Who sponsored this study?
GlaxoSmithKline

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A study of the safety of RSV vaccine in children

GSK would like to thank all the children 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.

General information about the research study

When was the study done?

The study started in January 2017 and ended in November 2020.

Why was this study done?

RSV (respiratory syncytial virus) can infect the airways and lungs. RSV is spread from person to person mostly by coughing and sneezing. It may lead to a runny nose, fever, cough, difficulty in breathing and loss of appetite. Infants, young children and older people are most likely to have a severe RSV infection. In young children, this severe infection can cause wheezing and difficulty breathing and might even require a child to be admitted to the hospital. More than half of all infants are infected with RSV during the first year of their lives. Almost all children are infected with RSV by their second birthday. Vaccines may be a way to help protect against RSV. They contain parts of RSV that cannot cause infection. These parts help the body make defenses, known as antibodies, against RSV.

The main goal of the study was to assess the safety of RSV 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?

82 children from 8 countries

12 to 23 months old when they got their first vaccination

41 girls (50%)

41 boys (50%)

Children could take part in the study if they:

- were in good health
- were born full-term
- had RSV antibodies in their blood
- were allowed by their parents to participate in the study

Children could not take part in the study if they:

- had birth defects or a weak immune system
- received any experimental vaccine or a drug within 30 days before study

Which vaccines were studied?

RSV vaccine: a vaccine that has been developed to protect against RSV infections. This vaccine was given by injection into the arm.

Placebo: a saline water solution. The placebo was given by injection into the arm.

How was the study done?

Figure 1 describes which vaccines children in each study group got and when they got them. It also shows when blood samples were taken. These samples were taken to measure antibodies and other blood components. Study doctors also collected information on the safety of the vaccine.

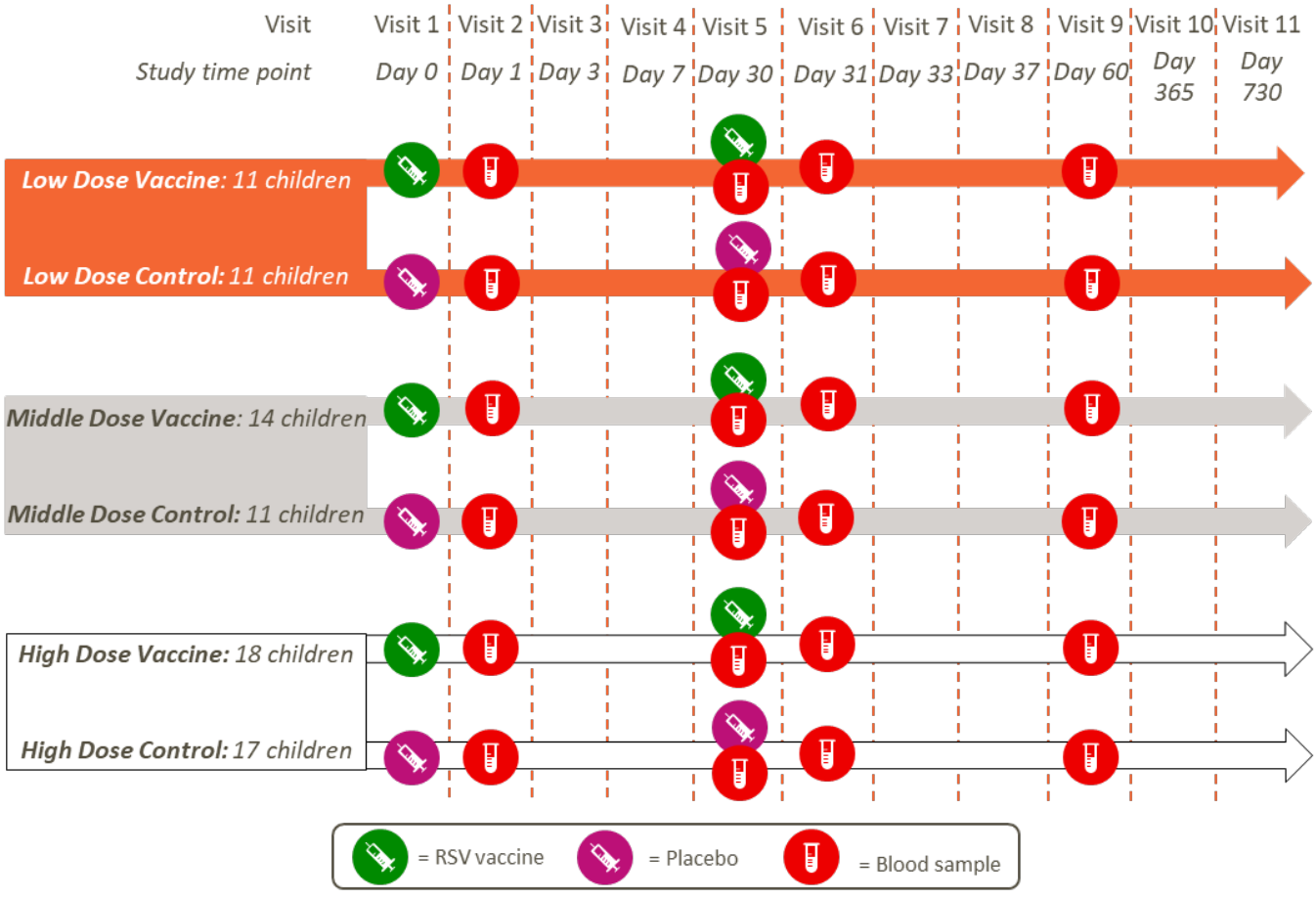
This study compared different doses of RSV vaccine with the placebo. Children were assigned to one of the six study groups, as shown in Figure 1.

The study took approximately 2 years for all children.

The children were assigned to a study group by chance (like tossing a coin).]

Neither the study staff nor the parents knew which treatment the children 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 RSV vaccine

The main goal of the study was to assess the safety of RSV 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.

Redness was the most frequently reported medical event at the place of injection after vaccination (Figure 2a).

Drowsiness was the most frequently reported other medical event after vaccination (Figure 2a).

No study participant withdrew from the study because of a vaccine side effect.

None of the serious medical events were considered to be caused by the study vaccine (Figure 2b).

The analysis of blood components did not reveal any safety concerns.

This study did not raise any safety concerns about the RSV vaccine. The side effects reported in this study are expected reactions to the RSV vaccine.

Figure 2a: All medical events (including side effects) reported for at least 2 children

	Low Dose Vaccine 11 children	Low Dose Control 11 children	Middle Dose Vaccine 14 children	Middle Dose Control 11 children	High Dose Vaccine 18 children	High Dose Control 17 children
	Medical events at the site of injection					
Redness	2 (18%)	3 (27%)	2 (15%)	0	4 (22%)	4 (24%)
Pain	3 (27%)	2 (18%)	3 (23%)	0	2 (11%)	4 (24%)
Swelling	0	<2	0	<2	<2	3 (18%)
	Other medical events					
Drowsiness	5 (46%)	6 (55%)	3 (23%)	5 (46%)	6 (33%)	6 (35%)
Loss of appetite	4 (36%)	5 (46%)	3 (23%)	4 (36%)	8 (44%)	7 (41%)
Irritability / Fussiness	4 (36%)	7 (64%)	4 (31%)	3 (27%)	6 (33%)	6 (35%)
Fever (37.5°C and above)	4 (36%)	4 (36%)	5 (39%)	3 (37%)	11 (61%)	<2
Common cold	2 (18%)	0	6 (43%)	4 (36%)	7 (39%)	5 (29%)
Diarrhea	2 (18%)	2 (18%)	2 (14%)	2 (18%)	0	3 (18%)
Stomach infection	0	0	<2	3 (27%)	4 (22%)	<2
Decreased appetite	<2	0	0	0	2 (11%)	3 (18%)
Cough	0	0	0	2 (18%)	2 (11%)	<2
Raised temperature	2 (18%)	<2	0	2 (18%)	0	<2
Conjunctivitis	3 (27%)	0	0	0	0	0
Vomiting	<2	<2	0	0	2 (11%)	0
Skin infection	0	0	0	0	2 (11%)	0
Flu	0	0	0	<2	2 (11%)	0

**Some volunteers had more than one side effect*

Figure 2b: Medical events of specific interest and serious medical events

	Low Dose Vaccine 11 children	Low Dose Control 11 children	Middle Dose Vaccine 14 children	Middle Dose Control 11 children	High Dose Vaccine 18 children	High Dose Control 17 children
Medical events of specific interest						
RSV infection	0	2 (18%)	1 (7%)	0	0	0
Bronchitis	0	1 (9%)	0	0	0	0
Coronivirus infection	0	1 (9%)	0	0	0	0
RSV bronchiolitis	0	1 (9%)	0	0	0	0
Tonsilitis	0	1 (9%)	0	0	0	0
Serious medical events						
RSV infection	0	2 (18%)	1 (7%)	0	0	0
Gastroenteritis	0	0	0	0	2 (11%)	0
Raised temperature	0	0	0	1 (9%)	0	0
Bronchitis	0	1 (9%)	0	0	0	0
Coronavirus infection	0	1 (9%)	0	1 (9%)	0	0
Enterovirus infection	0	0	0	1 (9%)	0	0
Urinary tract infection	1 (9%)	0	0	0	0	0
Herpangina	0	0	0	0	0	1 (6%)
Pneumonia	0	0	0	0	0	1 (6%)
RSV bronchiolitis	0	1 (9%)	0	0	0	0
Rhinovirus infection	0	0	0	1 (9%)	0	0
Tonsilitis	0	1 (9%)	0	0	0	0
Febrile convulsions	0	0	0	0	1 (6%)	0
Unresponsive to stimuli	0	0	0	1 (9%)	0	0

**Some volunteers had more than one side effect*

How has this study helped patients and researchers?

The results from this study indicate that RSV vaccine was safe when given to children.

This summary only shows results from one study. Other studies may find different results. Combined with results from other research studies, the findings from this study may help improve the understanding of RSV vaccine and RSV infections.

Are there plans for further studies?

At the time of preparation of this summary, other studies were ongoing to further evaluate RSV 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 1/2, randomized, observer-blind, controlled, multi-center, dose-escalation study to evaluate safety, reactogenicity and immunogenicity of GSK Biologicals' respiratory syncytial virus (RSV) investigational vaccine based on the RSV viral proteins F, N and M2-1 encoded by chimpanzee-derived adenovector (ChAd155-RSV) (GSK3389245A), when administered intramuscularly according to a 0, 1-month schedule to RSV-seropositive infants aged 12 to 23 months.

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	2016-000117-76
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT02927873

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.

Version 1 of this document was developed and approved by GSK on 25 October 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/trial/2016-000117-76/results
US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT02927873?term=204838&draw=2&rank=1