Who sponsored this study?
GlaxoSmithKline

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A study of the safety and immune response of RSV vaccine in pregnant mothers and their babies

GSK would like to thank all those who took part in this clinical study. 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 November 2019 and ended in May 2021.

Why was this study done?

RSV (respiratory syncytial virus) can infect the airways and lungs. Infants, young children and older people are most likely to have a severe RSV infection. 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. RSV is spread from person to person by coughing and sneezing. It leads to a runny nose, fever, cough, and loss of appetite. Vaccines can 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.

Newborns and young babies are at increased risk of developing severe RSV disease. One possibility to protect babies is to vaccinate their mothers against RSV during pregnancy. The mother's antibodies may be passed to the baby before birth, offering some protection during the first months of life.

The main goals of the study were to:

- Look at the safety of RSV vaccine when it is administered to the pregnant mothers - for both mother and baby.
- Check levels of two different types of RSV antibodies in pregnant mothers
- Check if pregnant mothers who got the RSV vaccine passed RSV antibodies to their newborns and check the levels of these antibodies in the babies.

Study doctors collected information about potential side effects to the vaccines given in this study. The results can be found in the section "What were the side effects?".

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?

213 pregnant mothers and 206 babies born to them from 9 countries

18 to 40 years old pregnant mothers

111 male babies (54%)

95 female babies (46%)

Pregnant mothers could take part in the study if they:

- were in good health

Pregnant mothers could not take part in the study if they:

- had significant complications in the current pregnancy

- allowed their babies to take part in this study
- allowed cord blood to be collected from them

- were carrying more than one baby
- had HIV, hepatitis B or hepatitis C infections
- had any genetic or congenital abnormalities of the fetus detected during their pregnancy
- had a history of stillbirth, preterm birth or multiple miscarriages

Which vaccines were studied?

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

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

How was the study done?

Figure 1a describes which vaccines pregnant mothers in each study group got and when they got them.

Two different dose levels of RSV vaccine were tested: 60 micrograms and 120 micrograms. Pregnant mothers in the Control group received placebo.

The pregnant mothers were assigned to a study group by chance (like tossing a coin). The study staff knew which treatment pregnant mothers got; however pregnant mothers and the study doctors did not know which treatment they got.

Figure 1a and 1b also show when blood samples were taken. Blood from the umbilical cord (called cord blood) was taken at delivery. These samples were taken to measure antibodies. Study doctors also collected information on the safety of the vaccine.

The pregnant mothers were followed for 6 months after delivery. Their infants were followed for one year after birth.

Figure 1a: Study design for mothers

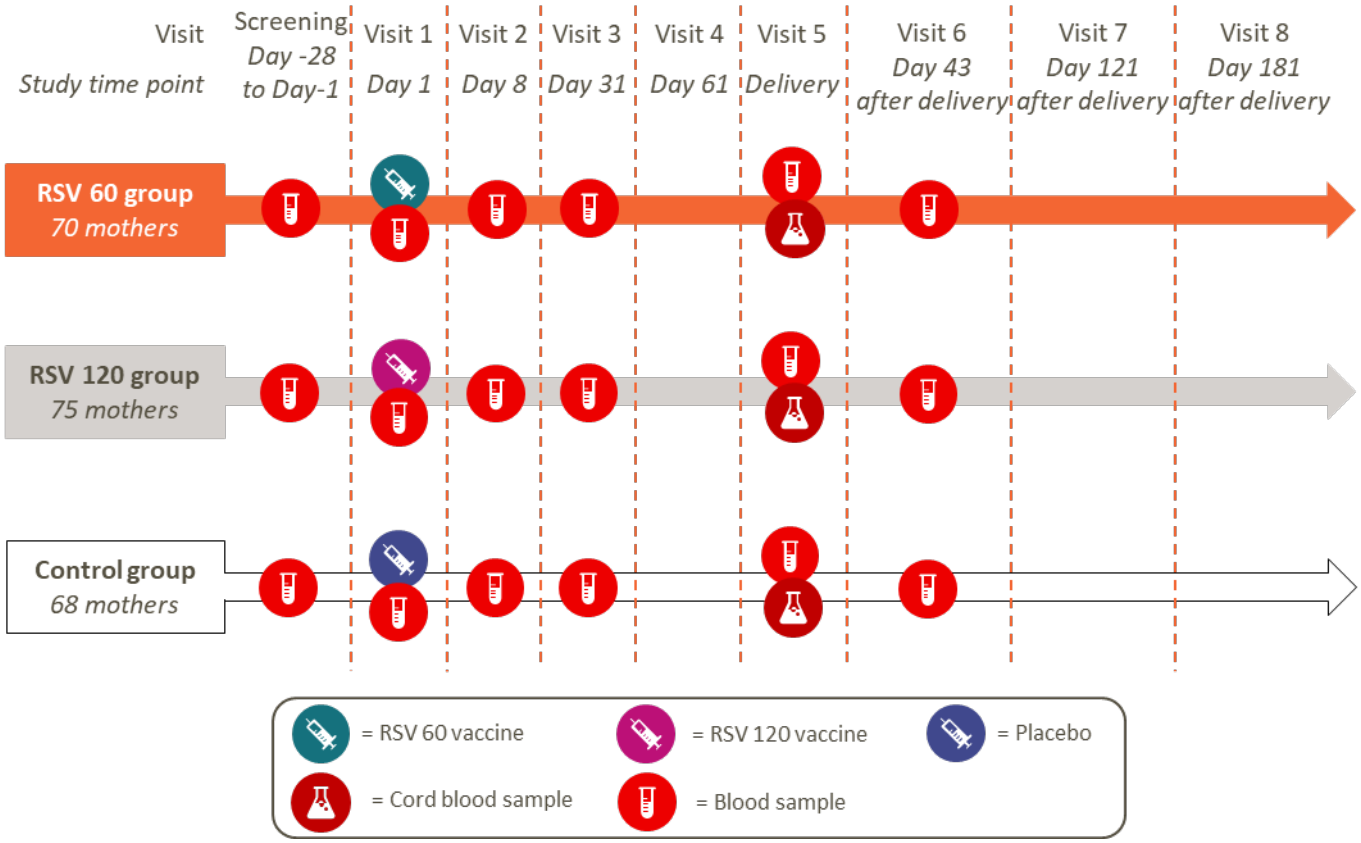
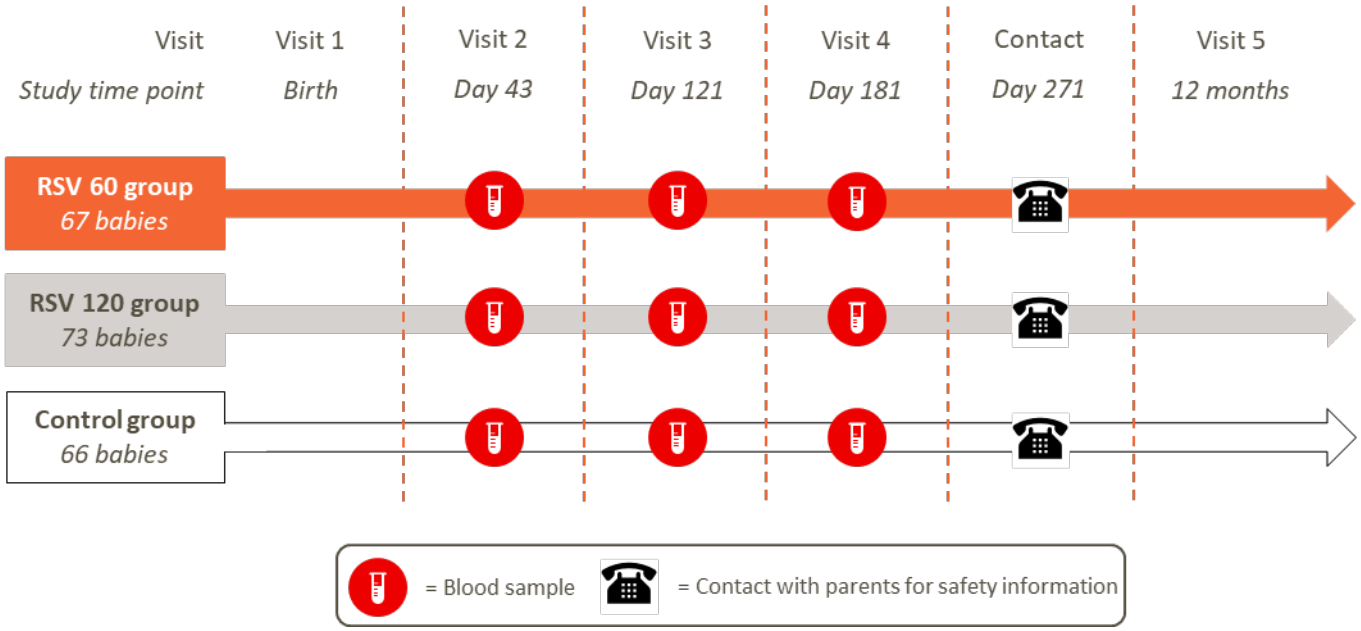


Figure 1b: Study design for babies



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**.*

RSV antibodies in mothers and babies

Average levels of the two types of RSV antibodies in mothers and babies were measured.

Levels of both types of antibodies were increased in vaccinated mothers. Antibodies were successfully passed from mothers to all babies.

What were the side effects?

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.

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

Pain at the place of injection was the most frequently reported side effect by pregnant mothers within the first 7 days after vaccination (Figure 2a).

Pregnant mothers reported throat pain as the most frequently experienced medical event within one month after RSV vaccine (Figure 2b).

Serious medical events up to 6 weeks after delivery were reported by:

- 30% pregnant mothers in the RSV 60 group,
- 27% pregnant mothers in the RSV 120 group, and
- 22% pregnant mothers in the Control group.

Serious medical events up to one year after birth were reported for:

- 25% babies in the RSV 60 group,
- 29% babies in the RSV 120 group, and
- 32% babies in the Control group.

None of the serious medical events were considered to be caused by the study vaccine.

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.

Additional safety results may be found in the ***clinical results summary***.

Figure 2a: Side effects reported by mothers within 7 days after vaccination

	RSV 60 group 70 mothers	RSV 120 group 75 mothers	Control group 66 mothers
	Side effects within 7 days after vaccination		
Pain	40 (57%)	39 (52%)	10 (15%)
Tiredness	28 (40%)	26 (35%)	17 (26%)
Headache	24 (34%)	21 (28%)	13 (20%)
Nausea	18 (26%)	17 (23%)	9 (14%)
Diarrhea	10 (14%)	13 (17%)	9 (14%)
Stomach pain	9 (13%)	17 (23%)	6 (9%)
Vomiting	5 (7%)	7 (9%)	3 (5%)
Redness	1 (1%)	5 (7%)	0
Swelling	3 (4%)	3 (4%)	0

**Some volunteers had more than one side effect*

Figure 2b: Medical events reported by mothers within one month of vaccination

	RSV 60 group 70 mothers	RSV 120 group 75 mothers	Control group 68 mothers
	Medical events within one month after vaccination		
Throat pain	1 (1%)	3 (4%)	2 (3%)
Common cold	0	1 (1%)	4 (6%)
Urinary tract infection	2 (3%)	1 (1%)	2 (3%)
Influenza	0	3 (4%)	1 (2%)
Pain in the abdomen	0	1 (1%)	3 (4%)
Back pain	1 (1%)	3 (4%)	0
Headache	1 (1%)	2 (3%)	1 (2%)
Upper respiratory tract infection	0	2 (3%)	1 (2%)
Swelling of hands or legs	2 (3%)	0	1 (2%)
Dizziness	2 (3%)	0	1 (2%)
Tiredness	0	2 (3%)	0
Uterine contractions during pregnancy	0	2 (3%)	0

**Some volunteers had more than one side effect*

How has this study helped patients and researchers?

The results from this study indicate that antibodies are produced by the mothers after vaccination with RSV vaccine. These antibodies are passed from mothers to their babies. This study did not raise any safety concerns about the RSV vaccine.

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 II, randomised, observer-blind, placebo controlled multi-country study to assess the safety, reactogenicity and immunogenicity of a single intramuscular dose of GSK Biologicals' investigational RSV Maternal unadjuvanted vaccine (GSK3888550A), in healthy pregnant women aged 18 to 40 years and infants born to vaccinated mothers.

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	2019-001991-12
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT04126213

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 1.1 of this document was developed and approved by GSK on 2 December 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=2019-001991-12US
NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT04126213?term=209544&cond=RSV&draw=2&rank=1