ISRCTN12108982 https://doi.org/10.1186/ISRCTN12108982

A preparatory cohort study to assess the feasibility of malaria incidence detection in Burkina Faso

Submission date
07/08/2026

Recruitment status
Recruiting

Registration date
10/08/2026

Overall study status
Ongoing

Last Edited
10/08/2026

Condition category
Infections and Infestations

[X] 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 disease caused by parasites that are spread by mosquitoes. Some people can carry malaria parasites without feeling ill, but they can still contribute to the spread of the disease. Seasonal Malaria Chemoprevention (SMC) is given to children aged under 5 years during the malaria season and helps protect them from malaria. However, it is not yet clear whether SMC also helps reduce malaria transmission across the wider community.
This study is a preparatory project for a larger future trial. The aim is to understand how often people become infected with malaria after treatment, how often they develop malaria illness, and whether study participants can be reliably identified and followed through local health facilities. The information collected will help researchers design a future study to investigate the wider community effects of SMC.

Who can participate?
People aged 3 months to 100 years who live in the study area and have already agreed to take part in the wider study census may be eligible. Adults must provide their own consent. For children, a parent or guardian must provide consent, and children who are old enough may also be asked to give assent.
Participants must be willing to provide small blood samples during the study. Some medical conditions, such as severe anaemia, severe malnutrition, or certain chronic illnesses, may prevent participation.

What does the study involve?
The study will recruit around 1,000 people from villages in Burkina Faso.
At the first visit, participants will be checked for signs of illness and will provide a small finger-prick blood sample. They will then receive a three-day course of the antimalarial medicine Co-artem to clear any malaria parasites that may be present.
Two weeks later, another finger-prick blood sample will be taken and tested for malaria. People who do not have malaria at this point will join the main study cohort.
Participants in the cohort will be visited every two weeks for up to 16 weeks. In total, there will be up to nine study visits. At each visit, researchers will ask about health and collect a small

finger-prick blood sample. The total amount of blood collected during the study will not exceed 2.5 mL.
Participants will also receive a study identification card. If they become unwell between scheduled visits, they will be encouraged to attend their local health facility, where study staff will assess them and provide appropriate care. Participants who appear unwell during study visits will also be referred for medical assessment and treatment.
At the end of the study, stored blood samples will be tested in the laboratory to look for malaria infections, including infections that did not cause symptoms.

What are the possible benefits and risks of participating?
Participants may benefit from regular health assessments, malaria monitoring, and access to free care from study staff if they become unwell during the study period. The information collected may also help improve future malaria control programmes.
The main risks are those associated with finger-prick blood sampling, including brief pain, discomfort, bruising, or a small risk of infection at the sampling site. Participants may also experience side effects from the antimalarial medicines used in the study, although these medicines are commonly used and approved for malaria treatment.

Where is the study run from?
The study is being carried out in Burkina Faso. It is led by researchers from the Groupe de Recherche Action en Santé (GRAS) in Burkina Faso and the London School of Hygiene & Tropical Medicine in the United Kingdom.
When is the study starting and how long is it expected to run for?
August 2026 to December 2026.

Who is funding the study?
The study is funded by Coefficient Giving (formerly Open Philanthropy).

Who is the main contact?
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Study information

Scientific Title
A preparatory study to inform the design of the Targeting school-Age Children for malaria Transmission Interruption at Community level trial (PreTACTIC study) in Burkina Faso: Cohort

Acronym
PreTACTIC

Study objectives
1. To understand the feasibility of identifying enrolled individuals at local health facilities using embedded study nurses and a study ID card system linked to census data
2. To estimate recurrence of P. falciparum infection in a cohort of individuals post clearance with antimalarial
3. To estimate occurrence of clinical episodes of malaria in a cohort of individuals post clearance with antimalarial

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 06/07/2026, London School of Hygiene and Tropical Medicine (Keppel Street, London, WC1E 7HT, United Kingdom; +44 (0)20 7636 8636; ethics@lshtm.ac.uk), ref: 34086

2. Approved 21/07/2026, Comité d'éthique pour la Recherche en Santé (CERS) (Ministere de la Santé, Ouagadougou, 03 BP 7009, Burkina Faso; +226 70 26 89 98; no email address provided), ref: 2026/060/MS/MESRI/CERS

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Malaria

Interventions
A cohort of randomly selected individuals, stratified by age (recruited from age groups <5, 5-15, and >15, in a 1:1:2 ratio – to maximise observations from adults [see sample size]), will be enrolled from two LHFs catchment area (covering 20 villages and 20,000 individuals, on average 50 individuals per village). The enrolled individuals will receive a study ID card, then a curative dose of antimalarial (Co-artem; Artemether-lumefantrine) prior to the beginning of the malaria season (June).
Fourteen days later, clearance will be confirmed by microscopy. Those individuals who are negative will be enrolled in the cohort and routinely assessed (fortnightly) for clinical malaria infection. Enrollment will continue until the requisite sample size (n=1000) is reached, and all enrollees will be given a study ID card for presentation at LHFs. Blood smears and spots will be collected during home visits but will only processed at the end of the follow up for molecular infection detection (PCR). During the home visit an objective fever or reported history of fever within the past 48 hours will prompt referral to the catchment LHF for testing for malaria using a rapid diagnostic test (RDT).
For the duration of the study (maximum 9 visits, over 18 weeks, between enrolment and the cross sectional survey), participants will be instructed to attend to the LHF at any time they feel unwell between home visits by the study team. Study nurses at the LHF will manage those coming for illness visit. A malaria RDT will be done if indicated for prompt case management, and a blood smear a dried blood spot will be collected for confirmatory reading later on. The final diagnosis will be recorded in the participant file. For easy recognition of the participant, his /her study ID card will be used. A listing of all enrolled participants with ID details will also be available and the nurse could make reference to this in case of the participant did not bring his /her ID card.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Artether-Lumefantrine

Primary outcome(s)
1. Incidence rate of clinical malaria measured using history of fever (within previous 48 hours) or a measured temperature ≥37.5C and a positive blood smear at August - November 2026 (Bi-weekly)

Key secondary outcome(s)
1. Attendence rate (referral and passive) at clinics of cohort enrolees measured using local health facility record at August - November 2026 (Bi-weekly)

2. Time to first or only clinical episode measured using local health facility record at August - November 2026 (Bi-weekly)

3. Time to reinfection with P. falciparum measured using microscopy and/or PCR after enrollment at August - November 2026 (Bi-weekly)

4. Monthly prevalence of P. falciparum measured using microscopy and/or PCR after enrollment at August - November 2026 (Bi-weekly)

Completion date
21/12/2026

Eligibility

Key inclusion criteria
1. Consented to be a part of the wider study census
2. Age 3 months or older
3. If aged ≥18 years, provides informed consent to participate in the cohort study
4. Parent or guardian provides consent for the child's participation (as relevant, according to age) in the cohort study
5. Child provides assent for participation (as relevant, according to age) in the cohort study
6. Willing to provide up to 18 blood samples, up to a total volume of 2.5 mL, over a maximum of 18 visits
7. If aged <5 years (recipient of SMC delivered by the national control programme): 7.1. Eligible to receive SPAQ as part of standard SMC delivery by the national malaria control programme according to NMCP guidelines, and has received any SMC dose (1st, 2nd, or 3rd) within 3 days of the enrolment visit

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
3 Months

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
If aged <5 years (recipient of SMC delivered by national control program):
1. Does not provide consent to participate in the study
2. Anaemia (Hb <8 g/dL)

3. Any chronic illness that requires immediate or continuous clinical care
4. Severe malnutrition (weight-for-height below -3 standard deviations or less than 70% of the median of the NCHS/WHO reference values)
5. Current participation in malaria vaccine or drug trials, or participation in vaccine trials within the last 2 years

If aged >5 years (recipient of presumptive second-line treatment):
1. Currently pregnant and has attended the first ANC visit
2. Anaemia (Hb <8 g/dL)
3. Any chronic illness that requires immediate clinical care
4. Family history of sudden death or congenital or clinical conditions known to prolong the QTcB or QTcF interval, for example family history of symptomatic cardiac arrhythmias, clinically relevant bradycardia, or severe cardiac disease
5. Any treatment that can induce prolongation of the QT interval
6. Known history of hypersensitivity, allergic reactions, or adverse reactions to the study drugs or their components
7. Severe malnutrition (weight-for-height below -3 standard deviations or less than 70% of the median of the NCHS/WHO reference values)
8. Current or previous participation in malaria vaccine trials

Date of first enrolment
10/08/2026

Date of final enrolment
24/08/2026

Locations

Countries of recruitment
Burkina Faso

Netherlands

Study participating centre
Radboud University Medical Center
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Sponsor information

Organisation

London School of Hygiene & Tropical Medicine

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type

Funder Name
Coefficient Giving (formerly Open Philanthropy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available