An Evaluation of the Pilot Implementation of RTS,S/AS01 Through Routine Health Systems in Moderate to High Malaria Transmission Settings in Africa (Malaria Vaccine Pilot Evaluation (MVPE))

First published: 27/07/2021

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS42048

Study ID

42049

DARWIN EU® study

No

Study countries

Ghana

Kenya

Malawi

Study description

The RTS,S/AS01 malaria vaccine is being introduced sub-nationally in phased pilot introductions through the EPI programmes in Malawi Ghana and Kenya. Vaccine introduction is by the respective MoH in selected areas randomly assigned to receive the vaccine at the beginning of the pilots. In the context of this programmatic activity, the Malaria Vaccine Pilot Evaluation (MVPE) registered here as observational evaluations during early vaccine introduction, include a series of 3 household surveys, and sentinel hospital and community mortality surveillance, building on routine systems. These observational evaluations will measure: 1. The programmatic feasibility of delivering a 4 dose schedule, 2. Safety in routine use, with focus on cerebral malaria and meningitis, 3. The impact of the malaria vaccine in routine use on severe malaria and all-cause mortality

Study status

Ongoing

Research institutions and networks

Institutions

World Health Organisation (WHO)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Ghana Kintampo Health Research Centre, Ghana, College of Medicine, School of Public Health, University of Malawi Malawi, CDC-Kenya Malaria Research Program Kenya

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/06/2017

Actual: 18/07/2017

Study start date

Planned: 01/10/2018

Actual: 01/03/2019

Data analysis start date
Planned: 01/06/2021

Date of interim report, if expected
Planned: 08/10/2021

Date of final study report
Planned: 20/12/2023

Sources of funding

- Other

More details on funding

GAVI, UNITAID, Global Fund

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)

Other study registration identification numbers and links

ClinicalTrials.gov ID: NCT03806465

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Main study objective:

To estimate the effect of RTS,S introduction on: • impact (on all-cause mortality (excluding accidents) and severe malaria • safety cerebral malaria, meningitis and gender specific mortality • feasibility of delivering a four dose malaria schedule

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Community mortality surveillance and sentinel hospital surveillance

Study drug and medical condition

Medicinal product name

MOSQUIRIX

Medical condition to be studied

Meningitis bacterial

Malaria

Population studied

Age groups

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

Estimated number of subjects

960000

Study design details

Outcomes

To estimate the effect of RTS,S introduction on: • on all-cause mortality (excluding accidents) • hospital admission with severe malaria (severe malaria anaemia or cerebral malaria) • hospital admission with probable or confirmed meningitis (pooled) • hospital admission with cerebral malaria (pooled) • gender specific mortality, To estimate the effect of RTS,S introduction on: • all-

cause and malaria specific mortality • incidence of (i) all cause hospital admission, (ii) admission with severe malaria anaemia and requirement for transfusion,(iii) admission with cerebral malaria, (iv) non malaria hospital admission • routine vaccine uptake, malaria and other childhood interventions and health seeking behavior

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Data analysis plan

Children will not be assigned individual identifiers at the time of vaccination and there will be no systematic linkage between records of children admitted to participating hospitals and records of children vaccinated with RTS,S/AS01 or any other vaccine. The effect of RTS,S/AS01 will therefore be assessed by comparing incidence in vaccine-eligible age groups, in populations where the malaria vaccine was introduced and populations in comparator areas. Effects will be measured in terms of the incidence rate ratio (the relative increase or decrease in incidence of the outcome due to introduction of RTS,S vaccine, in the age group of children eligible to receive the vaccine) as a result of RTSS vaccine being introduced into an area, in the age groups of children eligible for the vaccine, expressed per 1000 child years or other suitable units). As a secondary analysis, rate ratios will also be estimated in children known to have received DTP3.

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

Prospective patient-based data collection

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