



Who Sponsored this study ?
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IMPACT OF SIDE EFFECTS OF A SHINGLES VACCINE ON ADULTS 50 YEARS AND OLDER






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 at the end of this document.

Overview

Why was this study conducted?

To study whether the side effects of a shingles vaccine impact normal daily physical activities in older adults.

What was studied?

- Answers to health questionnaires were compared before and after vaccination.
- Side effects of the shingles vaccine.

Who was in this study?

- 235 women and 166 men living in the United States took part in the study.
- They were 50 years or older when the study started.

What kind of study was it?

- Open label: The study doctors and the participants knew which vaccine the participants got.
- In this study there was only one group.

Main results

- Overall, side effects of the shingles vaccine did not meaningfully impact normal daily physical activities in older adults.
- The side effects reported in this study were known side effects of shingles vaccination. They did not raise any new safety concerns.

NCT number: NCT02979639

General information about the research study

When was the study done?

The study started on 16 January 2017 and ended on 24 May 2018.

Why was this study done?

This study was done to see the impact of the side effects of a shingles vaccine.

Shingles is an infection caused by the same virus that causes chickenpox. After recovery from chickenpox, the virus stays in the body in an inactive state. It can become active again after many years. When it does, it causes shingles. Half of all shingles cases occur in people over 60 years of age.

Shingles causes a painful rash and blisters that lasts for 2 to 4 weeks. For some people, the pain can last for months or years, even after the rash has gone.

One way to protect against shingles is vaccination. We know from previous studies that the shingles vaccine used in this study can protect people against shingles.

However, as with all vaccines, side effects are common following shingles vaccination. To be sure that shingles vaccination is beneficial, it is important to understand if the side effects of vaccination outweigh the negative effects of shingles.

This study looked at the impact of side effects on the normal daily physical activities of the participants after the first and second vaccinations. Normal physical activities included categories such as walking, climbing stairs, carrying groceries or more strenuous activities such as participating in sports.

Additional measurements were also done to look at the impact of side effects on other daily activities and well-being. These were not the main goals of the study and the full results can be found in the *clinical results summary*.

Who took part in this study?

401 participants
from the United States

50 years or older when they got the first vaccination

235 women (59%)
166 men (41%)

Participant could take part in the study if they

- Were in good health

Participant could not take part in the study if they

- Had an allergy to anything in the vaccine
- Were vaccinated against shingles in the past
- Had a shingles infection in the past

Which vaccines were studied?

The vaccine tested in this study was the shingles vaccine. It was given by injection in the upper arm muscle.

How was the study done?

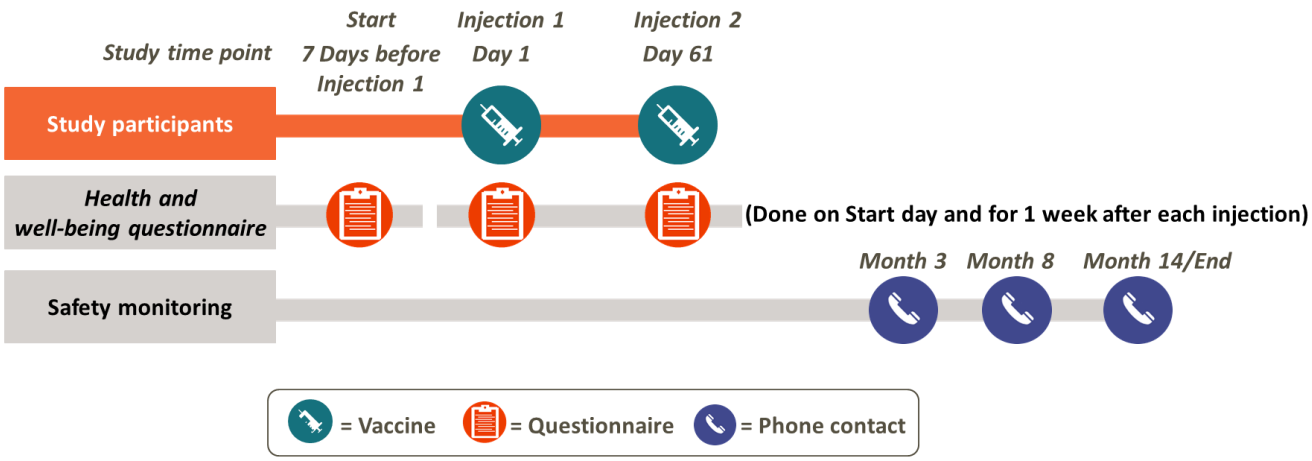
Figure 1 shows the study schedule and what happened at each study visit.

The participants got 2 injections of the shingles vaccine.

The participants answered questionnaires about their health and well-being. The answers were categorized and scored on a range of 0 to 100. A higher score represented better health and well-being. The scores before and after both vaccinations were compared to see if vaccination impacted participants' well-being and ability to perform normal physical activities.

The study doctors also collected information about the possible side effects of the vaccine from all participants.

Figure 1: Overview of time and events



What were the main results of the study?

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

There were two main results from this study:

1. Impact of vaccine side effects on normal physical activities.
2. Side effects of the vaccine. The side effects reported by participants during the whole study period are shown in Figure 2.

The average physical activity score for all participants was 82.2 before the first vaccination, and 84.1 after. For the second vaccination, the average physical activity score for all participants was 82.0 before vaccination, and 81.8 after. The difference in the scores before and after vaccination was small. Overall, the results indicate that there was no meaningful impact of vaccination on performing normal physical activities. However, 38 participants (9.5% of 401 participants) after the first vaccination, and 61 participants (15.2% of 401 participants) after the second vaccination reported side effects which

prevented their ability to perform normal physical activities for an average of 2 to 3 days.

What were the side effects?

Unwanted medical events (adverse events) can happen to people after they receive a vaccine. Study doctors record all these events. A summary of all events reported in this study may be found in the ***clinical results summary.***

If the study doctors think that the event was caused by the vaccine, they record this as a possible side effect (adverse reaction).

In this summary, "side effects[1]" refer to those events that the study doctor thinks may have been caused by the study vaccine.

The figure below shows the side effects at the site of injection (upper arm) and in other parts of the body.

The most common side effect at the injection site was pain.

The most common other side effect (not at injection site) was tiredness.

The side effects reported in this study were known side effects of shingles vaccination. They did not raise any new safety concerns.

Figure 2 shows the side effects reported by at least 4 (1%) or more participants during the whole study period.

Figure 2: Side effects

Side effects at the site of injection

	Number of participants (% of 401 participants)
Pain	341 (85.0%)
Redness	125 (31.2%)
Swelling	78 (19.5%)
Itching	6 (1.5%)

Other side effects

	Number of participants (% of 401 participants)
Tiredness	215 (53.6%)
Headache	170 (42.4%)
Muscle pain	159 (39.7%)
Shivering	105 (26.2%)
Fever	82 (20.4%)
Stomach and intestine problems	71 (17.7%)

How has this study helped patients and researchers?

Overall, the results from this study showed that the side effects of the shingles vaccine did not meaningfully impact normal physical activities in older adults. The side effects reported did not raise any new safety concerns.

[1] 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?

There are several ongoing and planned studies looking at the effects of shingles vaccination in different groups.

Where can I find more information about this study?

The detailed title for this research study is:
A phase III, open label, multicenter study to evaluate the impact of reactogenicity on Quality of Life (QoL), after intramuscular administration of GSK Biologicals' candidate Herpes Zoster subunit (HZ/su) vaccine (GSK1437173A) in adults ≥ 50 years of age.

Organization	Website	Study Number
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT02979639

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. Keep taking your current treatment unless instructed by your doctor.

This document was developed and approved by GSK on <<insert approval date>>. 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/NCT02979639?term=204928&rank=1