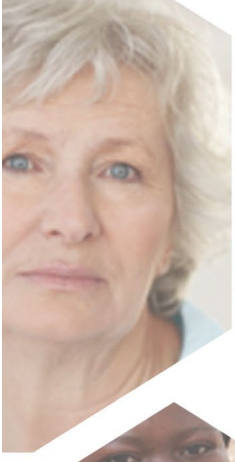



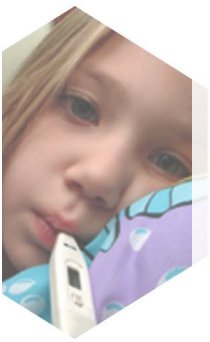

Who sponsored this study?
GlaxoSmithKline

Clinical Support Help Desk
- http://www.clinicalsupporthd.gsk.com
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A study of the immune response to a shingles vaccine when given together with a pneumococcal vaccine in 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 April 2018 and ended in March 2020.

Why was this study done?

The main goal of the study was to see if the immune responses to a shingles vaccine when given together with a pneumococcal vaccine are similar to immune responses when each vaccine is given separately

Study doctors also collected information about potential side effects to the vaccines given in this study.

Shingles is a disease of the nervous system caused by shingles virus. Shingles results in fever, headache, chills and upset stomach. Vaccines can help protect against shingles. Vaccines contain parts of shingles virus that cannot cause infection. These parts help the body make defenses, known as antibodies, against the shingles virus.

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?

912 adults from the US, Canada, Germany and Estonia.

50 years and older when they got their first vaccination.

543 women (60%)

369 men (40%)

Adults could take part in the study if they:

- did not have pneumonia infection within the last 5 years from the start of the study, and had never had shingles

Adults could not take part in the study if they:

- previously received the shingles vaccine
- previously received any pneumococcal vaccine
- received any drugs or medicines that may change their immune response to the study vaccines

Which vaccines were studied?

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

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

How was the study done?

Adults were given shingles vaccine and pneumococcal vaccine either on the same day ('Same day' group) or on different days ('Different days' group).

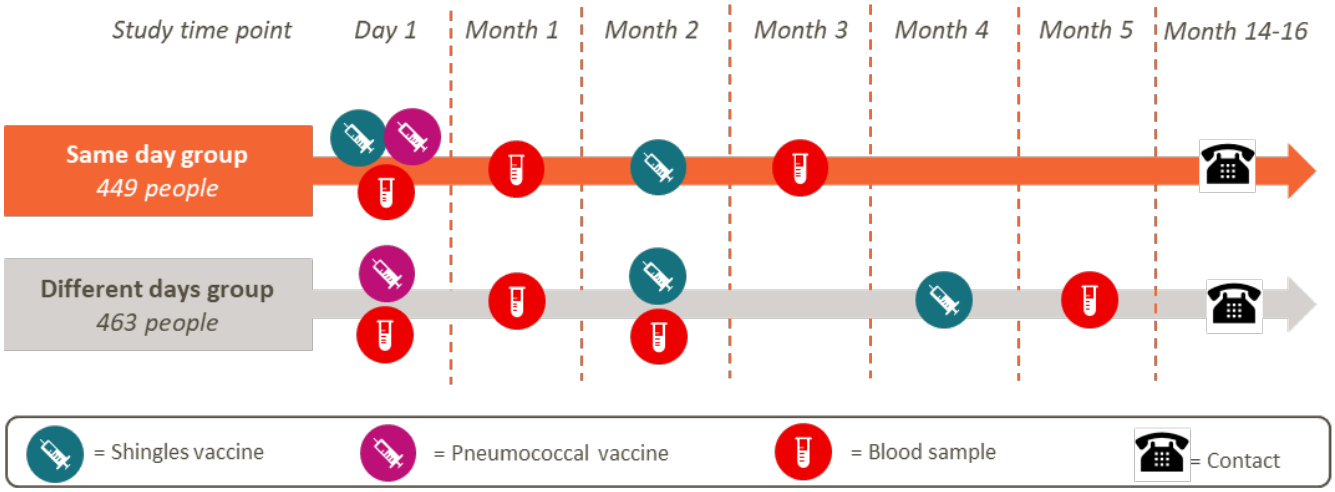
Figure 1 describes which vaccines adults in each study group got and when they got them. It also shows when blood samples were taken. These samples were taken to measure antibodies. Study doctors also collected information on the safety of the vaccine.

The study took approximately 14 months for adults in the 'Same day' group and approximately 16 months for adults in the 'Different days' group.

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

Both the study staff and the study participants knew which treatment they 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****.*

Immune responses to shingles and pneumococcal vaccines

The main goal of the study was to see if the immune responses to a shingles vaccine when given together with a pneumococcal vaccine are similar to immune responses when each vaccine is given separately.

The immune responses in both the study groups were similar (Figure 2a, 2b).

Figure 2a: Average levels of shingles antibodies

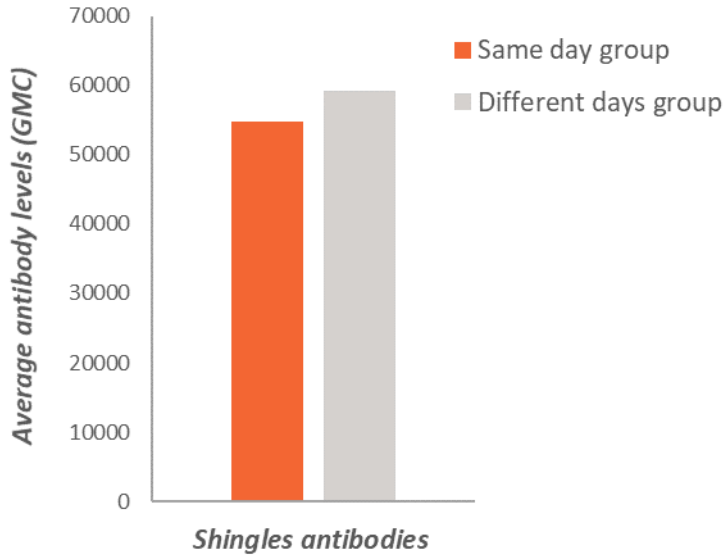
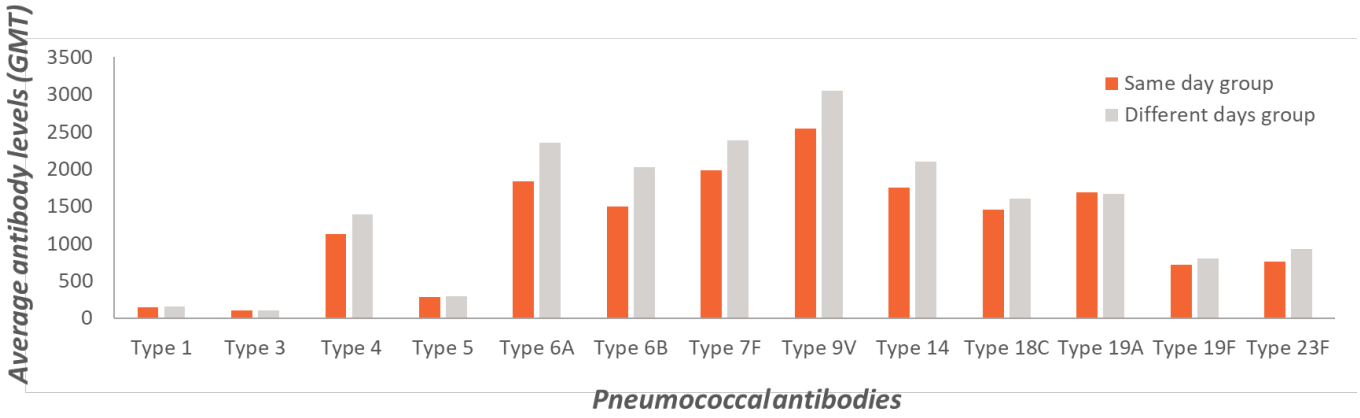


Figure 2b: Average levels of pneumococcal antibodies



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 (arm) after vaccination with both shingles vaccine and pneumococcal vaccine (Figure 3a).

Muscle pain was the most frequently reported other side effect after vaccination (Figure 3b).

The results from this study did not raise any concern regarding the safety of shingles vaccine and the pneumococcal vaccine. The side effects reported in this study are known reactions to both vaccines. There was no serious side effect to the shingles vaccine and the pneumococcal vaccine. No study participant withdrew from the study because of a vaccine 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.*

Less than 2% of study participants reported a serious medical event. None of them were believed to be caused by the study vaccines.

Figure 3a: Side effects at the site of injection in at least 2% of people

	Same day group 447 people	Different days group 463 people	Same day group 447 people	Different days group 463 people
	Shingles vaccine		*Pneumococcal vaccine*	
Pain	372 (83%)	385 (84%)	233 (52%)	241 (52%)
Redness	185 (41%)	177 (39%)	48 (11%)	31 (7%)
Swelling	100 (22%)	103 (23%)	33 (7%)	21 (5%)

**Some volunteers had more than one side effect*

Figure 3b: Other side effects in at least 2% of people

	Same day group 447 people	Different days group 463 people
	Shingles vaccine + Pneumococcal vaccine	
Muscle pain	238 (53%)	268 (58%)
Tiredness	225 (50%)	244 (53%)
Headache	190 (42%)	219 (47%)
Shivering	126 (28%)	138 (30%)
Stomach conditions	93 (21%)	105 (23%)
Fever (38°C and above)	16 (4%)	19 (4%)

**Some volunteers had more than one side effect*

How has this study helped patients and researchers?

The results from this study indicate that giving shingles vaccine together with a pneumococcal vaccine does not impact the immune response to the vaccines in adults. The results from this study did not raise any concern regarding the safety of shingles vaccine and the pneumococcal vaccine.

The results from this study will be submitted to regulatory agencies for evaluation and, if approved, will enable health care professionals to give shingles vaccine together with a pneumococcal vaccine to adults.

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Are there plans for further studies?

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

**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.*

Where can I find more information about this study?

The detailed title for this research study is:

A Phase IIIB, randomized, open-label, multicenter clinical trial to assess the immunogenicity and safety of GSK Biologicals' Herpes Zoster vaccine GSK1437173A when co-administered with *Prevenar 13* in adults aged 50 years and older.

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	2017-001220-22
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT03439657

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 21 June 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=2017-001220-22
US NIH/clinicaltrials.gov:
https://www.clinicaltrials.gov/ct2/show/NCT03439657?term=NCT03439657&draw=2&rank=1