

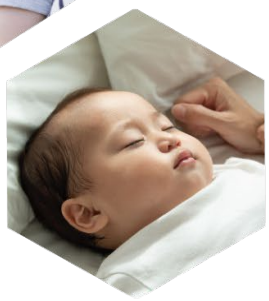

Who sponsored this study?

GlaxoSmithKline

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Can a rotavirus vaccine be given to healthy Japanese babies at the same time as a common 4-in-1 childhood vaccine?






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?

This study was done to find out if a rotavirus vaccine can be given to healthy Japanese babies at the same time as another vaccine that works against 4 diseases.

What was studied?

- Body defenses (antibodies) against 4 diseases (diphtheria, tetanus, whooping cough, and polio).
- Possible vaccine side effects.

Who was in this study?

The study included 292 healthy Japanese babies (155 boys and 137 girls).

What kind of study was it?

- Phase 4: both vaccines are already approved for use in babies in Japan.
- Randomized: Babies were placed in 2 vaccination groups by chance (like tossing a coin). One group got the two vaccines on the same day. The other group got them on different days.
- Open label: the study doctor and the babies' parents knew which vaccine they got.

Main results

- The babies in the 2 study groups made similar amounts of antibodies.
- Vaccine side effects in the two groups of babies were similar. There were no serious vaccine side effects.
- Rotavirus vaccine can be safely given on the same day as the 4-in-1 childhood vaccine.

NCT number: NCT02907216
EudraCT number: 2014-005282-78

General information about the research study

When was the study done?

The study started in September 2016 and ended in May 2017.

Why was this study done?

The researchers wanted to find out if the rotavirus vaccine and the 4-in-1 vaccine could be safely given at the same time to 3-month old Japanese babies. Giving the vaccines together could help make it easier for families by reducing the number of trips to the doctor.

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

Who took part in this study?

292 babies from **Japan**

6 to 12 weeks old when they started the study

137 girls (47%)

155 boys (53%)

Babies could take part in the study if:

- they were born full-term (after 37 to 42 weeks of pregnancy)
- their parents agreed that their babies could participate in the study

Babies could not take part in the study if they:

- had already been vaccinated against rotavirus, diphtheria, tetanus, whooping cough, and polio
- were previously sick with any of the 5 diseases covered by the vaccines

Which vaccines were studied?

Two vaccines were studied:

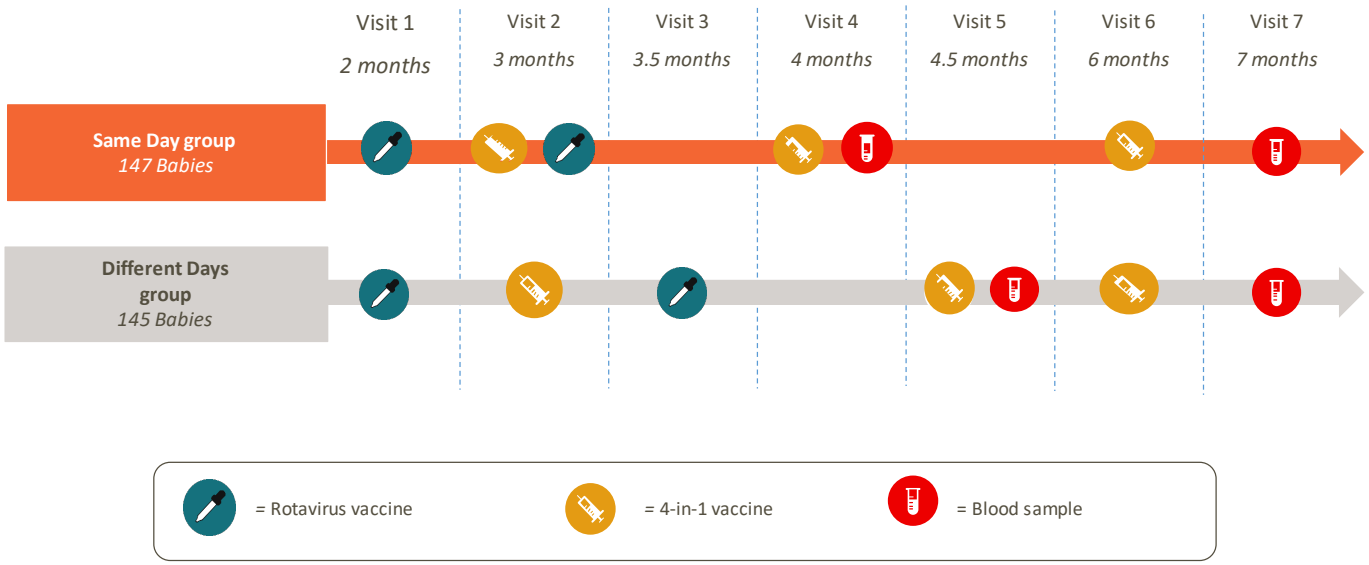
- The rotavirus vaccine helps prevent infection caused by rotavirus. It was given to the babies by mouth.
- The 4-in-1 vaccine, helps prevent 4 childhood diseases (diphtheria, tetanus, whooping cough, and polio). A shot of 4-in-1 vaccine was given in the upper arm or upper thigh.

How was the study done?

There were 2 groups: The **Same Day group** received the 2 vaccines on the same day. The **Different Days group** were given the 2 vaccines on different days.

Study doctors collected information on vaccine safety from parents and guardians of babies in 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, whooping cough, and polio were measured 1 month after the third shot of the 4-in-1 vaccine. All the babies in both study groups made similar amounts of antibodies.

Antibodies against diphtheria, tetanus, and polio

Most people are protected against diphtheria, tetanus, and polio (types 1, 2, and 3), if the average amounts of antibodies in their blood are above levels called **protective antibody levels**.

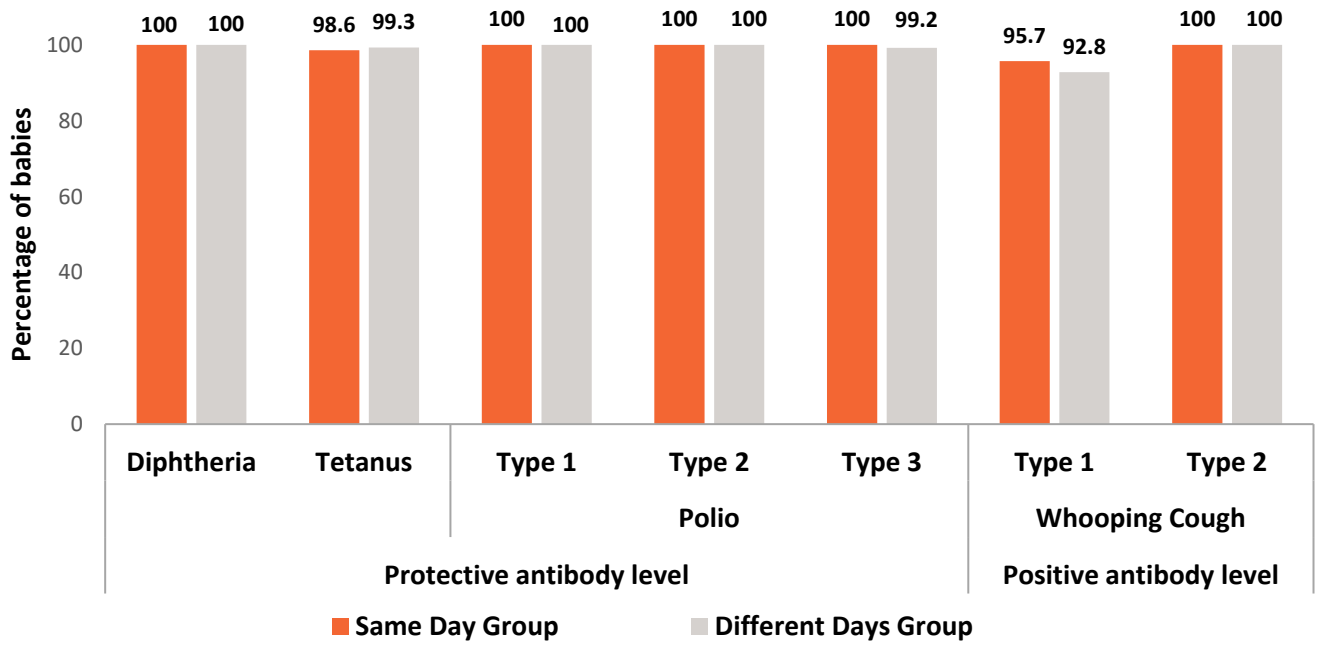
Antibodies against whooping cough

Most people may be protected if the average amounts of whooping cough antibodies in their blood are above levels called **positive antibody levels**.

Main results

The antibody results are illustrated in Figure 2, below.

Figure 2 Babies with protective or positive antibody levels



What were the side effects?[1]

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 doctors think that the adverse event was caused by the vaccine, they record it as a possible side effect.

Overall, side effects were similar between the 2 study groups (Table 1 and Table 2). The side effects reported in this study were already known reactions to the vaccine.

Side effects of the rotavirus vaccine

Irritability or fussiness was the most common side effect in babies in both groups.

Table 1 Side effects of the rotavirus vaccine

	Same Day group 147 babies	Different Days group 145 babies
Irritability/fussiness	51 (35%)	49 (34%)
Cough	12 (8%)	19 (13%)
Fever (38°C and above)	28 (19%)	19 (13%)
Diarrhea	19 (13%)	27 (19%)
Loss of appetite	17 (12%)	6 (4%)
Vomiting	9 (6%)	9 (6%)

Note: Some babies had more than one side effect

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

Side effects after the first 4-in-1 vaccine shot

The most common side effect where the shot was given (in the upper arm or upper thigh) was redness. The other most common side effect (not where the shot was given) was irritability or fussiness.

Table 2 Side effects of the 4-in-1 vaccine*

	Same Day group 147 babies	Different Days group 144 babies
Side effects at the site of injection		
Redness	85 (58%)	84 (58%)
Swelling	50 (34%)	44 (31%)
Pain	32 (22%)	24 (17%)
Skin thickening	1 (1%)	4 (3%)
Other side effects		
Irritability/fussiness	61 (42%)	59 (41%)
Drowsiness	37 (25%)	39 (27%)
Fever (38°C and above)	31 (21%)	32 (22%)
Loss of appetite	17 (12%)	18 (13%)

Note: Some babies had more than one side effect

*One baby in the Different Days Group did not finish the study.

How has this study helped patients and researchers?

This study tells us that doctors can give babies both vaccines on the same day and get results like those when the vaccines are given on different days. This could help make it easier for families by reducing the number of trips to the doctor.

Are there plans for further studies?

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

Where can I find more information about this study?

The detailed title for this research study is:

A phase IV, randomized, open-label, controlled study to assess the immunogenicity and safety of the diphtheria, tetanus, pertussis, and inactivated poliovirus (DPT-IPV) vaccine Squarekids when co-administered with GSK Biologicals' oral live attenuated HRV liquid vaccine Rotarix in healthy Japanese infants aged 6-12 weeks at the time of the first dose of HRV vaccination.

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	2014-005282-78
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT02907216

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 15 October 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=2014-005282-78

US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT02907216