

Assessing if prevention of malaria through vaccination and use of bed nets affects thoughts and emotional problems, learning difficulties and school attendance

Submission date 05/01/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/02/2022	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/03/2024	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Malaria is a serious tropical disease spread by mosquitoes. If it isn't diagnosed and treated promptly, it can be fatal.

Severe malaria continues to infect and kill many children despite the gains from improved treatment and prevention of malaria in the last 30 years. Some of the consequences of being ill with severe malaria include thoughts and emotional problems, learning difficulties, and convulsions including epilepsy; all of which can affect involvement in schooling. Some of these problems may be addressed by the prevention of malaria through vaccination and the use of bed nets, but the impact needs to be tested in research studies.

We are funded by EDCTP to assess if children who received a malaria vaccine 10 years ago, and those who slept under a bed net 26 years ago, are at the present showing fewer thoughts and emotional problems, learning difficulties, convulsions including epilepsy and non-attendance at school, compared to their peers who did not receive these malaria prevention measures.

Who can participate?

Children who received either a phase II malaria vaccine in Kilifi or phase III malaria vaccine in Kombewa and Siaya or who did not receive the vaccines.

What does the study involve?

The malaria vaccine follow-up study will be conducted by researchers from KEMRI research centre in Kilifi county, in a defined area that undergoes routine monitoring of births, migrations deaths and exposure to malaria (in some areas) and in two research centers in Western Kenya (KEMRI/Walter Reed Project in Kombewa and KEMRI/CDC Research and Public Health Collaboration in Siaya). Outcomes for children who received either a phase II malaria vaccine in Kilifi or phase III malaria vaccine in Kombewa and Siaya will be compared with those who did not receive the vaccine.

What are the possible benefits and risks of participating?
Findings from this study may inform the inclusion of routine evaluation of brain function into future malaria prevention interventions including vaccines. Additionally, feedback on these results may encourage the community to embrace future malaria prevention measures.

Where is the study run from?
KEMRI-Wellcome Trust Research Programme (Kenya)

When is the study starting and how long is it expected to run for?
March 2019 to February 2023

Who is funding the study?
European and Developing Countries Clinical Trials Partnership

Who is the main contact?
Prof Symon Kariuki, skariuki@kemri-wellcome.org

Contact information

Type(s)
Principal investigator

Contact name
Dr Symon Kariuki

ORCID ID
<https://orcid.org/0000-0002-3934-5132>

Contact details
P O Box 230
Kilifi
Kenya
80108
+254 723926339
skariuki@kemri-wellcome.org

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title

Impact of RTS,S/AS01 vaccine and insecticide treated bed nets on neurobehavioral impairments and school participation in children and young adults from rural Kenya (Mal-Brain study)

Acronym

MalBrain

Study objectives

Protection against malaria in the first 5 years of life, during which there is critical brain development, is associated with subsequent improvement in neurobehavioral outcomes (particularly cognitive outcomes, behavioral and emotional problems and seizure disorders), which then improves school participation (school enrollment, absenteeism and performance) as shown in hypothetical framework.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 05/08/2021, Scientific Ethics and Review Unit (P.O. BOX 54840 00200 Off Mbagathi Road, Nairobi, Kenya; +254713 788 787; seru@kemri.org), ref: none provided

Study design

Observational cohort (follow-up) study

Primary study design

Observational

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Prevention of neurobehavioural impairments in children exposed to falciparum malaria infection

Interventions

The malaria vaccine follow-up study will be conducted by researchers from KEMRI research Centre in Kilifi county, in a defined area that undergoes routine monitoring of births, migrations deaths and exposure to malaria (in some areas) and in two research centers in Western Kenya (KEMRI/Walter Reed Project in Kombewa and KEMRI/CDC Research and Public Health Collaboration in Siaya). Outcomes for 368 children who received either a phase II malaria vaccine in Kilifi or phase III malaria vaccine in Kombewa and Siaya will be compared with those who did not receive the vaccine (N=368). About 68% of these children will be recruited from the KEMRI-Wellcome Trust Research programme in Kilifi and the recruitment for the remainder will be shared between KEMRI/Walter Reed Project in Kombewa (N=113) and KEMRI/CDC Research and Public Health Collaboration in Siaya (N=113). The bed net follow-up study will only be conducted at the KEMRI research Centre in Kilifi where 368 children will be selected by chance from those who slept in bed nets and similar numbers from those who did not use bed nets.

Intervention Type

Biological/Vaccine

Phase

Phase II/III

Drug/device/biological/vaccine name(s)

RTS,S/AS01 vaccine and insecticide treated bed nets

Primary outcome(s)

Prevalence of neurobehavioral impairments assessed using a battery of standardised neuropsychological measures 10 years after vaccination and 26 years after administration of the preventative interventions.

Key secondary outcome(s)

Improvement in school participation i.e. enrollment rates, school performance and cases of absenteeism assessed using parental and children questionnaires 10 years after vaccination and 26 years after administration of the preventative interventions.

Completion date

28/02/2023

Eligibility**Key inclusion criteria**

1. All children who participated in phase II (in Kilifi) and III (in Kombewa and Siaya) of the RTS,S /AS01 trial study and were included in the intention-to-treat population or analysis. Intention-to-treat population is chosen to allow analysis of the impact of number of doses received for vaccine
2. Participants of the ITN intervention trial who give written informed consent to participate in the follow-up studies of neurodevelopment and school participation

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Child

Sex

All

Total final enrolment

421

Key exclusion criteria

1. Children who will not have been included in the intention-to treat population or analysis in the RTS, S/AS01 trial study to facilitate analysis of the impact of number of doses received for vaccine on neurobehavioral outcomes
2. Children who will not have been included in the ITN intervention

Date of first enrolment

01/09/2019

Date of final enrolment

31/12/2022

Locations**Countries of recruitment**

Kenya

Study participating centre

KEMRI/Wellcome Trust Research Programme

P O Box 230

Kilifi

Kenya

80108

Study participating centre

KEMRI/Walter Reed Project Kombewa

PO Box 54

Kisumu

Kenya

40100

Study participating centre

KEMRI/CDC Research and Public Health Collaboration

P.O. Box 1578

Kisumu

Kenya

40100

Sponsor information**Organisation**

KEMRI-Wellcome Trust Research Programme

Funder(s)**Funder type**

Government

Funder Name

European and Developing Countries Clinical Trials Partnership

Alternative Name(s)

Le partenariat Europe-Pays en développement pour les essais cliniques, A Parceria entre a Europa e os Países em Desenvolvimento para a Realização de Ensaaios Clínicos, The European & Developing Countries Clinical Trials Partnership, European and Developing Countries Clinical Trials, EDCTP

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

The sponsoring research institution has a data-sharing policy which requires that external requests for data are made through the data governance committee which meets monthly to deliberate on such requests. Should data access requests be approved, all confidential personal details will be anonymised using unique identifiers such that there can be no recognition by the data borrowers, for purposes of safeguarding confidentiality.

Added 12/03/2024:

Contact the data governance committee of the KEMRI-Wellcome Trust Research Programme at dgc@kemri-wellcome.org.

The type of data that will be shared: Deidentified quantitative data from the study, which involves the follow-ups completed for the RTS,S group (n = 221) and placebo group (n = 200).

Dates of availability: From 01 March 2027 or as soon as the primary manuscript is published, whichever comes first.

The permission to share deidentified data was sought from participants during the study, as part of the informed consenting process.

Personal identification details e.g. name, study number and household names will dropped from the dataset to be shared.

Full acknowledgement of the participants and Researchers or Researcher centres that facilitated data collection should be observed. Concepts/proposals outlining to use the data should also be discussed with lead investigators to avoid duplication of interests.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		12/03/2024	12/03/2024	No	No

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan			27/01/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes