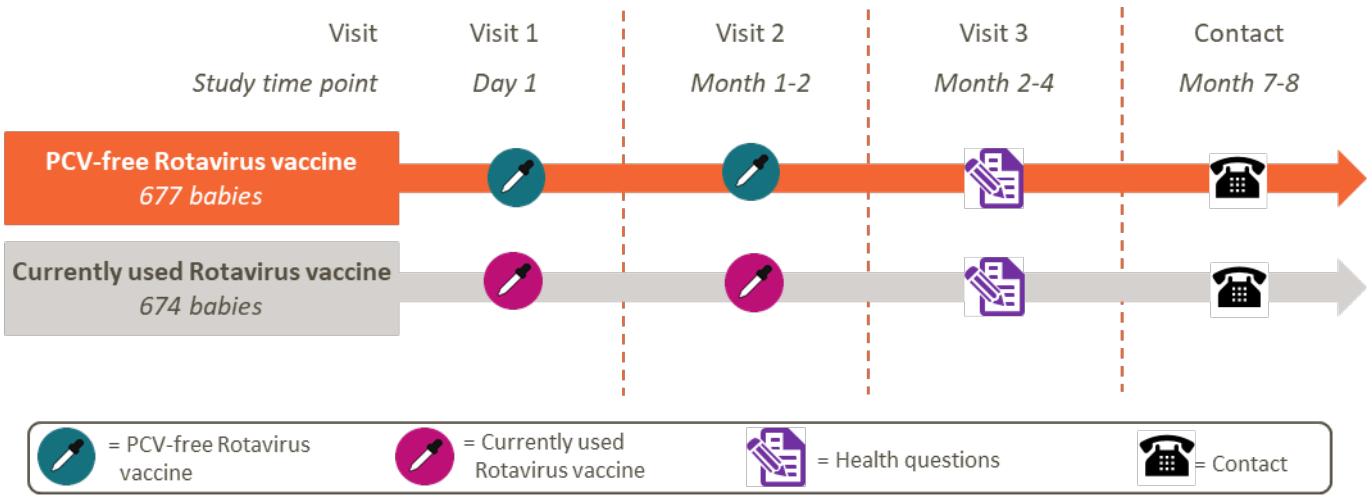
Figure 1 describes which vaccines babies in each study group got and when they got them. Study doctors collected information on the safety of the vaccine.

The study took approximately 7-8 months for each baby.

Babies who joined this study were assigned to a study group by chance (like tossing a coin).

Neither the babies' parents or guardians nor the medical staff responsible for evaluation of the study results knew which vaccine the babies got.

Figure 1: Study design



What were the main results of the study?

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

Safety of PCV-free Rotavirus vaccine

The main goal of this study was to assess safety of the PCV-free Rotavirus vaccine.

Unwanted medical events (adverse events) can happen to people when they receive a vaccine. Study doctors record 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.

The medical event is called 'serious' if it:

- is a threat to life

**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.*

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

Less than 1% of study participants reported a serious medical event. Of these, one was a serious side effect. One baby developed constipation six days after the first dose of PCV-free Rotavirus vaccine. The baby recovered within two weeks.

One baby withdrew from the study because of a vaccine side effect (hematochezia or blood in the stool).

This study did not raise any safety concerns.

Irritability or fussiness was the most frequent side effect overall.

Cough/runny nose was the most frequent side effect leading to a visit to a doctor.

The list of most frequent side effects is shown in **Figure 2.**

Figure 2: Medical events in at least 3% of babies

	PCV-free Rotavirus vaccine 677 babies	Currently used Rotavirus vaccine 674 babies
Medical events within 1 week after vaccination		
Irritability / Fussiness	507 (75%)	486 (72%)
Loss of appetite	290 (43%)	259 (38%)
Cough / runny nose	237 (35%)	235 (35%)
Vomiting	151 (22%)	162 (24%)
Fever	66 (10%)	56 (8%)
Diarrhea	58 (9%)	71 (11%)
Medical events within 1 month after vaccination		
Upper respiratory tract infection	27 (4%)	37 (6%)
Common cold	30 (4%)	22 (3%)
Fever	29 (4%)	19 (3%)
Eczema	17 (3%)	<3%

**Some babies had more than one side effect*

How has this study helped patients and researchers?

The results from this study indicate that the safety of the PCV-free Rotavirus vaccine was similar to that of currently used Rotavirus vaccine. This study did not raise any safety concerns about the PCV-free Rotavirus vaccine.

Combined with results from other research studies, the findings from this study may help improve the understanding of Rotavirus vaccine and gut infections caused by rotavirus.

Are there plans for further studies?

At the time of preparation of this summary, other studies were planned to further evaluate the PCV-free Rotavirus vaccine.

The results of any future studies will be available on the websites of European Medicines Agency and/or the United States National Institutes of Health. Links are provided at the end of the document.

Where can I find more information about this study?

The detailed title for this research study is:

A phase III, observer-blind, randomized, multi-country study to assess the reactogenicity and safety of the *Porcine circovirus* (PCV) free liquid formulation of GSK's oral live attenuated human rotavirus (HRV) vaccine as compared to the lyophilized formulation of the GSK's HRV vaccine, when administered as a 2-dose vaccination in infants starting at age 6-12 weeks.

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	2018-001986-18
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT03954743

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 11 May 2021. 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=2018-001986-18
US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT03954743