Who sponsored this study?
GlaxoSmithKline

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A study of the safety and immune response of an RSV vaccine in older adults.

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 December 2020 and ended in October 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 and older adults are most likely to have a severe RSV infection. 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.

In an earlier study, 2 doses of different recipes of RSV older adult (OA) vaccine were given to older adults and their immune response and safety were studied. Based on the results of that study, a high-dose recipe was selected.

The main goal of this study was to see the safety and immune response to a third dose of the high-dose recipe of RSV OA vaccine in the same older adults.

Study doctors also 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?

122 older adults from United States and Belgium.

60 years and older when they got vaccinated.

72 women (59%)

50 men (41%)

Older adults could take part in the study if they:

- received 2 doses of different recipes of RSV OA vaccine in the previous study
- were medically stable

Older adults could not take part in the study if they:

- had a weak immune system
- were bed-ridden
- received any investigational product within 30 days before the study

Which vaccines were studied?

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

How was the study done?

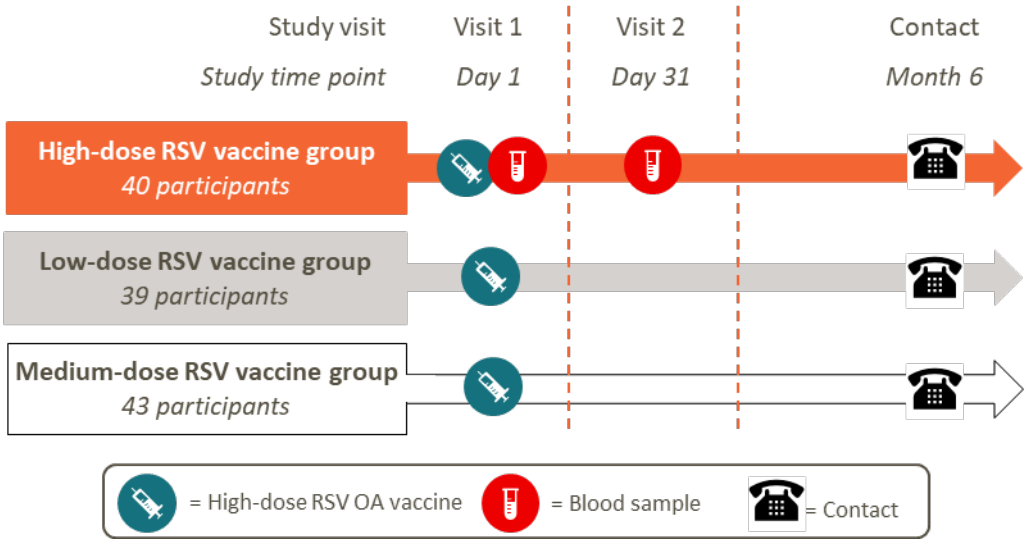
The older adults who joined this study remained in the same groups as the previous study. They all received the high-dose recipe of the RSV OA vaccine in this study (Figure 1).

Figure 1 also shows when blood samples were taken. These samples were taken to measure antibodies. Study doctors also collected information on the safety of the vaccine.

The study took approximately 6 months for all older adults.

Both the study team and the older adults knew which treatment the older adults 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****.*

The main goal of the study was to look at the safety and immune response to a third dose of RSV OA vaccine in older adults who had received 2 doses of this vaccine in a previous study.

RSV antibody levels

There were 3 types of RSV antibodies measured. Older adults in the high-dose RSV vaccine group showed an increase in all types of RSV antibodies after vaccination with the third dose of RSV OA vaccine.

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.

Pain was the most frequently reported side effect at the place of injection after RSV OA vaccination (Figure 2).

Headache was the most frequently reported other side effect after vaccination (Figure 2).

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

The results from this study did not raise any concern regarding the safety of RSV OA vaccine.

Figure 2: Side effects reported by at least 2 participants

	High-dose RSV vaccine group 40 participants	Low-dose RSV vaccine group 39 participants	Medium-dose RSV vaccine group 43 participants
Side effects reported within 4 days after injection			
Pain	21 (53%)	23 (59%)	26 (61%)
Redness	1 (3%)	6 (15%)	5 (12%)
Swelling	0	2 (5%)	4 (9%)
Fever (38°C and above)	1 (3%)	1 (3%)	4 (9%)
Side effects reported up to 30 days after injection			
Headache	1 (3%)	4 (10%)	1 (2%)
Chills	0	2 (5%)	2 (5%)
Tiredness	0	0	3 (7%)
Flu-like illness	0	2 (5%)	2 (5%)

Note: Some volunteers had more than one side effect. Side effects reported by less than 2 participants in all the groups are not listed above but can be found in the clinical trial summaries.

How has this study helped patients and researchers?

The results from this study did not raise any concern regarding the safety of RSV OA vaccine when a third dose of the vaccine was given to older adults. The older adults in the high dose group were able to produce antibodies after the third dose.

This summary only shows results from one study. Other studies may find different results.

The results from this and other studies will be submitted to regulatory agencies for evaluation and, if approved, will enable health care professionals to administer the RSV OA vaccine in older adults.

**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.*

Are there plans for further studies?

At the time of preparation of this summary, other studies were ongoing to further evaluate the RSV OA 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.

Where can I find more information about this study?

The detailed title for this research study is:

A phase 2b, open-label, multi-center, extension study to evaluate the safety and immunogenicity of a revaccination dose of the RSVPreF3 older adults (OA) investigational vaccine administered intramuscularly 18 months post-Dose 2 in adults 60 years and older who participated in the RSV OA=ADJ-002 study.

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	2020-000692-21
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT04657198

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 01 of this document was developed and approved by GSK on 09 May 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/trial/2020-000692-21/BE

US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT04657198