

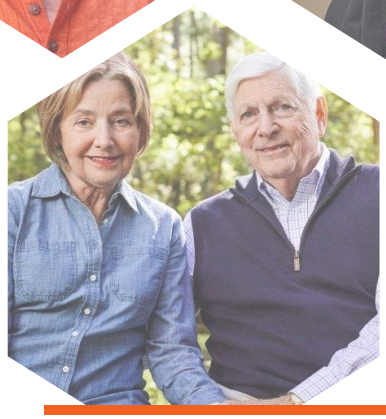


Who sponsored this study?
GlaxoSmithKline

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

Is the new shingles vaccine safe and effective in older adults who had received a different shingles vaccine before this study?



GSK would like to thank all the adults 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.

Overview

Why was this study done?

This study was done to learn how well a new shingles vaccine works in older adults who had already received a different shingles vaccine.

What was studied?

- Body defenses (such as antibodies) against shingles.
- Possible side effects of the new vaccine.

Who was in this study?

- 430 older adults (210 men and 220 women) from the United States.

What kind of study was it?

- Open-label: Both study doctors and the adults in the study knew the vaccine which was given.
- Phase 3 study: The new vaccine was not yet approved for general use when this study was done.
- Controlled: The researchers compared 2 groups of adults. Both got the new vaccine. One group had also been given a different shingles vaccine 5 or more years before the study started. They were compared with the other group, which had not been given the different vaccine.

Main results

- Both groups of adults responded well to the new vaccine whether or not they had received the other shingles vaccine before the study.
- The 2 groups of adults had similar side effects. Most side effects were those that are typically associated with the vaccine. This study did not raise any safety concerns.

NCT number: NCT02581410

General information about the research study

When was the study done?

The study started in December 2015 and ended in August 2017.

Why was this study done?

This study was done:

- To see how well the new vaccine works in adults who had received another shingles vaccine 5 or more years before the study started.
- To collect side effect information on the new vaccine.

After a chickenpox infection, the virus stays in the body. It may become active again many years later to cause shingles (also called herpes zoster). Vaccines make the body create defenses against bacteria and viruses. A vaccine that increases the body's defenses against the shingles virus may prevent shingles from developing. The vaccine may also ease shingles symptoms.

People over age 50 are more likely to develop shingles. Shingles causes a painful rash and blisters that can last for 2 to 4 weeks or more. Sometimes, the pain lasts for months or years after the rash is gone.

Who took part in this study?

430 adults from the United States

65 to 87 years old when they got the first shot of the new shingles vaccine

220 women (51%)

210 men (49%)

Adults could take part in the study if they:

- were at least 65 years old
- were in good health

Adults could not take part in the study if they:

- received the different shingles vaccine less than 5 years before the study started
- had planned to take another shingles vaccine during the study

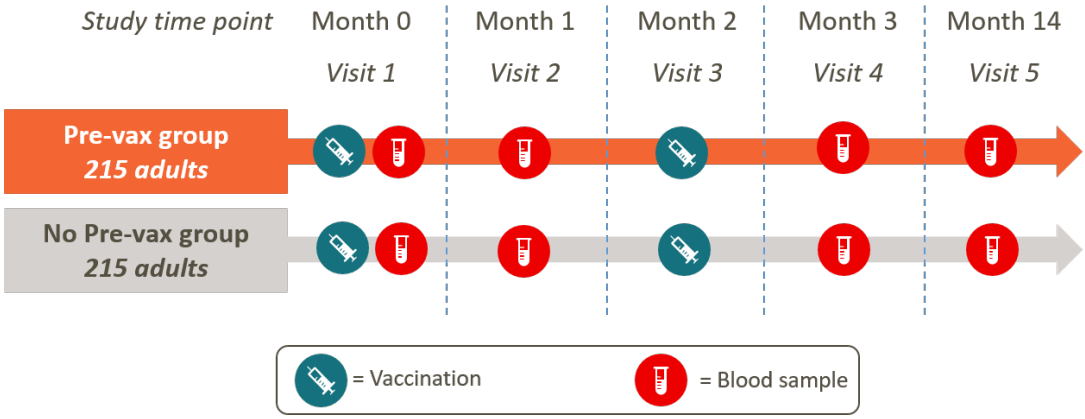
Which vaccines were studied?

A new shingles vaccine was studied.

How was the study done?

There were 2 groups of older adults in this study:

- Pre-vax: Adults were vaccinated with the different shingles vaccine 5 or more years before this study started.
- No Pre-vax: Adults did not get any shingles vaccine before this study.

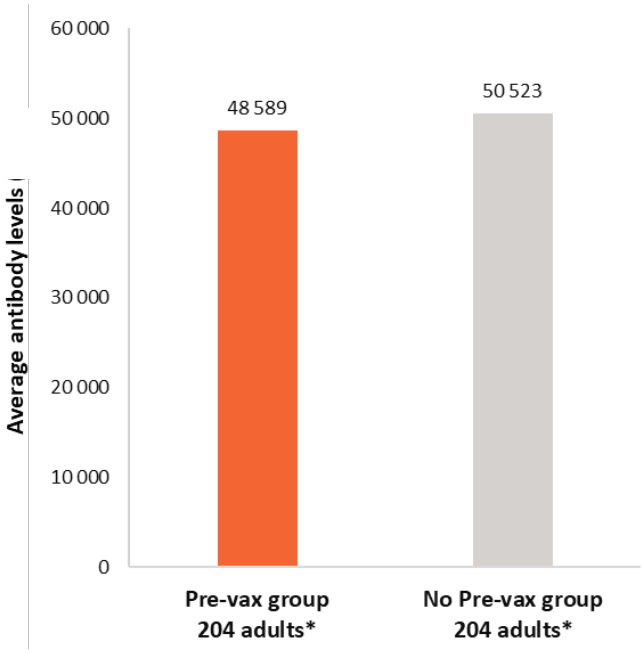


What were the main results of the study?

This report focuses on the results of the main goals of the study. All results can be found in the clinical results summary

There were no important differences in antibody levels against shingles virus between the 2 groups, as illustrated in Figure 1.

Figure 1. Antibody levels 1 month after 2 shots of the new shingles vaccine



* Number of participants who received 2 doses of vaccine, followed the requirements of the study protocol, and for whom results were available.

What were the side effects?

Side effects of the new vaccine in this study were collected as a main study goal.

Unwanted medical events (adverse events) can happen to people while they are in the study. The cause of these events is not always known.

A summary of all unwanted medical events reported in this study can be found in the clinical results summary.

If the unwanted medical event was caused by the vaccine, it is recorded as a possible side effect.

There was no important difference in the number of unwanted medical events experienced by older adults in the two study groups.

In this summary, "side effects**" refer to those events that may have been caused by the study vaccine.

Side effects within 7 days of vaccination are shown in Table 1, below.

Table 1. Side effects reported in the study within 7 days after vaccination*

	Pre-vax group 215 adults	No Pre-vax group 214 adults
Side effects at the site of injection		
Pain	189 (88%)	181 (85%)
Redness	96 (45%)	73 (34%)
Swelling	50 (23%)	37 (17%)
Other side effects		
Fatigue	114 (53%)	111 (52%)
Muscle pain	81 (38%)	77 (36%)
Headache	78 (36%)	89 (34%)
Shivering	51 (24%)	37 (17%)
Stomach and intestine issues	49 (23%)	38 (18%)
Fever (38°C and above)	36 (17%)	32 (15%)

** Some adults had more than one side effect. One adult in the No Pre-vax group did not report side effects*

***The use of the term side effects in this summary may be different from that in the Informed Consent or other documents related to the vaccine.*

How has this study helped patients and researchers?

In this study, getting another shingles vaccine at least 5 or more years before the study started did not change how older adults responded to the new shingles vaccine. Both groups had similar side effects.

Are there plans for further studies?

Several studies of the new shingles vaccine are ongoing and planned in different groups of people.

Where can I find more information about this study?

The detailed title for this research study is:

A phase III, open label, multicenter study of GSK Biological' herpes zoster HZ/su candidate vaccine (GSK1437173A) administered intramuscularly on a 0 and 2 month schedule evaluating the immunogenicity, safety and reactogenicity in adults ≥65 years of age with a previous Zostavax vaccination ≥5 years earlier, compared to group-matched adults not previously vaccinated with Zostavax.

Clinical studies have unique study numbers. Below is the unique study number associated with this study.

Organization	Website	Study Number
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT02581410

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.

This document provides a short summary of this study for a general audience. You can find more information in the scientific summary of the study. Link to this summary is provided at the end of this document.

This document was developed and approved by GSK on 6 December 2019. The information in this summary does not include additional information available after this date.

For readers of this document in text form, the websites associated with the hyperlinks above are:

US NIH/clinicaltrials.gov: https://clinicaltrials.gov/ct2/show/NCT02581410