Who Sponsored this study ?
GlaxoSmithKline

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COMPARISON OF A COMBINED HEPATITIS B/MALARIA VACCINE TO A HEPATITIS B VACCINE IN BABIES

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?

The study tested a new combined vaccine against malaria and hepatitis B. The new combined vaccine was developed for use in babies at risk of both malaria and hepatitis B.

Researchers wanted to find out if the new combined vaccine had the same ability to protect against hepatitis B infection as the licensed vaccine.

What was studied?

- Body defenses (called "antibodies") against hepatitis B.
- Side effects

Who was in this study?

508 babies from Burkina Faso and 197 from Ghana. These 705 babies got their first vaccination between 8 and 12 weeks of age.

Main results

About the same proportion of babies had protective Hepatitis B antibody levels after receiving the new combined vaccine or the licensed hepatitis B vaccine. The side effects did not raise any specific safety concern.

NCT number: NCT01345240
EudraCT number: 2011-001508-37

General information about the research study

When was the study done?

The study start date was 15-November-2011. The study finished on 15-February-2017.

Why was this study done?

Hepatitis B is a disease of the liver caused by a virus (a germ). It can be prevented by a vaccine.

The licensed hepatitis B vaccine in this study has been used in countries around the world for several years.

This study tested a new combined vaccine that was developed to protect against both malaria and hepatitis B.

Researchers wanted to find out if the new combined vaccine had the same ability to protect against hepatitis B infection as the licensed vaccine.

They looked at the amount of body defenses (called "antibodies") against hepatitis B in babies who either got the new combined vaccine or the licensed vaccine.

Who took part in this study?

In total, **705 babies** took part in this study

age 8 to 12 weeks
at the start of the study

healthy
babies

about half **boys**
about half **girls**

Burkina Faso and Ghana were chosen as countries where malaria and hepatitis B diseases are common.

Which vaccines were studied?

Two vaccines were tested:

- A vaccine against hepatitis B and malaria (the “new combined vaccine”)
- A licensed vaccine against hepatitis B (hepatitis B vaccine).

How was the study done?

This study followed each baby for about 4 years.

Three groups of babies received three injections of the new combined vaccine and two groups got three injections of the hepatitis B vaccine. All the babies in this study also got 6 standard childhood vaccines. The 5 groups differed in the timing of these standard childhood vaccines.

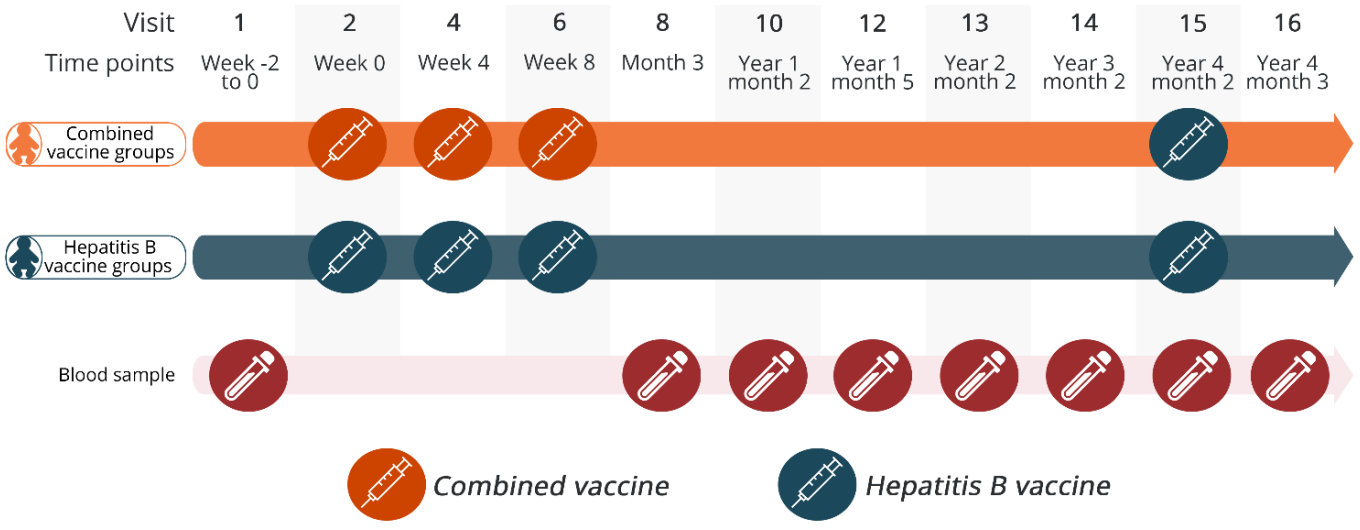
Figure 2 shows when the babies received the new combined vaccine (3 groups combined) or the licensed hepatitis B vaccine (2 groups combined).

All children also got a shot of the licensed hepatitis B vaccine at the end of the study (about 4 years after the first vaccinations). This shot was given for long-lasting protection against hepatitis B infection.

Blood samples were taken throughout this study (about 4 years) to determine the amounts of antibodies against hepatitis B. The first 2 blood samples were used to find out if the percentages of babies with protective antibody levels were similar in the combined groups.

The study doctor and the parents knew which vaccines were given to each baby.

Figure 2 Study design



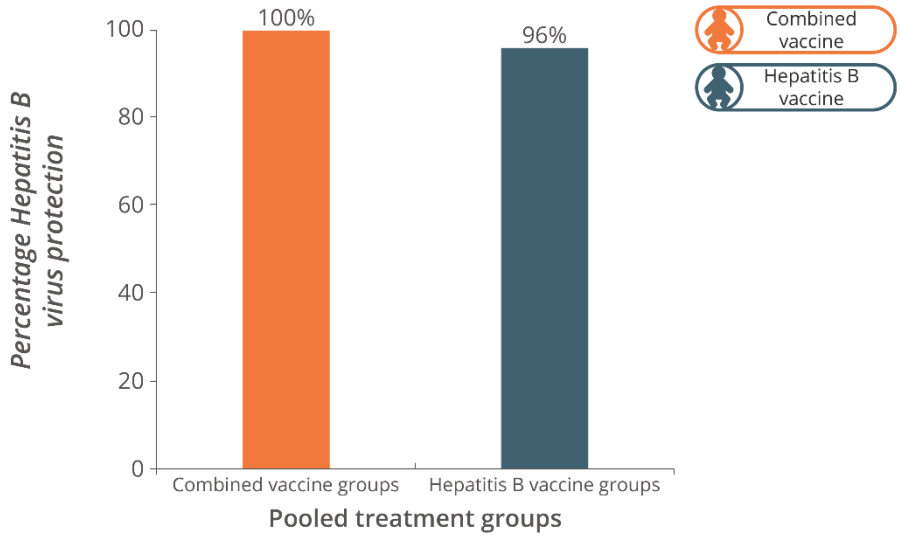
The combined vaccine groups and hepatitis B groups had small differences in the timing of two chilhood vaccines for preventing rotavirus infection and pneumococcal infection.

What were the main results of the study?

*This report describes the main study results. All results including results for other study vaccines can be looked at in the **clinical results summary**.*

Figure 3 shows the percentages of babies with protective antibody levels against hepatitis B at 1 month after the third vaccination. The percentages were similar for the new combined vaccine and the licensed hepatitis B vaccine.

Figure 3 Percentages of babies with protective hepatitis B antibody levels at 1 month after the third vaccination



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 4 shows the side effects reported in this study.

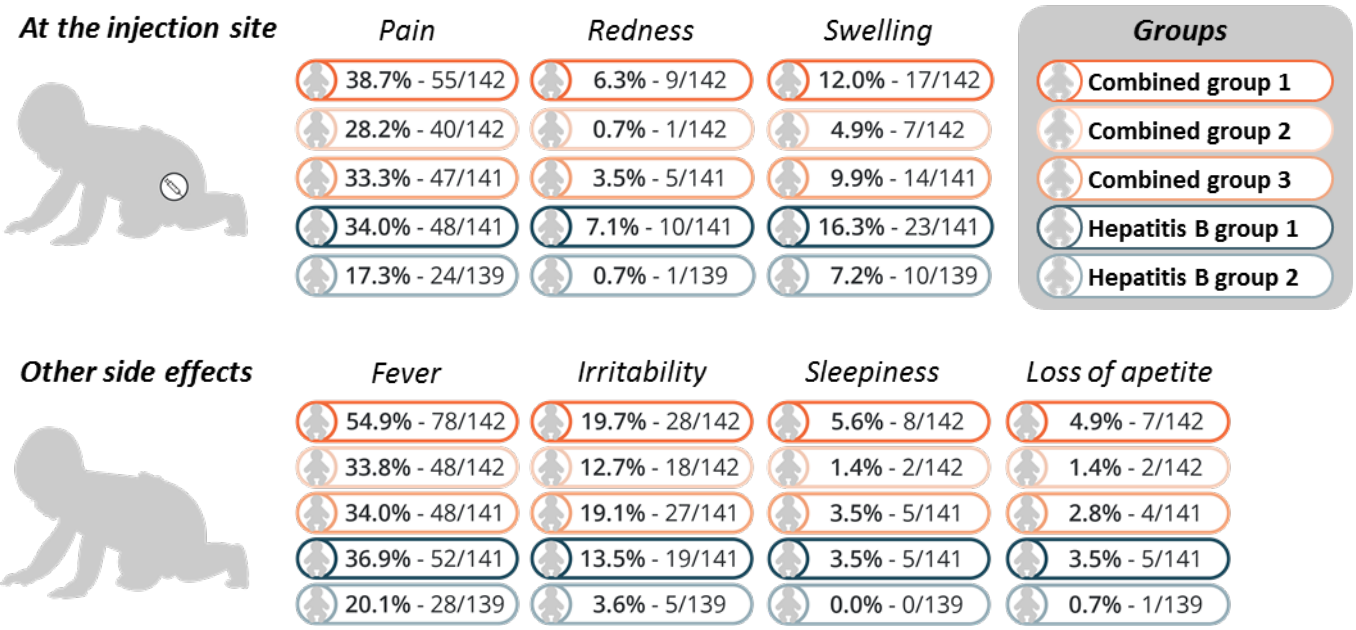
The most common side effect at the place where the injection was given was pain.

The most common other side effect was fever.

The side effects in this study did not raise any specific safety concern.

**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 4 Side effects



Percentages for all combined vaccine or hepatitis B vaccine injections (it should be noted that this may include side effects of the routine childhood vaccinations.

The combined vaccine groups and hepatitis B vaccine groups were different because of the timing of routine vaccinations.

How has this study helped patients and researchers?

This study shows that doctors vaccinating babies against hepatitis B may safely add the benefit of vaccination against malaria without sacrificing hepatitis B protection.

Are there plans for further studies?

These study results will help researchers plan future studies of the combined vaccine.

Where can I find more information about this study?

The detailed title for this research study is:

Phase III randomized, open, controlled study to evaluate the immune response to the hepatitis B antigen of the RTS,S/AS01$_E$ candidate vaccine, when administered as primary vaccination integrated into an EPI regimen to infants living in sub-Saharan Africa.

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

Organization	Website	Study Number
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT01345240
European Medicines Agency	www.clinicaltrialsregister.eu	2011-001508-37

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 23 January 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=2011-001508-37