115055-A prospective study to estimate the incidence of diseases specified as adverse events of special interest, of other adverse events leading to hospitalisation or death, and of meningitis in infants and young children in sub-Saharan Africa prior to implementation of the RTS,S/AS01E candidate vaccine (EPI-MALARIA 002 VS AME)

First published: 20/01/2022

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS45288

Study ID

50414

DARWIN EU® study

No

Study countries

Burkina Faso

Ghana

Kenya

Study description

The purpose of this pre-licensure cohort study is to estimate the incidence of adverse events of special interest (AESI), other adverse events (AE) leading to hospitalisation or death, meningitis and malaria in sub-Saharan African children under 5 years of age. The outcomes of this study will provide the baseline data for the post-licensure EPI-MALARIA-003 (115056) study that will evaluate the safety, effectiveness and impact of the RTS,S/AS01E vaccine. An interim analysis was performed on a sub-group of study participants enrolled in active surveillance from sites where the vaccine is currently implemented, having 6 months of follow-up following the administration of dose 3 of DTP/HepB/Hib vaccine (6-12 weeks group), or 6 months after Visit 3 (mimicking the RTS,S/AS01E primary vaccination schedule) for the 5-17 months group, corresponding to Visit 5. The interim analysis concerned primary safety endpoints and the main secondary endpoints.

Study status

Finalised

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Centre National de Recherche et de Formation sur le Paludisme (CNRFP), Ouagadougou Burkina Faso, Centre de Recherche en Santé de Nouna, Nouna Burkina Faso, Kintampo Health Research Centre (KHRC), Kintampo Ghana, Navrongo Health Research Centre (NHRC), Navrongo Ghana, KEMRI-Walter Reed Project (KEMRI-WRAIR), Kombewa Kenya, Network: CLS (Clinical Laboratory Services)

South Africa

Networks

PATH (Program for Appropriate Technology in Health), AMP (Agence de Médecine Préventive) (in French), RAFT (Réseau en Afrique Francophone pour la Télémédecine) (in French)

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: 01/06/2012

Actual: 08/05/2014

Study start date
Planned: 09/10/2015

Actual: 05/10/2015

Date of final study report
Planned: 06/06/2023

Actual: 24/05/2023

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline, Program for Appropriate Technology in Health (PATH)

Study protocol

gsk-115055-protocol-redact.pdf (1.42 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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

• To estimate the incidence of AESI, and of other AE leading to hospitalisation or death, in children, prior to implementation of RTS,S/AS01E. • To estimate the incidence of aetiology-confirmed meningitis, in children, prior to implementation of RTS,S/AS01E.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Intensive monitoring schemes, Disease surveillance study with prospective cohort event monitoring

Study drug and medical condition

Medical condition to be studied

Malaria

Population studied

Short description of the study population

The study population included infants and young children < 5 years of age living in a geographically limited area with a health and demographic surveillance system (HDSS) or equivalent surveillance system in place, and an existing infrastructure to monitor population health and vaccination programmes in sub-Saharan Africa (SSA) countries.

Inclusion criteria:

• Subjects’ parent(s)/ LAR(s) who, in the opinion of the investigator, can and will comply with the requirements of the protocol.

• Written informed consent provided from either the parent(s) or LAR of the subject.

• Subject living in the HDSS or equivalent surveillance system area.

• For enrolment in the active surveillance: children must be < 18 months of age OR For enrolment in the enhanced hospitalisation surveillance: children must be

< 5 years of age and hospitalised at any time during the study.

Exclusion criteria:

• Child in care.

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)

Special population of interest

Other

Special population of interest, other

Patients with malaria

Estimated number of subjects

30000

Study design details

Outcomes

Incidence of AESI, adverse events (AEs) leading to hospitalisation or death and aetiology-confirmed meningitis. Aetiology-confirmed/probable meningitis, probable meningitis, clinically suspected meningitis, Meningitis cases, risk factors for AESI and other AEs (OAEs), Hospitalisation due to AESI, OAEs, meningitis/malaria, Number of deaths by cause, Febrile convulsions, Any, severe and cerebral malaria, Anaemia for hospitalised children, All-cause

malaria hospitalisations, Mortality rate

Data analysis plan

• The incidence rate of each AESI and other AE leading to hospitalisation or death will be calculated by dividing the number of subjects reporting at least one event over the follow-up period by the total person-time. A 95% CI will be computed using an exact method for a Poisson variable. • The person-time for an event of interest will be calculated as the time between the reference date (date of first administration of DTP/HepB/Hib or date of first virtual vaccination, corresponding to the week before first visit) and the end of the at-risk period or the earliest of the date of: first diagnosis of event of interest, end of study period, enrolment in EPI-MAL-003 (when applicable), when child reaches 5 years, last contact (lost-to follow-up) or death. • Each AESI will be grouped after case ascertainment (for both confirmed and non-confirmed cases). • The incidence rate of aetiology-confirmed meningitis and of cerebral malaria will be computed with 95% CI as described above

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 sources (types)

Other

Data sources (types), other

Health Demographic Surveillance System (HDSS), Active surveillance, Enhanced hospitalisation surveillance.

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