



## Who Sponsored this study ? **GlaxoSmithKline**

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## **A STUDY COMPARING 2 HUMAN PAPILLOMAVIRUS VACCINES IN GIRLS 9 TO 14 YEARS OLD**



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.

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## Overview



### Why was this study conducted?

Two vaccines against human papillomavirus (HPV) were studied:

- 2-type vaccine (helps fight infection against the 2 types of HPV that cause most cervical cancers)
- 4-type vaccine (helps fight infection against 4 types of HPV, including the 2 types that cause most cervical cancers)

The main goal of this study was to compare these vaccines after 2 injections.



### What was studied?

- Body's defenses (called **antibodies**) against infection caused by 2 types of HPV that can cause cervical cancer.
- Vaccine safety



### Who was in this study?

There were 1075 girls from 4 countries. All the girls were 9 to 14 years old when the study started.



### What kind of study was it?

Both vaccines have been approved for use in many countries, including the 4 countries that took part. The study was:

- Randomized: girls' assignment to vaccination groups was decided by chance (like tossing a coin).
- Observer-blinded: neither the study doctors nor the girls knew what treatment each girl got.



### Main results

Girls who got 2 injections of the 2-type vaccine made more antibodies than girls who got 2 injections of the 4-type vaccine. Higher antibody amounts may provide better protection.

The side effects of the vaccines reported in this study did not raise any safety concerns.

Study number: [NCT01462357](#)

EudraCT: [2011-002035-26](#)

## General information about the research study

### When was the study done?

The study started on 21 November 2011 and ended on 27 October 2015.

### Why was this study done?

Human papillomaviruses (HPVs) are common and are spread through sexual contact. HPVs can cause cancers of the cervix, vulva, vagina, penis, and anus. They also cause skin growths on the genitals (genital warts).

Vaccines have been developed to protect mainly against the HPV virus types that cause cervical cancer. The vaccines contain parts of the viruses that cannot cause infection. These parts help the body make defenses, called “**antibodies**”, against those viruses.

Two HPV vaccines are approved for use in many countries:

- A **2-type vaccine** has parts of the HPV-16 and HPV-18 viruses. The vaccine helps protect against cervical cancer.
- A **4-type vaccine** has parts of the HPV-16, HPV-18, HPV-6 and HPV-11 viruses. The vaccine helps protect against cervical cancer and genital warts.

The main goal of the study was to measure **antibodies** after 2 injections of HPV vaccines. Some girls also got 3 injections of the 4-type vaccine. As the assessment of 3 injections was not a main goal, those results are not shown here but can be found in the [clinical results summaries](#).

## Who took part in this study?

1075 healthy 9 to 14-year-old girls from 4 countries took part in the study (**Figure 1**). Girls who were pregnant or breastfeeding, or who had previously been given HPV vaccines could not take part in the study.



## Which vaccines were studied?

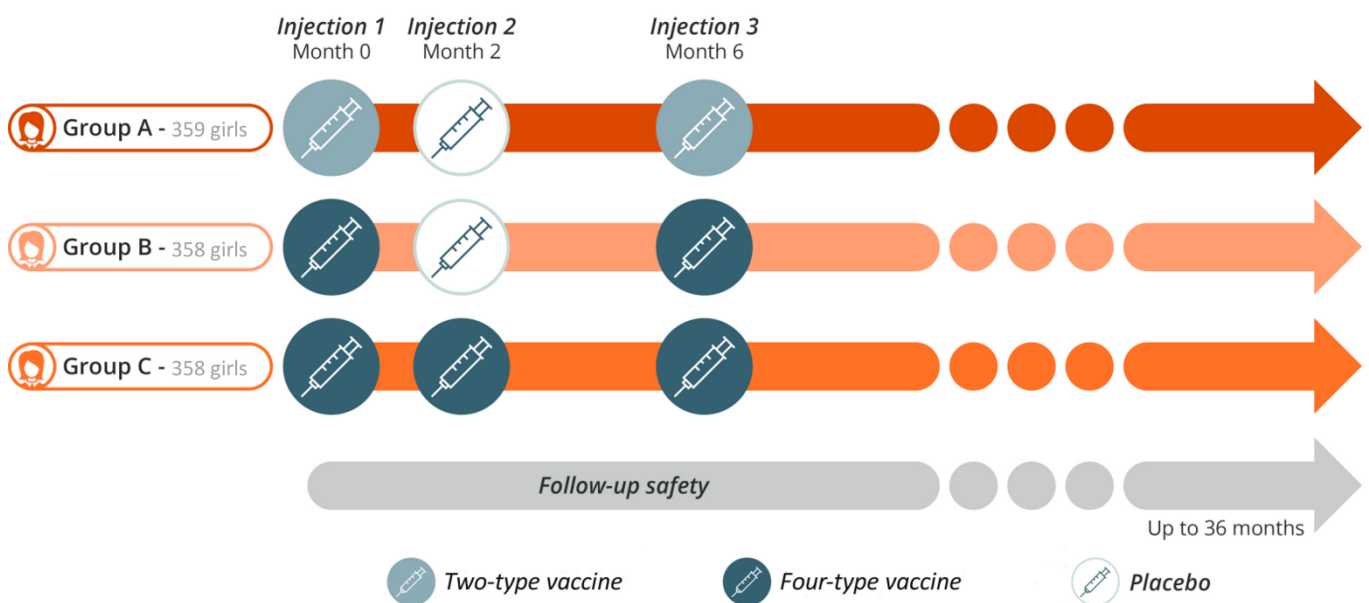
Two kinds of vaccine were studied:

- The 2-type vaccine
- The 4-type vaccine

A liquid that does not have any vaccine (called a placebo) was also used.

## How was the study done?

**Figure 2.** Study design



- Study Group A got 2 injections of the 2-type HPV vaccine and 1 injection of placebo.
- Study Group B got 2 injections of the 4-type HPV vaccine and 1 injection of placebo.
- Study Group C got 3 injections of the 4-type HPV vaccine

Because all girls got 3 injections, the girls, their parents and the study doctors didn't know who was given which vaccine (this is called **observer-**

**blind**). This was done to avoid bias in the study results.

Study doctors took blood samples from all girls one month after the last injection. Blood tests measured the amounts of HPV-16 and HPV-18 antibodies. Study doctors also collected information from the girls about the safety of the vaccines.

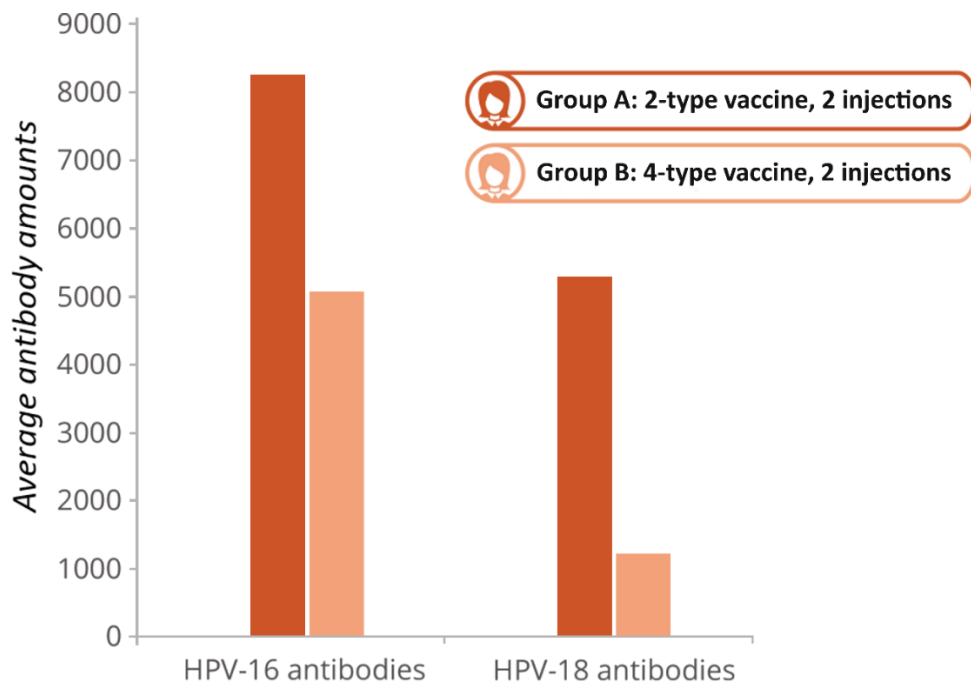
## What were the main results of the study?

This report focuses on the results for the main goals of the study. Other results may be found in the [clinical results summaries](#).

### Antibodies against HPV-16 and HPV-18

**Figure 3** shows the main results of the study. The average amounts of antibodies were measured one month after the last injection. Antibody amounts are measured as Geometric Mean Titers. Antibody amounts were higher in Group A than in Group B. Results for Group C can be found in the [clinical results summaries](#).

**Figure 3.** HPV-16 and HPV-18 antibody amounts one month after injection



## What were the side effects?

Unwanted medical events can happen to people while they are in the study. Study doctors collect all these events.

A side effect is an unwanted medical event that the study doctor thinks may have been caused by the study vaccines.

The side effect is called 'serious' if it:

- is a threat to life,

- leads to permanent damage,
- requires a stay in hospital, or
- is fatal

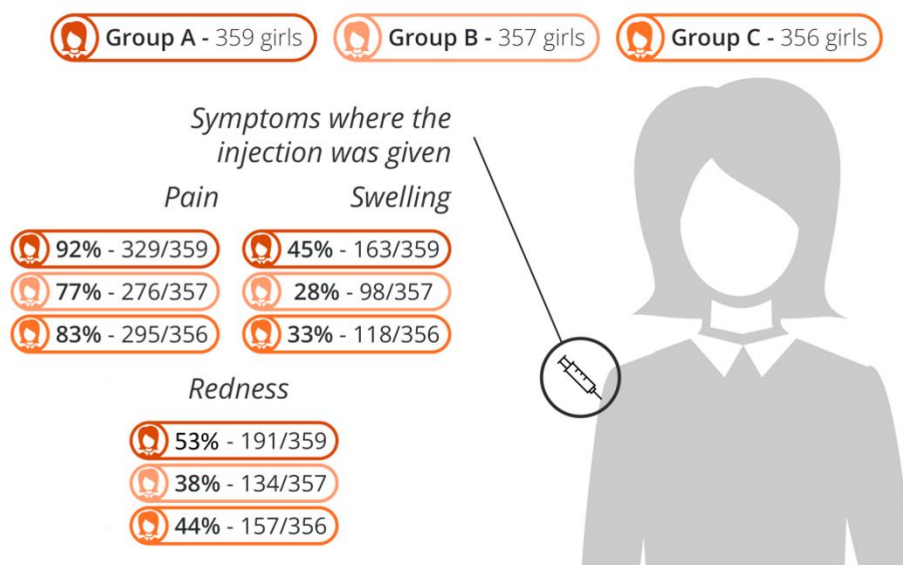
None of the girls reported serious side effects.

**Figure 4** shows the non-serious side effects reported by 2 or more girls. The side effects in any of the groups did not raise any safety concerns.

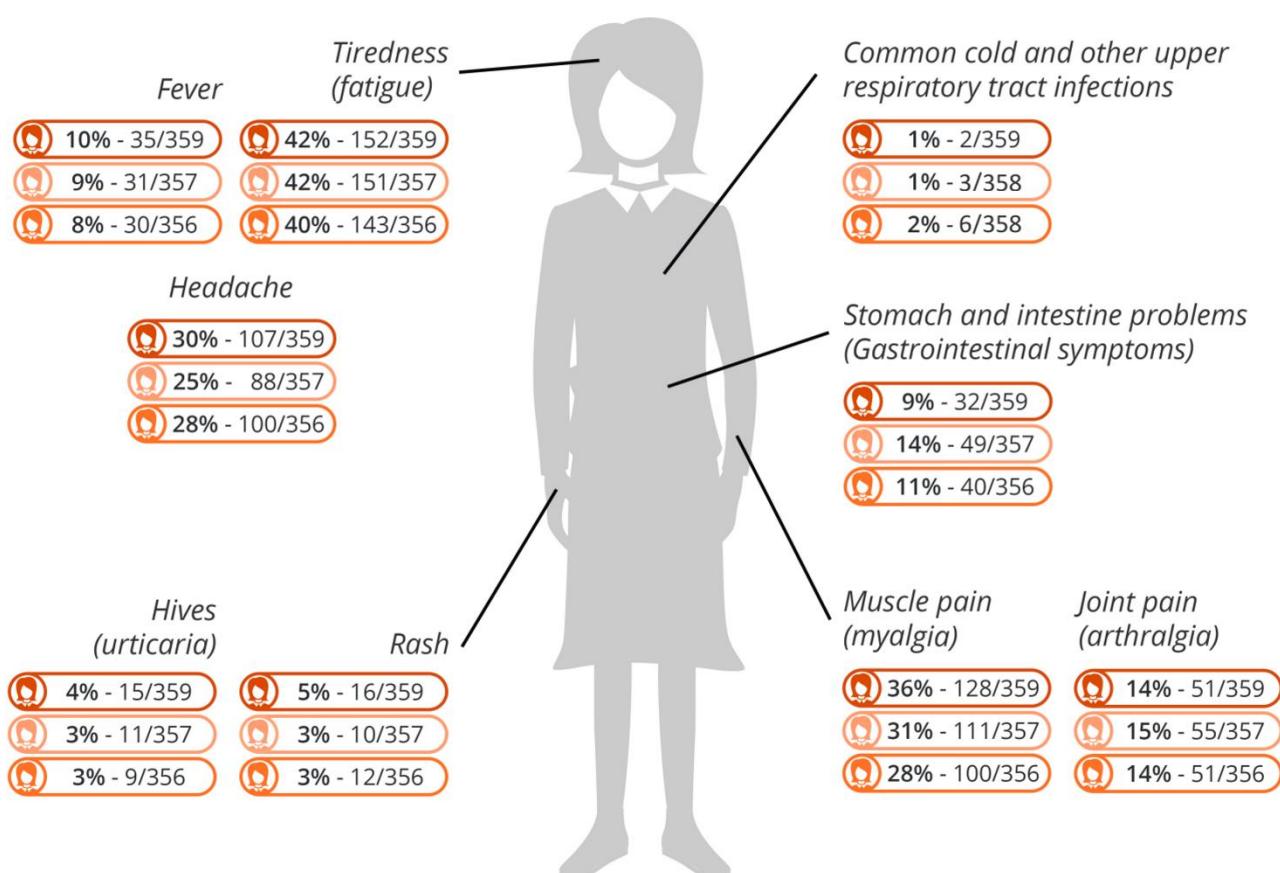
**Figure 4.** Non-serious side effects reported by 2 or more girls in any group during the whole study.

**Group A:** 2-type vaccine, 2 injections. **Group B:** 4-type vaccine, 2 injections. **Group C:** 4-type vaccine, 3 injections

**Panel A. Side effects at the site of injection**



**Panel B. Other side effects (not at the site of injection)**





## How has this study helped patients and researchers?

The results from this study showed that amounts of antibodies were higher after 2 injections of the 2-type vaccine than of the 4-type vaccine. Higher antibody amounts may give better protection from the viruses.

The side effects reported in this study did not raise any safety concerns. There were no serious side effects reported in this study.

This summary only shows results from one study. Other studies may find different results.

## Are there plans for further studies?

At the time of preparation of this summary, other studies of the 2-type HPV vaccine were planned and/or ongoing. The results of these studies will be available on GlaxoSmithKline's Study Register (See link at the end of this document).

## Where can I find more information about this study?

### The detailed title for this research study is:

A Phase IIIb observer-blind, randomized, multi-centre primary immunization study to evaluate the immunogenicity and safety of GSK Biologicals' HPV-16/18 L1 VLP AS04 vaccine and Merck's Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine, when administered intramuscularly according to alternative 2-dose schedules in 9-14 year old healthy females.

Organization	Website	Study Number
European Medicines Agency	<a href="http://www.clinicaltrialsregister.eu">www.clinicaltrialsregister.eu</a>	<a href="#"><u>2011-002035-26</u></a>
United States National Institutes of Health (NIH)	<a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a>	<a href="#"><u>NCT01462357</u></a>
GlaxoSmithKline (GSK)	<a href="http://www.gsk.clinicalstudyregister.com">www.gsk.clinicalstudyregister.com</a>	<a href="#"><u>115411</u></a>



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 25 July 2018. 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/trial/2011-002035-26/SE>

US NIH/clinicaltrials.gov:

<https://clinicaltrials.gov/ct2/show/NCT01462357?term=115411&rank=1>

GSK Clinical Study Register:

<https://www.gsk-clinicalstudyregister.com/study/115411?search=study&#ps>