

Risk of malaria in children aged 5 years or more following seasonal malaria chemoprevention or seasonal vaccination discontinuation

Submission date 21/06/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/07/2021	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/11/2023	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Malaria is a mosquito-borne infectious disease. Current effective malaria control tools include seasonal malaria chemoprevention (SMC), which is tailored for the countries of the Sahel and Sub Sahel. This strategy involves doses of sulfadoxine-pyrimethamine plus amodiaquine once monthly over the highest malaria transmission period. SMC has the ability to clear a current infection and to prevent the acquisition of a new one. This sustained suppression of the parasite's presence in the body may slow down the development of an effective immune response to combat the infection. In research studies in which the intervention was given over only a short period of time (no more than two transmission seasons), there was no consistent evidence of this impairment; some studies found a slight effect, whilst others failed to find any. However, in programs in which the intervention is given many times (children born while the intervention is being deployed will receive SMC from the age of 3 months up to 5 years each malaria transmission season without interruption), such crucial information is missing and it is important to evaluate this potential "rebound effect" to alert policymakers to this potential threat as several million children are being treated currently with SMC. To investigate the issue of rebound the researchers will conduct two studies (one for uncomplicated malaria and one for severe malaria). Two community controls will be recruited for each case in the uncomplicated malaria study while two community and two hospital controls will be recruited for each case in the severe malaria study. The participants will all be interviewed with regard to their use of long-lasting insecticide treated nets (LLINs), their socio-economic status, SMC history, and housing. The aim of this study is to determine whether the risk of malaria is higher in children who have had a high level of coverage with SMC compared to those who have not, taking into account any potential confounding factors.

Who can participate?

Children aged 5 years or more, previously enrolled in the seasonal malaria chemoprevention or seasonal vaccination trial

What does the study involve?

The study involves passive surveillance of cases at health facilities. It also involves the recruitment of controls either in the communities or at the health facilities.

What are the possible benefits and risks of participating?

There is no direct benefit of participating in the study. Participants will not be paid to join. However, all participants' care at the health facility will be paid for by the project. The follow-up at the health facilities involves a finger prick to perform a rapid diagnostic test and a blood smear for malaria diagnosis. This can involve brief pain and the risk of infection is very low as the sampling will be done by experienced staff trained for this purpose.

Where the study is run from?

Institut de Recherche en Sciences de la Santé (Burkina Faso)

When is the study starting and how long is it expected to run for?

July 2021 to December 2024

Who is funding the study?

European and Developing Countries Clinical Trials Partnership (Netherlands)

Who is the main contact?

Issaka Zongo, MD, PhD

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

TMA2019SFP-2834

Study information

Scientific Title

Risk of malaria in children who have reached the age of 5 years and are no longer eligible for seasonal malaria chemoprevention and or seasonal vaccination in Burkina Faso and Mali

Acronym

SEVR-SMC

Study objectives

Children 3-59 months previously submitted to seasonal malaria chemoprevention (SMC) or seasonal vaccination are more susceptible to malaria when the intervention is stopped.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 21/04/2021, National Ethics Committee For Health Research (09 BP 7009, Ouagadougou 09, Burkina Faso; +226 25488937; no email provided), ref: 2021-04-100

Study design

Observational study with nested case-control study

Primary study design

Observational

Secondary study design

Nested case-control study

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Malaria

Interventions

The study is built on a large randomised clinical trial investigating whether combining seasonal malaria chemoprevention (SMC) and seasonal vaccination is better than seasonal malaria chemoprevention and seasonal vaccination alone. This study started on January 2017 and now that children are getting older (aged more than 59 months), they are no longer eligible for SMC or seasonal vaccination. This study will proceed by two methods : a) Children aged over 59 months who are no longer receiving SMC will be followed at the health facility to record their medical history and malaria episode from July 1 2021 to December 31 2024. Malaria episodes will be compared between the previous study arm to see whose group is providing more episodes of malaria, b) case control studies. One for uncomplicated malaria and the second for severe malaria.

In these case control studies, children presenting at the study clinics with uncomplicated malaria or severe malaria will be recruited as cases. Two community controls will be recruited to match the cases in the uncomplicated malaria case control study while four controls (two communities and two hospital) will be recruited for one severe malaria case.

Case controls studies will take place in 2021 (July-Dec 2021) and if any rebound is seen another set of case control studies will be carried out in 2022 (July-Dec).

Intervention Type

Mixed

Primary outcome measure

Incidence of uncomplicated malaria or severe malaria in the year after the interventions are stopped measured using patient records

Secondary outcome measures

1. Incidence of asymptomatic malaria parasitemia at the end of the malaria transmission season in the year after the interventions are stopped measured using patient records
2. Incidence of mild or moderate anemia or of malnutrition at the end of the malaria transmission season in the year after the interventions are stopped measured using patient records

Overall study start date

01/01/2021

Completion date

31/12/2025

Eligibility

Key inclusion criteria

1. Belonging to the seasonal malaria chemoprevention or seasonal vaccination cohort and aged over 59 months
2. Provision of signed informed consent

Participant type(s)

Mixed

Age group

Child

Lower age limit

59 Months

Sex

Both

Target number of participants

5,000

Key exclusion criteria

Absence of informed consent

Date of first enrolment

01/07/2021

Date of final enrolment

31/12/2024

Locations**Countries of recruitment**

Burkina Faso

Mali

Study participating centre

Institut de Recherche en Sciences de la Santé, Direction Régionale de l'Ouest

399 Ave Liberté

BP/ 545

Bobo-Dioulasso

Burkina Faso

226

Study participating centre

Malaria Research and Training Center

Department of Epidemiology of Parasitic Diseases

Faculty of Pharmacy

University of Science, Techniques and Technology of Bamako

PO Box: 1805 Point G

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Mali

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Sponsor information

Organisation

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Sponsor type

Research organisation

Website

http://www.irss.bf/index.php?option=com_content&view=frontpage&Itemid=1

Funder(s)**Funder type**

Research organisation

Funder Name

European and Developing Countries Clinical Trials Partnership

Alternative Name(s)

Le partenariat Europe-Pays en développement pour les essais cliniques, A Parceria entre a Europa e os Países em Desenvolvimento para a Realização de Ensaio Clínicos, The European & Developing Countries Clinical Trials Partnership, European and Developing Countries Clinical Trials, EDCTP

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

Netherlands

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request - zongoissaka08@gmail.com

IPD sharing plan summary

Available on request