115056 - A prospective study to evaluate the safety, effectiveness and impact of the RTS, S/AS01E vaccine in young children in sub-Saharan Africa (EPI-MALARIA-003 VS AME)

First published: 20/03/2019

Last updated: 23/04/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS28541

Study ID

50529

DARWIN EU® study

No

Study countries

- [ ] Ghana
- [ ] Kenya

☐ Malawi

Study description

The RTS, S/AS01E vaccine has been developed for routine immunization of children living in malaria-endemic countries of sub-Saharan Africa. This study is a post-implementation safety study (after vaccine implementation), with the primary objective to evaluate the safety of vaccine after its administration. In addition to the primary objective, the study will also evaluate the impact and effectiveness of the vaccine. Active surveillance refers to prospective cohort monitoring of the AESI and other diseases during study follow-up visits at the community level as well outpatient and inpatient visits. Enhanced hospitalisation surveillance (EHS) is defined as case detection during hospitalisation through monitoring of medical records and registries for the study participants not enrolled in active surveillance. The study targets enrolling at least 45,000 children in active surveillance (AS), including 22,500 in the exposed clusters and 22,500 in the unexposed clusters for evaluation of the vaccine safety, effectiveness and impact. In the exposed clusters are included a minimum of 20,250 children vaccinated with RTS,S/AS01E for evaluation of the vaccine safety, and a minimum of 2,250 unvaccinated children for evaluation of effectiveness and impact assuming that 80% of the 22,500 study participants will receive three doses of RTS,S/AS01E,10% will receive one or two doses and 10% will not have any dose. Malaria Vaccine Implementation Programme is considering implementing the malaria vaccine in unexposed clusters as from 2023. This decision will directly impact the temporal (before/after) and concurrent (exposed vs. unexposed clusters) comparisons. Based on this, the EHS recruitment will be stopped as from 1 Jan 2023 in sites that were not involved in the NCT02374450 study and study conclusion will be conducted in a timely manner for already enrolled subjects in those sites (EHS will stop in all sites in Malawi, Siaya and Nyando sites in Kenya and unexposed sites in Ghana).

Study status

Ongoing

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Kintampo Health Research Centre Ghana, Navrongo Health Research Centre Ghana, Malawi College of Medicine Malawi, Malawi Liverpool Welcome Trust Malawi, KEMRI (WRP) Kenya, KEMRI (Ahero Clinical Trials Unit) Kenya, KEMRI (CGHR) Kenya

Contact details

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Study contact

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Primary lead investigator
Call Center EU Clinical Trials

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 18/10/2017

Study start date
Actual: 21/03/2019

Date of final study report
Planned: 24/04/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-115056-protocol-redact-02.pdf(1.92 MB)

Protocol Amendment 3 Anonymised 14 Apr 2025.pdf(2.68 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

• To estimate the incidence of adverse events of special interest (AESI) in children vaccinated with RTS,S/AS01E. • To estimate the incidence of aetiology-

confirmed meningitis in children vaccinated with RTS,S/AS01E.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Cluster Design

Study drug and medical condition

Name of medicine

MOSQUIRIX

Medical condition to be studied

Meningitis

Population studied

Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Estimated number of subjects

45000

Study design details

Setting

Specific locations in sub-Saharan Africa with moderate to high malaria transmission.

A geographically confined region equipped with a demographic surveillance system and robust infrastructure for tracking population health and vaccination programs.

Outcomes

- Incidence rates of adverse events of special interest (AESI);
- Incidence rates of aetiology-confirmed meningitis cases;
- Incidence rates of probable meningitis (final classification);
- Incidence rates of clinically suspected meningitis (final classification);
- Number of meningitis cases identified at site level (first line laboratory);
- Incidence rates of cerebral malaria cases (diagnosed by Rapid Diagnostic Test [RDT] and/or microscopy);
- Incidence rates of malaria episodes diagnosed by RDT and/or microscopy;
- Incidence rates of anaemia cases at hospital entry among hospitalised children;
- Incidence rates of hospitalisation cases;
- Number of deaths.

Data analysis plan

All data analyses will be computed in a descriptive manner. Data regarding the hospitalisation will be uniformly collected whether the child is enrolled in active surveillance or in enhanced hospitalisation surveillance.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Other data source

Data source(s), other

Health and Demographic Surveillance System (HDSS) or equivalent surveillance system.

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Health and Demographic Surveillance System (HDSS) or equivalent surveillance system

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No