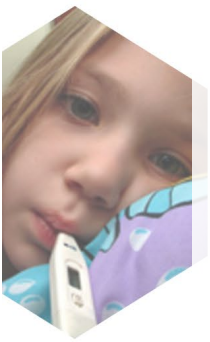






Who sponsored this study?
GlaxoSmithKline

Clinical Support Help Desk
- http://www.clinicalsupporthd.gsk.com
- GSKClinicalSupportHD@gsk.com
- Telephone: +1-438-899-8201

A study of the immune response and safety of malaria vaccine when given together with 2 other childhood vaccines in children






GSK would like to thank all the children who took part in this clinical study and their parents. 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.

General information about the research study

When was the study done?

The study started in May 2017 and ended in October 2020.

Why was this study done?

Malaria is a disease caused by the malarial parasite. The malarial parasite is spread to humans through the bite of infected mosquitoes. Infection from the malarial parasite can result in high fever and flu-like symptoms. Vaccines may help protect against the malarial parasite. Vaccines contain parts of the parasite that cannot cause infection. These parts help the body make defenses, known as antibodies, against those parasites.

In some countries selected vaccines are given to children to keep them from becoming sick. Sometimes more than one vaccine is given at a time to children to reduce the number of hospital visits. The study was done to see if the malaria vaccine is well tolerated and works well when it is given together with 2 other childhood vaccines.

The main goal of the study was to compare antibodies levels between children who either got:

- malaria vaccine alone.
- malaria vaccine together with a yellow fever vaccine and a combined measles and rubella vaccine (MeRu vaccine)

Study doctors also collected information about potential side effects to the vaccines given in this study. The results can be found in the section "What were the side effects?".

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

Who took part in this study?

699 children from **Ghana**.

About 6 months old when they got their first vaccination.

348 girls (49%)

351 boys (51%)

Children could take part in the study if they:

- were in good health
- received 3 doses of diphtheria, tetanus, pertussis and hepatitis B vaccine
- received 3 doses of oral polio vaccine

Children could not take part in the study if they:

- previously received a malaria vaccine
- previously received yellow fever, measles, rubella vaccines

Which vaccines were studied?

Malaria vaccine: a vaccine that has been developed to protect against malaria. This vaccine was given by injection into the arm.

Yellow fever vaccine: a vaccine that has been developed to protect against yellow fever disease. This vaccine was given by injection into the thigh. This vaccine is licensed in Ghana.

MeRu vaccine: a combined vaccine that has been developed to protect against measles and rubella. This vaccine was given by injection into the thigh. This vaccine is licensed in Ghana.

How was the study done?

Children were assigned to:

- Same day group: The 3rd dose of malaria vaccine was given the same day as the yellow fever/MeRu vaccines
- Different days group: The 3rd dose of malaria vaccine and yellow fever/MeRu vaccines were given on different days
- Control group: The yellow fever/MeRu vaccines were given on different days according to the routine schedule. Antibodies were then measured. The malaria vaccine was given a few months later.

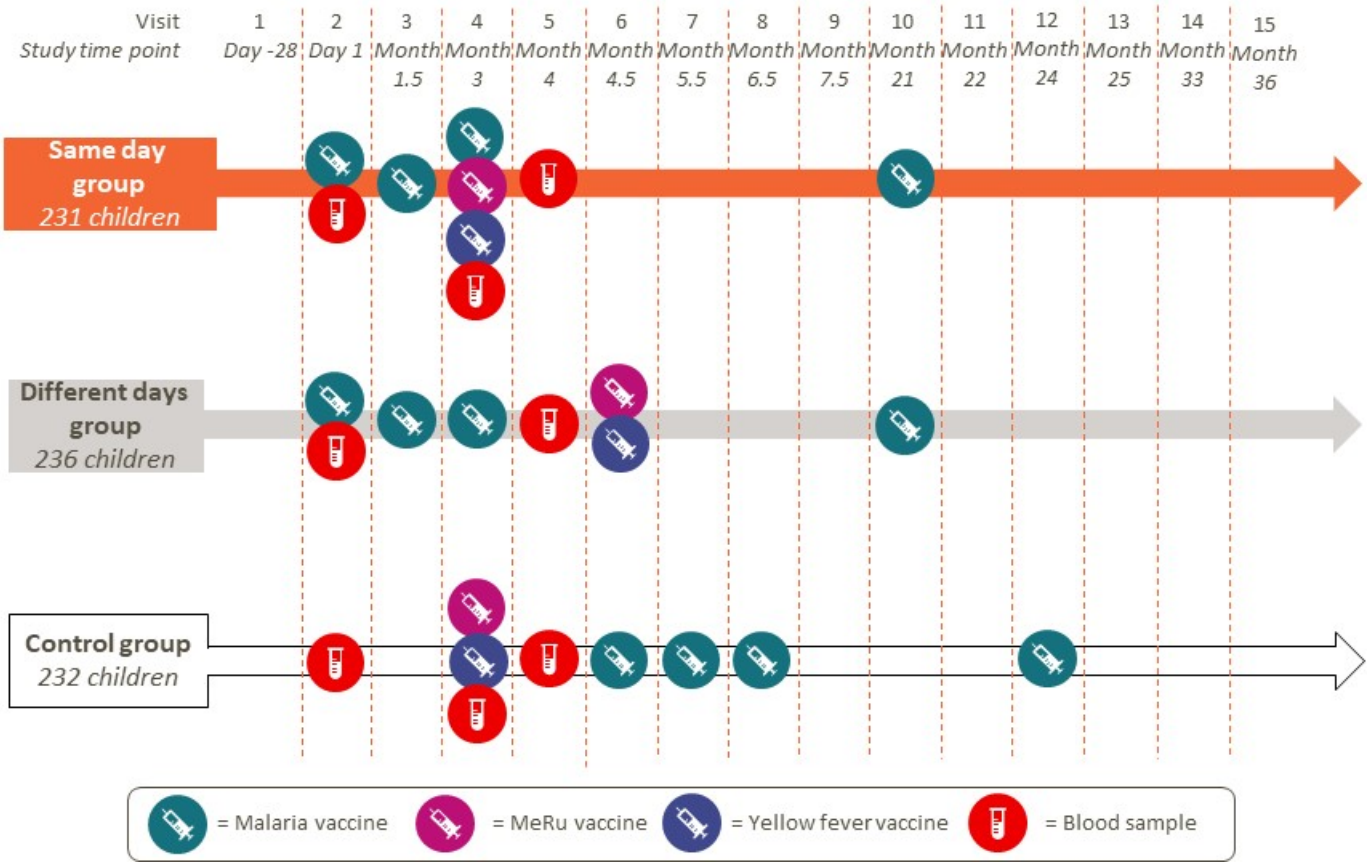
The children were assigned to a study group by chance (like tossing a coin).]

The study staff and the parents knew which treatment the children got.

Figure 1 describes which vaccines children in each study group got and when they got them. It also shows when blood samples were taken. These samples were taken to measure antibodies. Study doctors also collected information on the safety of the vaccine.

The study took up to 36 months.

Figure 1: Study design



Note: Same day group was called the Coad group; Different Days group was called the RTS,S group. All children received Vitamin A as part of a routine program for children receiving supplements.

What were the main results of the study?

This report provides the results of the main goal of the study. All results may be found in the ***clinical results summary****.*

Immune response to the malaria, yellow fever and MeRu vaccines

The main goal of the study was to compare antibodies between children who either got malaria vaccine alone or together with yellow fever vaccine and a combined measles and rubella vaccine (MeRu vaccine).

We looked at whether giving the yellow fever and MeRu vaccines with the malaria vaccine had an impact on malaria antibodies (**Figure 2a)**, OR

giving the malaria vaccine with the yellow fever and MeRu vaccines had an impact on the yellow fever and MeRu antibodies (**Figure 2b)**.

When the vaccines were given together or given separately, the immune responses were similar.

Figure 2a: Malaria antibody levels

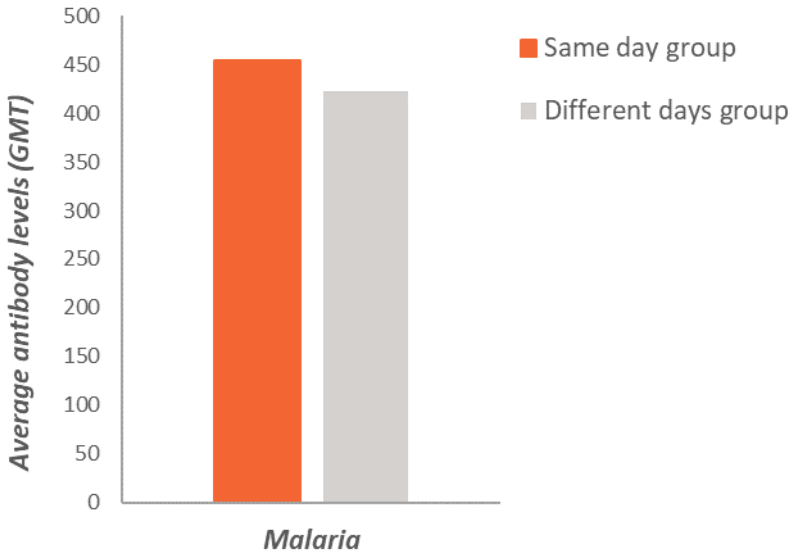
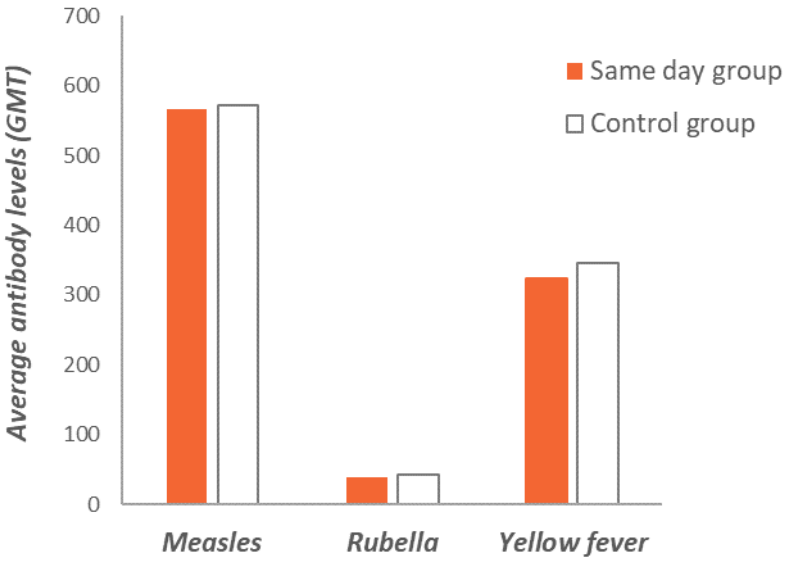


Figure 2b: Measles, rubella and yellow fever antibody levels



What were the side effects?

Unwanted medical events (adverse events) can happen to people when they receive a vaccine. Study doctors record 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.

Side effects for the same day and different days group are shown in **Figure 3.** Pain was the most frequently reported side effect at the place of injection. Fever was the most frequently reported other side effect after vaccination.

In the control group, fever was reported for 4% of children. All other side effects were reported

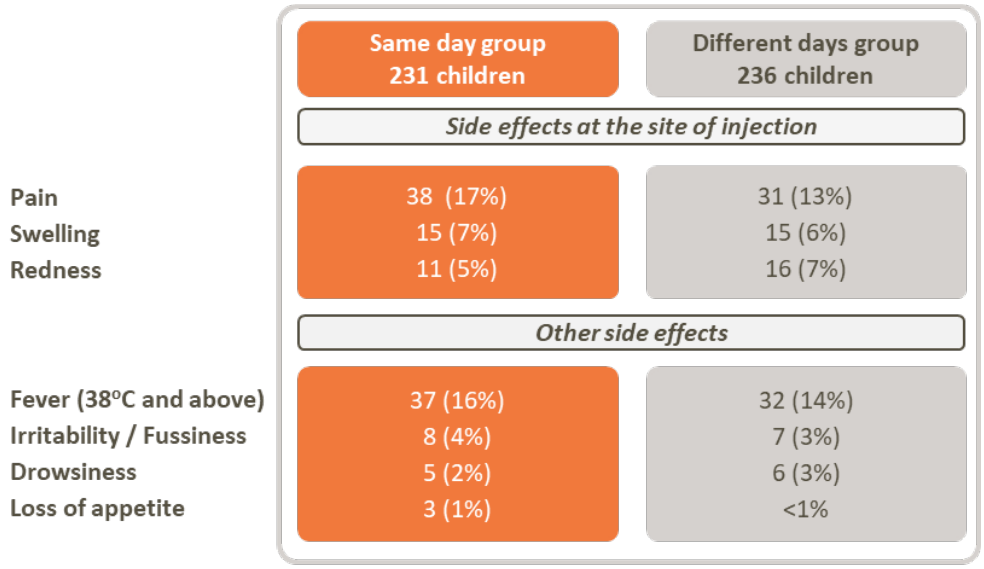
**The use of the term side effects in this summary may be different to that in the Informed Consent or other documents related to the vaccine.*

for less than 1% of children, and all control group results are presented in the ***clinical results summary.***

The results from this study did not raise any safety concern. The side effects reported in this study are known reactions to the study vaccines.

None of study participants reported a serious side effect. No study participant withdrew from the study because of a side effect.

Figure 3: Side effects in at least 1% of children



**Some volunteers had more than one side effect*

How has this study helped patients and researchers?

The results from this study indicate that giving malaria vaccine together with 2 other childhood vaccines is well tolerated and does not impact the response to the vaccines in children.

The results from this study have been shared with the regulatory agencies for evaluation and, if approved, will enable health care professionals to give the malaria vaccine together with 2 other childhood vaccines to children.

Are there plans for further studies?

At the time of preparation of this summary, other studies were ongoing to further evaluate the malaria vaccine.

The results of any future studies will be available on the websites of European Medicines Agency and/or the United States National Institutes of Health. Links are provided at the end of the document.

Where can I find more information about this study?

The detailed title for this research study is:

Phase IIIB randomized, open, controlled, multi-center study to evaluate the immunogenicity and safety of the RTS,S/AS01$_E$ candidate malaria vaccine, when administered as primary vaccination at 6, 7.5 and 9

**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.*

months of age with or without co-administration of measles, rubella and yellow fever vaccines followed by an RTS,S/AS01$_E$ booster vaccination 18 months post Dose 3, to children 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	NCT02699099

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.

Version 1 of this document was developed and approved by GSK on 15 July 2021. 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 below.

For readers of this document in text form, the website associated with the hyperlinks above is:

US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT02699099