



Who Sponsored this study?
GlaxoSmithKline

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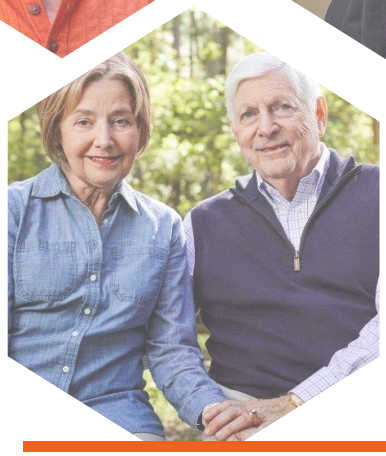
Safety of a new shingles vaccine

in adults aged 50 years and older



GSK would like to thank all the volunteers 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 offer the shingles vaccine to volunteers who received inactive shots in previous shingles vaccine studies and to gather safety information.

What was studied?

- Side effects of the new shingles vaccine.

Who was in this study?

- 8687 men and women 50 years of age or older.

What kind of study was it?

- Open label: The doctors and volunteers knew which vaccine was being studied.

Main results

- The side effects in this study were already known to be associated with the vaccine. No health concerns were raised during the study.

NCT number: NCT02690207
EudraCT number: 2015-000965-30

General information about the research study

When was the study done?

The study started on 16 March 2016 and ended on 15 March 2019.

Why was this study done?

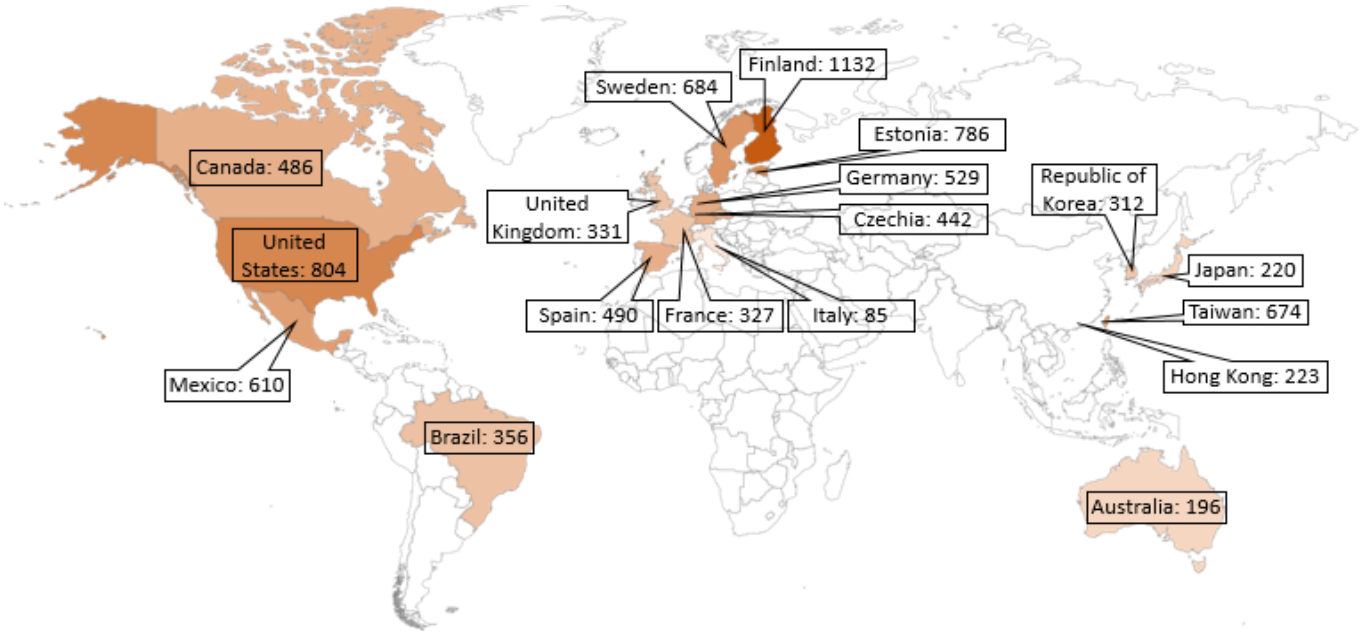
This study was done to learn more about the safety of the new shingles vaccine.

Study volunteers had received an inactive shot in earlier studies of this vaccine. They were offered a chance to receive the shingles vaccine by taking part in this study.

Shingles is caused by the chickenpox virus. 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.

Who took part in this study?

Adult volunteers, 50 years or older, from 18 countries, took part in this study.



	50-59 years	60-69 years	70-79 years	≥80 years	Total
Men	700	1405	1947	1202	**5254**
Women	340	784	1402	907	**3433**
Total	**1040**	**2189**	**3349**	**2109**	**8687**

Volunteers could take part in the study if they:

- Received an inactive shot in the previous study

Volunteers could not take part in the study if they:

- Had shingles at the time of vaccination
- Were vaccinated against shingles in the past
- Were allergic to the vaccine

Which vaccines were studied?

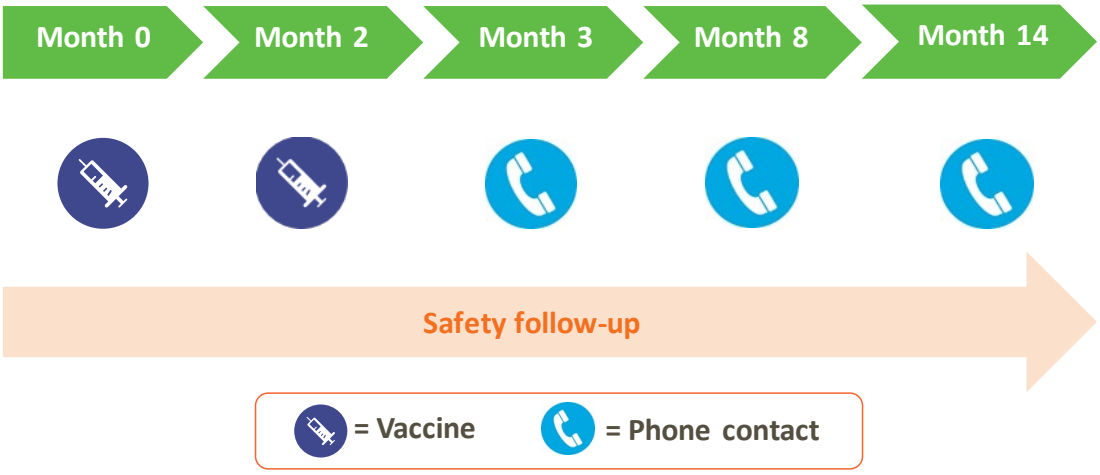
The vaccine tested in this study was the new shingles vaccine. It was given by injection in the upper arm muscle.

How was the study done?

The men and women volunteers in the study got 2 injections of the shingles vaccine, 2 months apart (Figure 1).

The study doctors collected information about the possible vaccine side effects from all study volunteers.

Figure 1. Study schedule



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.

The most common side effects reported by volunteers during the whole study period are shown in Table 1.

What were the side effects?[1]

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 Table 1 and in the ***clinical results summary***.

If the study doctor thinks that the event was caused by the vaccine, they record it as a possible side effect (adverse reaction).

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

Table 1. The most commonly reported side effects

	Age group			
	1040 adults aged 50-59 years	2189 Adults Aged 60-69 years	3349 Adults Aged 70-79 years	2109 Adults 80 years and Older
	Side effects in the arm where the vaccine was injected			
Pain	495 (47.6 %)	1000 (45.7 %)	1152 (34.4 %)	525 (24.9 %)
Redness	179 (17.2 %)	383 (17.5 %)	529 (15.8 %)	220 (10.4 %)
Swelling	125 (12.0 %)	307 (14.0 %)	349 (10.4 %)	147 (7.0 %)
	Other side effects			
Fever	222 (21.3 %)	342 (15.6 %)	315 (9.4 %)	116 (5.5 %)
Headache	135 (13.0 %)	207 (9.5 %)	164 (4.9 %)	57 (2.7 %)
Muscle pain	97 (9.3 %)	136 (6.2 %)	83 (2.5 %)	35 (1.7 %)
Tiredness	59 (5.7 %)	121 (5.5 %)	128 (3.8 %)	43 (2.0 %)

Note: Some volunteers had more than one side effect

How has this study helped patients and researchers?

The researchers learned more about the safety of the new shingles vaccine. The results from this study did not raise any health concerns. This additional safety information provides reassurance to people who receive this vaccine. Also, the people who took part in this study benefit from receiving a shingles vaccine.

Are there plans for further studies?

There are several ongoing and planned studies of the new shingles vaccine in different groups of adults.

Where can I find more information about this study?

The detailed title for this research study is:
A phase IIIB, non-randomized, open-label, multi-country, multi-centric cross-vaccination study to evaluate the safety of GSK Biologicals' Herpes ZOSTER subunit (HZ/su) vaccine when administered intramuscularly on a two-dose schedule to subjects who previously received placebo in ZOSTER-006 and ZOSTER-022 studies.

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

Organization	Website	Study Number
European Medicines Agency	www.clinicaltrialsregister.eu	2015-000965-30
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT02690207

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 scientific summaries of the study. Links to those summaries are provided at the end of this document.

This document was developed and approved by GSK on 17 October 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:

EudraCT summary : **https://www.clinicaltrialsregister.eu/ctr-search/search?query= 2015-000965-30**

US NIH/clinicaltrials.gov: **https://clinicaltrials.gov/ct2/show/NCT02690207**