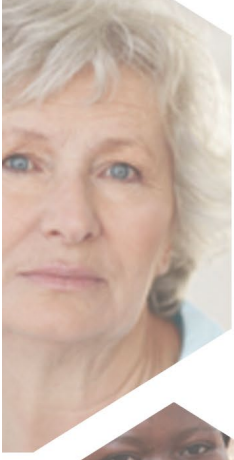
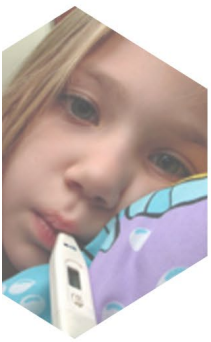






Who sponsored this study?
GlaxoSmithKline

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

A study of the safety of RSV 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.

General information about the research study

When was the study done?

The study started in April 2019 and ended in July 2021.

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.

This study compared 2 different doses (low and high) of RSV vaccine with placebo or other childhood vaccines.

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

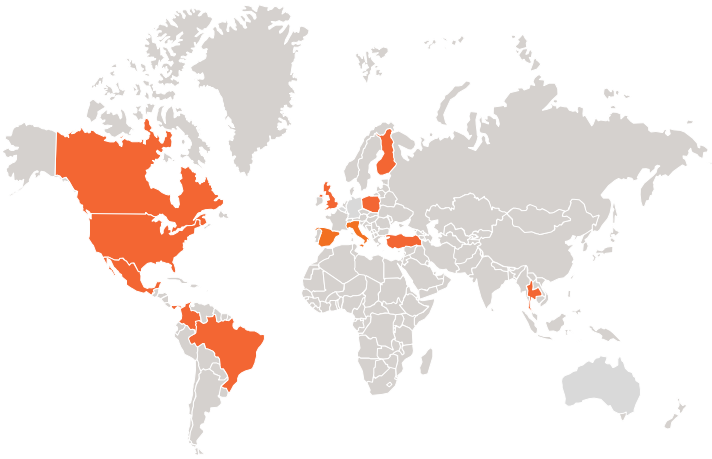
Who took part in this study?

201 babies from **13 countries**

6 to 7 months old when they got their first vaccination

96 girls (48%)

105 boys (52%)



Babies could take part in the study if they:

- were in good health
- were born full-term, weighing at least 2.5 kg (5.5 pounds)
- were between 6 and 7 months of age
- were allowed by their parents to participate in the study

Babies could not take part in the study if they:

- previously had RSV infection
- had birth defects or a weak immune system
- received any investigational product within 30 days before study
- 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.

Other childhood vaccines: four different vaccines that are routinely given to children were used. These included vaccines that have been developed to protect against pneumonia, and meningitis caused by bacteria of different types (A, B, C, W and Y).

Placebo: an inactive solution. The placebo was given by injection into the thigh.

How was the study done?

Figure 1 describes which vaccines babies in each study group got and when they got them.

This study compared 2 different doses (low and high) of RSV vaccine with placebo or other childhood vaccines. Babies were assigned to different groups, as shown in Figure 1.

The low-dose RSV vaccine was given as a single dose, and the high-dose RSV vaccine was given as 2 doses, along with either placebo or childhood vaccines as recommended locally.

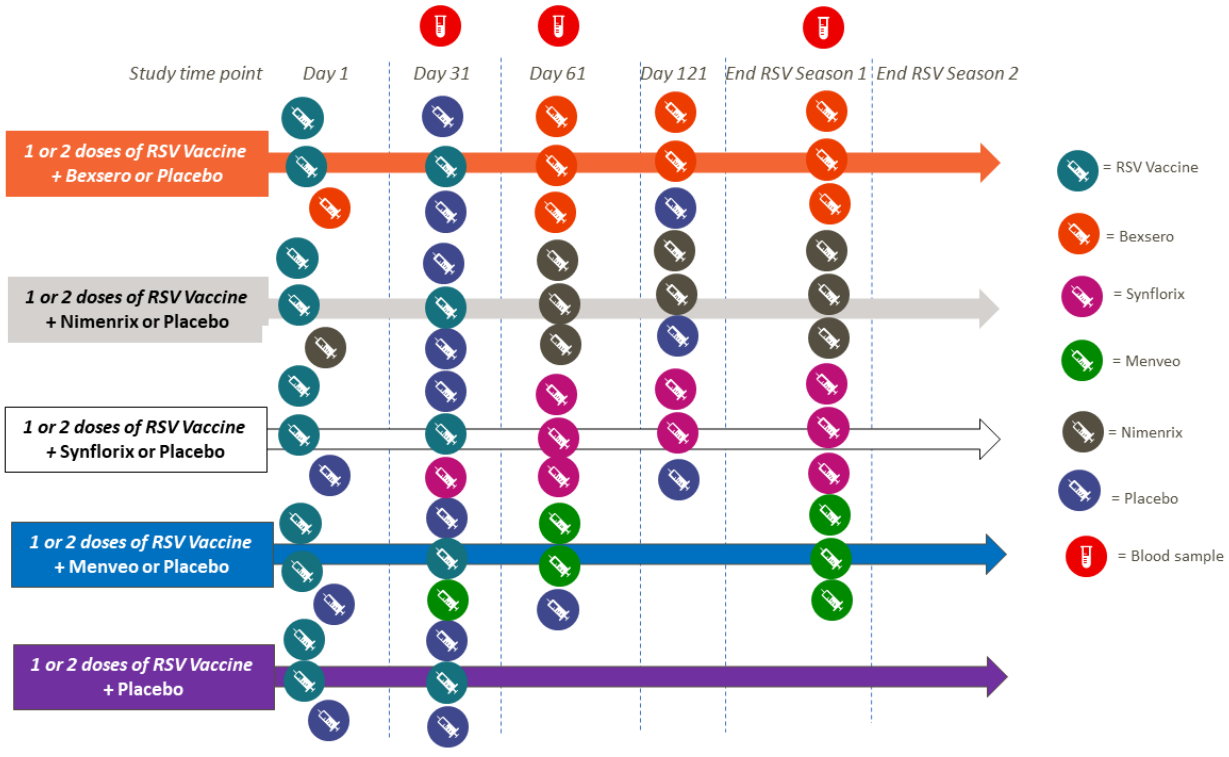
It also shows when blood samples were taken. These samples were taken to measure antibodies and other blood components. Study doctors also collected information on the safety of the vaccine.

The study took approximately 2 years for all babies.

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

Neither the study staff/GSK nor the parents knew which treatment 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 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.

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.

Pain and redness were the most frequently reported side effect at the place of injection after vaccination (Figure 2).

Drowsiness was the most frequently reported other side effect during the 7 days after vaccination (Figure 2).

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

Serious medical events possibly caused by the RSV vaccine were reported in less than 1% of babies and were resolved.

This study did not raise any safety concerns about the RSV vaccine.

Figure 2: Side effects reported for at least 2 babies

	RSV Vaccine 1 Dose 65 babies	RSV Vaccine 2 Dose 71 babies	Placebo 22 babies	Childhood Vaccines Comparator 42 babies
	Side effects at the site of injection			
Pain	13 (20%)	12 (17%)	1 (4%)	18 (43%)
Redness	9 (14%)	11 (15%)	0 (0%)	26 (62%)
Swelling	3 (5%)	4 (6%)	2 (9%)	16 (38%)
	Other side effects			
Drowsiness	18(28%)	29 (41%)	8 (36%)	18 (43%)
Irritability / Fussiness	34 (52%)	41 (58%)	9 (41%)	27 (64%)
Loss of appetite	17 (26%)	32 (45%)	8 (36%)	17 (40%)
Fever (38°C and above)	15 (23%)	37 (52%)	5 (23%)	16 (38%)

**Some volunteers had more than one side effect*

**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?

The results from this study show that RSV vaccine was safe when given to babies. 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, no other studies to evaluate RSV vaccine were ongoing or planned. New studies with RSV vaccine may be planned in the future.

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.

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 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 as a single dose or as two doses according to a 0, 1- month schedule**,** to infants aged 6 and 7 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	2018-000431-27
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT03636906

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 22 April 2022. 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=2018-000431-27
US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT03636906