

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: 28/05/2024

Study

Ongoing

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/45256>

EU PAS number

EUPAS42948

Study ID

45256

DARWIN EU® study

No

Study countries

Ghana

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

Ongoing

Research institution and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Amsterdam UMC

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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

Call Center EU Clinical Trials

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:

30/05/2025

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

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

Age groups

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Estimated number of subjects

5600

Study design details

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. falciparum* haplotype infections by age group, gender and RTS,S/AS01E vaccination status per study site, Trends in longitudinal prevalence of specific *P. falciparum* haplotypes among subjects infected or not with *P. falciparum*, vaccinated or not with RTS,S/AS01E, Trends in longitudinal frequency of specific *P. falciparum* haplotypes among the individual malaria clones in subjects vaccinated or not with RTS,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.

Data management

Data sources

Data sources (types)

[Other](#)

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