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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

Registration date
02/07/2021

Overall study status
Completed

Last Edited
03/12/2025

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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
zongoissaka08@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Issaka Zongo

ORCID ID
https://orcid.org/0000-0002-9045-4713

Contact details
Institut de Recherche en Science de la Santé
399 Ave Liberté
Bobo-Dioulasso
Burkina Faso
226
+226 (0)66392982
zongoissaka08@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
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

Study type(s)
Prevention

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
59 months

Upper age limit
96 months

Sex
All

Total final enrolment
1433

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

Sponsor information

Organisation
Institut de Recherche en Sciences de la Santé

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 Ensaios 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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes