



Who sponsored this study?
GlaxoSmithKline

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A study of the immune response and safety of liquid and powder preparations of an oral human rotavirus vaccine in healthy Indian infants.






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 study was done to find out if a liquid rotavirus vaccine can work as well as and is as safe as the dry powder version of the same vaccine.

What was studied?

- Antibody levels against rotavirus were measured in all the infants in this study before and after vaccination.
- Possible vaccine side effects.

Who was in this study?

- 449 Indian infants aged 6-10 weeks took part in the study.

What kind of study was it?

- Controlled: Infant responses to the liquid vaccine were compared to the dried powder vaccine.
- Randomized: The infants were placed in 1 of 2 study groups by chance (like tossing a coin). One group got the dry powder vaccine. The other group got the liquid vaccine.
- It was an open study: Doctors and parents knew which vaccine the infants were getting.

Main results

- Antibody levels in the 2 groups of infants were similar.
- Side effects of the 2 vaccines were similar. They did not raise any safety concerns.

NCT number: NCT02141204
EudraCT number: 2012-001875-35

General information about the research study

When was the study done?

This study was done between 20 February 2019 and 28 December 2019. Each infant was in the study for around 3 months.

Why was this study done?

The main goal of the study was to find out if the new liquid vaccine works as well as the powdered rotavirus vaccine in Indian infants.

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

The dried powder version of this vaccine has been used to protect infants in India against rotavirus since 2008. The Indian government asked for more information about the liquid vaccine.

Who took part in this study?

449 infants from India

6 to 10 weeks old when they got the first vaccination

220 girls (49%)

229 boys (51%)

Infants could take part in the study if:

- they were in good health
- their parents/guardians gave permission for them to be in the study

Infants could not take part in the study if they:

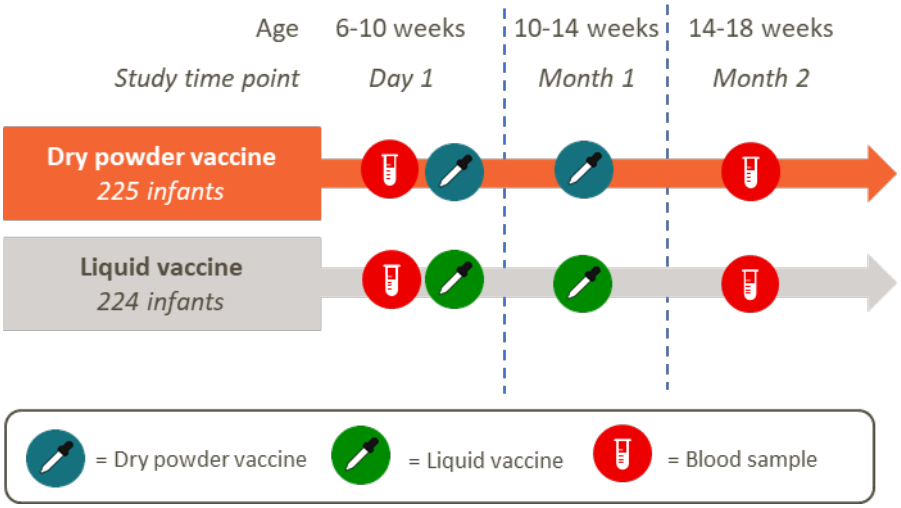
- previously got a rotavirus vaccine
- previously got sick from rotavirus infection

Which vaccines were studied?

Two versions of the same vaccine were studied. One was an oral dry powder rotavirus vaccine. The dry powder was mixed with a liquid before it was given to the infants. The other was an oral liquid version of the same vaccine.

How was the study done?

Figure 1. Study design

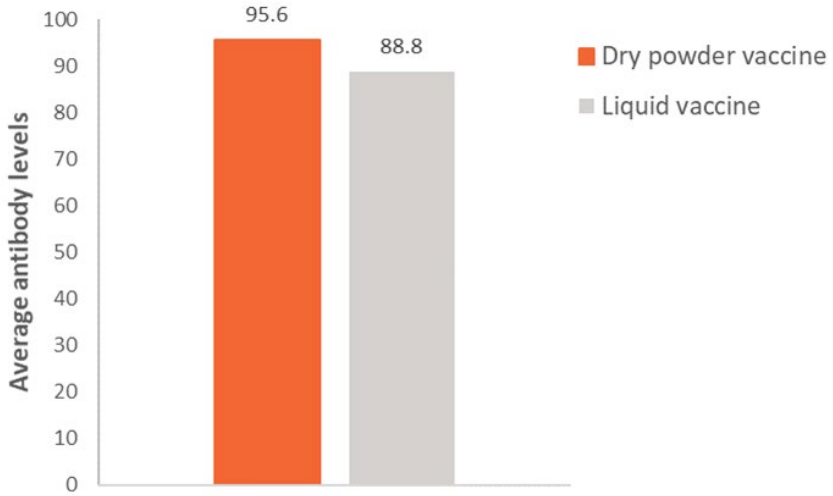


What were the main results of the study?

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

The researchers compared the babies who got the dry powdered vaccine with those who got the liquid vaccine. They found that average antibody levels were similar in the two groups of infants and would help protect against diarrhea caused by the virus. Anti-rotavirus antibody levels shown in Figure 2 (below) were measured 1 month after infants had received their 2nd vaccine dose.

Figure 2: Anti-rotavirus antibody levels 1 month after vaccination



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 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[1]" refer to those events that the study doctor thinks may have been caused by the study vaccine.

The researchers found that the 2 vaccines had similar side effects during the week after vaccination, when most side effects happen. Neither vaccine caused any serious side effects.

Table 1. Side effects in more than 1% of infants up to 8 days after vaccination

	Dry powder vaccine group (215 infants)	Liquid vaccine group (214 infants)
Cough/runny nose	7 (3%)	5 (2%)
Diarrhea	3 (1%)	5 (2%)
Fever (38°C and above)	25 (11%)	32 (14%)
Irritability/fussiness	43 (19%)	36 (16%)
Loss of appetite	8 (4%)	3 (1%)
Vomiting	15 (7%)	8 (4%)

[1] *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 showed that the liquid oral rotavirus vaccine worked as well as the dry powder vaccine. This can make it easier for infants to be vaccinated against rotavirus by eliminating the need to dissolve the dry powder in the oral liquid that comes with it.

Are there plans for further studies?

Other studies of the liquid rotavirus vaccine were ongoing and planned at the time this summary was prepared. Their results and those of any future studies will be available on the websites of European Medicines Agency and/or the United States National Institutes of Health. Links to this study are provided at the end of this summary.

Where can I find more information about this study?

The detailed title for this research study is:

A phase III, randomized, open study to assess the immunogenicity, reactogenicity and safety of two different formulations of GlaxoSmithKline (GSK) Biologicals' oral live attenuated human rotavirus (HRV) vaccine, *Rotarix,* when given as a two-dose primary vaccination, in healthy infants with no previous history of rotavirus illness or vaccination.

Organization	Website	Study Number
European Medicines Agency	www.clinicaltrialsregister.eu	2012-001875-35
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT02141204

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 October 2020. 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=2012-001875-35
US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT02141204