116682 - An epidemiology study to assess Plasmodium falciparum parasite prevalence and malaria control measures in catchment areas of two studies pre- and post RTS,S/AS01E introduction (EPI MAL-002 and EPI-MAL-003) to assess, in field conditions, vaccine benefit:risk in children in sub Saharan Africa. (EPI-MALARIA-005 BOD AME)

First published: 22/12/2021

Last updated: 11/02/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47949

EU PAS number

EUPAS43920

Study ID

47949

DARWIN EU® study

No

Study countries

- [ ] Burkina Faso
- [ ] Ghana
- [ ] Kenya
- [ ] Malawi
- [ ] Senegal
- [ ] Tanzania, United Republic of

Study description

This epidemiology study is planned to run in parallel with the EPI-MAL-002 and EPI-MAL-003 studies, enrolling from the same health and demographic surveillance system (HDSS) (or equivalent system) populations.
The co-primary objectives are to produce longitudinal estimates of parasite prevalence in humans, and record malaria control measures usage in areas where EPI-MAL-002 and EPI-MAL-003 studies will take place.

Study status

Ongoing

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Biologicals

Centre de Recherche en Santé de Nouna (CRSN) Nouna, Burkina Faso, Centre National de Recherche et de Formation sur le Paludisme (CNRFP) Ouagadougou, Burkina Faso, Kintampo Health Research Centre (KHRC) Kintampo, Ghana, Navrongo Health Research Centre (NHRC) Navrongo, Ghana, KEMRI-Walter Reed Project (KEMRI-WRAIR) Kombewa, Kenya, KEMRI / CDC Research and Public Health Collaboration Kisumu, Kenya, KEMRI (Ahero Clinical Trials Unit) Kisumu, Kenya, Malawi College of Medicine (COM) Mangochi, Malawi, Malawi Liverpool Welcome

Trust (MLW) Blantyre, Malawi, Département de Parasitologie, Centre de Recherche de Keur Socé, Faculté de Médecine, Université Cheikh Anta Diop Dakar, Senegal

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: 21/01/2014

Actual: 21/01/2014

Study start date

Planned: 31/10/2014

Actual: 22/10/2014

Date of final study report
Planned: 04/08/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-116682-protocol-redact.pdf(1.37 MB)

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 obtain longitudinal estimates of P. falciparum parasite prevalence, assess malaria transmission intensity, and evaluate malaria control interventions at EPI-MAL-002 and EPI-MAL-003 study centers pre- and post- introduction of the RTS,S/AS01E malaria vaccine in sub-Saharan Africa.

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

54000

Study design details

Outcomes

Number of subjects infected with P. falciparum parasitaemia (using microscopy) and number of subjects using malaria control interventions (primarily bednets), Number of subjects infected with Plasmodium species other than P. falciparum, with uptake of the third dose of DTP pentavalent and the first dose of the measles EPI vaccines, using anti-malarial therapy in the 14 days prior to the visit, with measured fever at the visit or reported fever in the 24 hours prior to the visit, demonstrating care seeking behavior, and/or presenting risk factors.

Data analysis plan

• The parasite prevalence will be estimated as the proportion of subjects infected among subjects tested. The estimates of parasite prevalence will be done each year and for each site separately.

• The estimates of the use of malaria control measures will be estimated as the number of subjects using malaria control measures divided by the number of subjects for which this information is available. The estimates of the use of malaria control measures will be done each year and for each site separately.

• The trends in parasite prevalence between each cross-sectional malariometric surveys will be tested using the Cochran-Armitage trend test. This hypothesis test will be performed on the parasite prevalence computed on the independent samples of subjects in each survey separately within each site.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Collection of centre specific information about interventions from malaria control program in the study area and meteorological data such as rainfall, humidity, and temperature.
Information will be collected with a questionnaire recorded in a separate database for subject-specific data.
Other 2 participating centres are IRD, Dakar, Senegal, and JMP Nat. Inst. Medical Research, Korogwe, Tanzania.

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