



Who Sponsored this study ?
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A STUDY OF BODY DEFENCES 9 AND 10 YEARS AFTER SHINGLES VACCINATION






GSK would like to thank all the people 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 conducted?

This was an extension of an earlier study on vaccination against the shingles virus. The study looked at the long-term effects of this vaccine and the effect of booster shots of the vaccine.

What was studied?

- The body's defences against the shingles virus.
- Possible vaccine side effects.

Who was in this study?

- 43 women and 27 men from Germany, Sweden, and the Czech Republic took part in the study.
- They were at least 70 years old when this study started.

What kind of study was it?

- An extension study: This means that we looked at how the body's ability to fight off a shingles infection changed in people who got their first vaccination in an earlier study
- An open label study: This means that the study doctors and volunteers knew which vaccine they received.

Main results

- The body's defences against shingles were still stronger 10 years after the vaccination than before it. Body defences were stable from year 4 to year 10 after first vaccination. However, we do not currently know the level of body defences needed to protect against shingles.
- This study did not raise any safety concerns.

NCT number: NCT02735915
EudraCT number: 2015-004400-30

General information about the research study

When was the study done?

This extension study started on 11 April 2016 and ended on 8 October 2018.

Why was this study done?

This was an extension study of a shingles vaccine to look at the long-term effects of vaccination and the effect of booster doses of the vaccine.

We know from previous studies that we can protect people against the shingles virus by vaccination.

But many vaccines do not provide life-long protection. Booster doses may be needed to maintain their protective effect.

This study had two parts. The first part looked at two types of body defences (antibodies and immune system cells) 9 and 10 years after vaccination. The second part looked at the body's defences against shingles virus after two extra (booster or re-vaccination) doses of the shingles vaccine.

This summary will focus on the main goals of the study (the body's long-term defences against infection and key safety information). All study results can be found in the ***clinical results summary.***

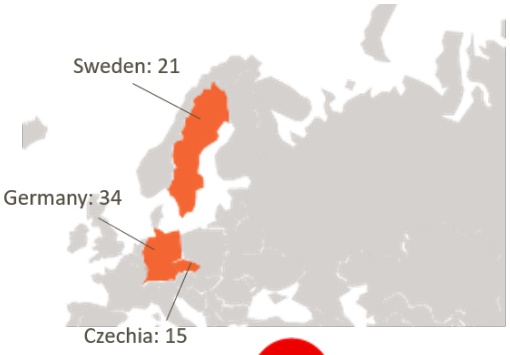
Who took part in this study?

70 adults age 70 or older from Germany, Sweden, Czechia

60 years or older when they got the first vaccination

43 females (61%)

27 males (39%)



Adults could take part in the study if they:

- had completed the vaccinations in the previous study
- were available for the first study visit

Adults could not take part in the study if they:

- had another vaccination against shingles after the previous study
- had a previous history of shingles

Which vaccines were studied?

In this extension study, we used the GSK shingles vaccine which has been approved for use in many countries. This is the same vaccine given to study volunteers 10 years earlier. It was given by injection in the upper arm muscle.

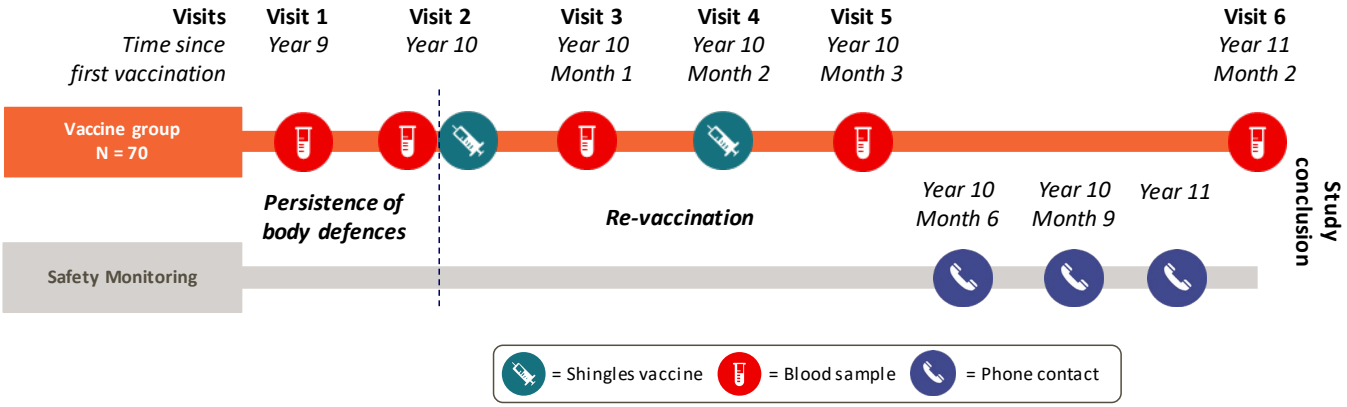
How was the study done?

Small amounts of blood were taken 9 and 10 years after vaccination against shingles (Figure 1). These blood samples were used to measure body defences against the shingles virus.

After this blood was taken, two booster (or re-vaccination) doses of the same shingles vaccine were given to see how people who had received the vaccine 10 years earlier would respond.

Blood samples were also taken after the booster (re-vaccination) doses. The blood was used to measure the body's defences against infection.

Figure 1: Study Design



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.***

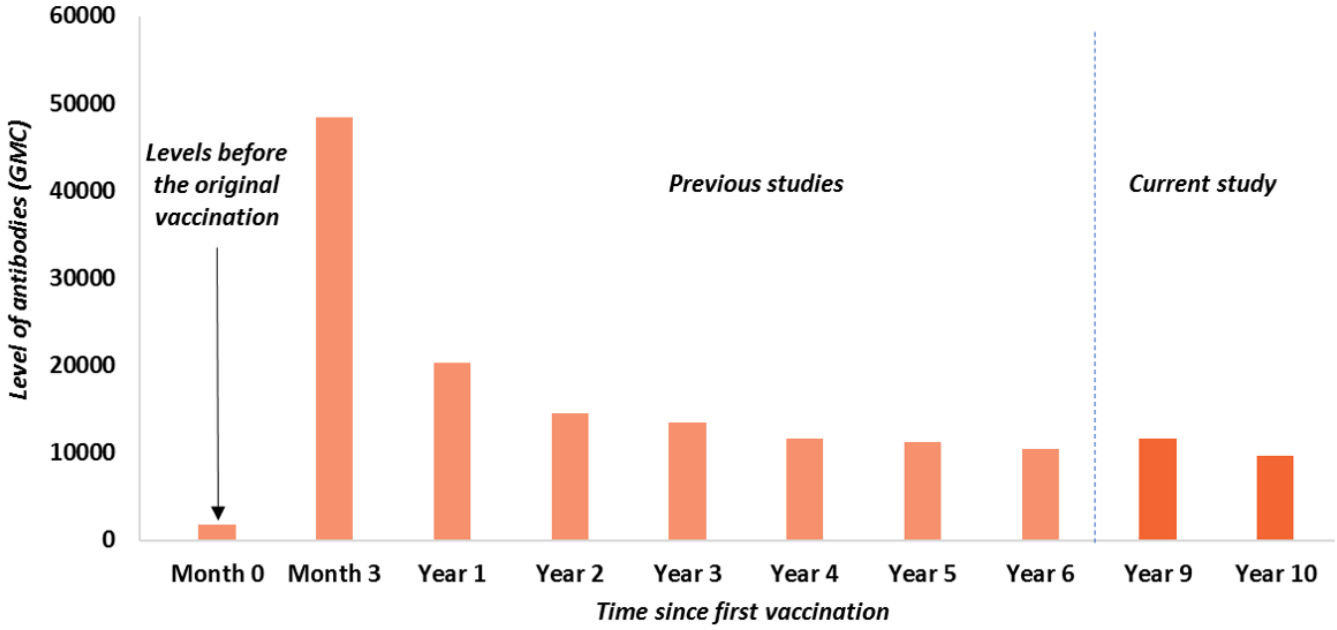
Antibodies measured at 9 years and 10 years after vaccination

After 10 years, the body's defences against the shingles virus were higher than before the original vaccination. At year 10, the body's defences were at similar levels to those 4 years after vaccination. Figure 2 shows antibody responses. The responses of immune system cells followed a similar pattern.

Antibodies measured after booster (re-vaccination) doses

Booster doses stimulated body defences against the shingles virus. The response of the body's defence system to the first re-vaccination was similar to the first vaccination, given 10 years earlier.

Figure 2 Antibody Levels before and up to 10 years after vaccination



Antibody levels are measured as geometric mean concentrations (GMC).

What were the side effects?

Unwanted medical events (adverse events) can happen to people when 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 doctor thinks that the event was caused by the vaccine, they record this as a possible side effect (adverse reaction).

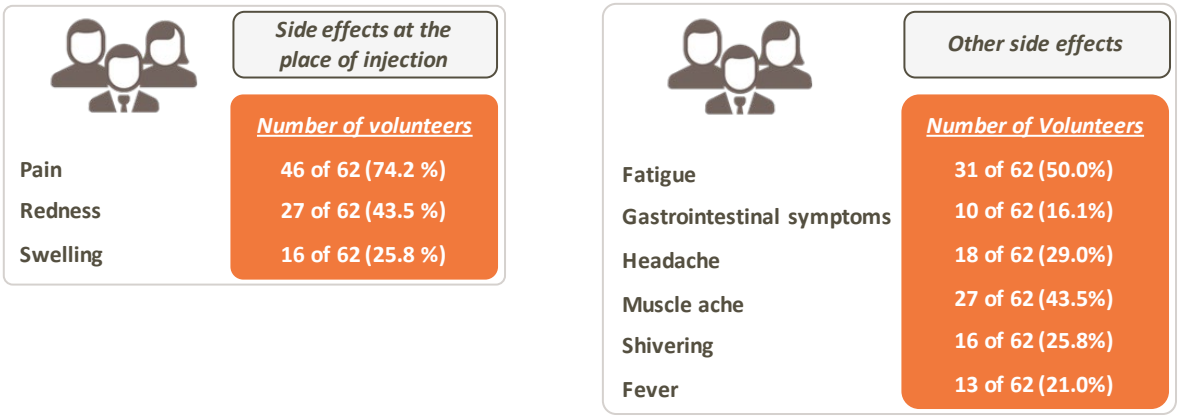
In this summary, "side effects*" refer to those events that the study doctor thinks may have been caused by the study vaccine.

Figure 3 shows side effects reported by 1% or more of volunteers in the week after re-vaccination.

The most common side effects were pain at the place where the vaccine was injected (upper arm muscle) and fatigue.

**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.*

Figure 3 Side effects after re-vaccination**



How has this study helped patients and researchers?

This study showed that 10 years after vaccination, levels of body defences against shingles were higher than before first vaccination and similar to levels 4 years after first vaccination. Currently, we do not know the level of the body's defences needed for protection against this disease. However, the persistence of antibodies suggests that the vaccine may still work against the shingles virus for up to 10 years after vaccination.

Are there plans for further studies?

There are no further studies planned of the persistence of response to shingles re-vaccination. There are several ongoing and planned studies looking at the effects of this shingles vaccine in different age groups and in people with different medical conditions.

Where can I find more information about this study?

The detailed title for this research study is:

A phase IIIB, open, long-term extension study to evaluate the persistence of immune responses and the safety of GSK Biologicals' Herpes Zoster subunit (HZ/su) vaccine 1437173A, at Months 108 and 120 post-vaccination and the assessment of re-vaccination with 2 additional doses administered 10 years after the initial vaccination in study ZOSTER-003 in healthy subjects aged 60 years of age and older.

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

**Some volunteers had more than one side effect

Organization	Website	Study Number
European Medicines Agency	www.clinicaltrialsregister.eu	2015-004400-30
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT02735915

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 was developed and approved by GSK on 27 August 2019. 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 at the end of this document.

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=2015-004400-30
US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT02735915