205071 - A phase IV, longitudinal, cross-sectional, retrospective, ancillary epidemiology study of the EPI-MAL-005 study to evaluate the genetic diversity in the Plasmodium falciparum parasite circumsporozoite sequences before and after the implementation of the RTS,S/AS01E vaccine in malaria-positive subjects ranging from 6 months to less than 5 years of age (EPI-MALARIA-010 VS AME)

First published: 07/10/2021

Last updated: 17/12/2025

Study

Finalised

Administrative details

EU PAS number

EUPAS42948

Study ID

45256

DARWIN EU® study

No

Study countries

☐ Ghana

☐ Kenya

Study description

The RTS,S/AS01E vaccine has been developed for routine immunization of infants and children living in malaria-endemic countries of Sub-Saharan Africa. The aim of this retrospective, ancillary epidemiology study is to monitor the genetic diversity in circumsporozoite sequences in the Plasmodium falciparum (P. falciparum) parasite in malaria-positive subjects aged 6 months to <5 years vaccinated or not with RTS,S/AS01E.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Amsterdam UMC

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Educational Institution

Hospital/Clinic/Other health care facility

Kintampo Health Research Centre Kintampo, Ghana, KEMRI-Walter Reed Project Kombewa, Kenya, Broad Institute (BI), Harvard T.H. Chan School of Public Health (HSPH)

Contact details

Study institution contact

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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
Planned: 07/10/2020

Actual: 07/10/2020

Study start date
Planned: 08/10/2021

Actual: 08/10/2021

Date of final study report
Planned: 13/08/2025

Actual: 05/08/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-205071-protocol-redact.pdf (817.71 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

Genetic

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

Longitudinal, retrospective, epidemiological, cross-sectional study, ancillary to the EPI-MAL-005 study.

Main study objective:

To monitor the genetic diversity in circumsporozoite sequences in the P. falciparum parasite population before and after vaccine implementation in children aged 6 months to <5 years.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Malaria

Population studied

Short description of the study population

Subjects aged 6 months to <5 years of age, enrolled in the EPI-MAL-005 study at the two sites
before and after the start of RTS,S/AS01E vaccination, may be included in the EPI-MAL-010 study

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Age groups

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)

Estimated number of subjects

5600

Study design details

Setting

The two pre-selected sites for the EPI-MAL-010 study are Kintampo in Ghana (Western Africa) and Kombewa in Kenya (Eastern Africa). The sites are located in the planned RTS,S/AS01E pilot implementation areas of Ghana and Kenya, which are moderate-to-high transmission areas as recommended by the WHO for the MVIP. Based on the results from MALARIA-066, selecting one site situated in Western Africa and the other in Eastern Africa will allow further exploring the already observed P. falciparum strain diversity differences between Western and Eastern Africa, as well as giving to EPI-MAL-010 a certain level of continental diversity in terms of human populations.

Outcomes

Prevalence of P. falciparum haplotype infections among subjects infected or not with P. falciparum and frequency of P. falciparum haplotype infections among the individual malaria clones in subjects vaccinated or not with RTS,S/AS01E per study site. Prevalence and frequency of P.falciparumhaplo type infections by age group, gender and RTS,S/AS01Evaccinationstatusper study site, Trends in longitudinal prevalence of specific P.falciparumhaplotypesamongsubjectsinfectedornotwith P.falciparum,vaccinatedornotwith RTS,S/AS01E,Trends inlongitudinalfrequencyofspecific P.falciparum haplotypes among the individualmalariaclonesinsubjectsvaccinatedornotwithRTS,S/AS01E.

Data analysis plan

- The haplotype prevalence will be estimated by site, as the number of subjects infected with a specific P. falciparum haplotype, divided by the total number of subjects. Thus, the denominator will be all the subjects aged 6 months to <5 years included in the EPI-MAL-010 study for each of the 2 sites considered: malaria positive and negative subjects based on malaria blood reading and/or NAAT.

- The haplotype frequency will be estimated by site, as the number of occurrences of a specific P. falciparum haplotype, divided by the total number of clones. Thus, in case of multiple infections with P. falciparum malaria, the same subject will contribute multiple times in the denominator. The frequency will be estimated using data only from subjects aged 6 months to <5 years, measured malaria positive by microscopy and/or NAAT, included in the EPI-MAL-010 study for each of the 2 sites considered.

Documents

Study report

Clinical Study Report Anonymised 10 Nov 2025.pdf (3.25 MB)

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

Retrospective, ancillary study, re-using samples of the EPI-MAL-005 study

Data sources (types), other

Retrospective, ancillary study, re-using samples of the EPI-MAL-005 study

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