ISRCTN17164969 https://doi.org/10.1186/ISRCTN17164969

# The acceptability of seasonal antimalarial medication in Korogho, Côte d'Ivoire

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| **Submission date**<br>22/06/2021 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>02/07/2021 | **Overall study status**<br>Completed | |
| **Last Edited**<br>21/12/2021 | **Condition category**<br>Infections and Infestations | |

**Plain English summary of protocol**

Background and study aims

Malaria is a mosquito-borne infectious disease. Seasonal malaria chemoprevention (SMC) involves giving children full malaria treatment courses intermittently during the malaria season. It is a proven effective strategy largely used in the countries of the Sahel and sub-Sahel where most malaria cases occur in the rainy season. The extreme South and South West of Burkina Faso are being covered by SMC with an impact on the burden of malaria. Following recent data on SMC adaptation based on the incidence of clinical malaria and where 60% of cases occur in a limited period of time, the extreme North of Ivory Coast border with South and South West of Burkina Faso has a West Sudanian savannah climate with annual rainfall of up to 1300 mm and could benefit from five cycles of SMC. The aim of this study is to assess the acceptability of five cycles of SMC with sulfadoxine-pyrimethamine and amodiaquine.

Who can participate?

Children aged 3-59 months living in the study area

What does the study involve?

Participants are treated with seasonal malaria chemoprevention (SMC) drugs (unique dose of sulfadoxine-pyrimethamine and one dose of amodiaquine on the first day and two further doses of amodiaquine on the second and third days over 5 months). Then acceptability and feasibility studies are carried out along with the drug distribution. Before and after the SMC distribution, surveys will be done to assess parasitemia (parasites in the blood) and molecular markers.

What are the possible benefits and risks of participating?

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?
Dr Orphée Kangah
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# Contact information

### Type(s)
Scientific

### Contact name
Dr Orphee Kangah

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Protocol serial number
/TMA2019SF2834_PAF-SMC/RCI

# Study information

### Scientific Title
Pilot seasonal malaria chemoprevention implementation in Korogho

### Acronym
PAF-SMC/RCI

### Study objectives
Seasonal malaria chemoprevention is acceptable and feasible in Korogho, Côte d'Ivoire

### Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 14/06/2021, Comité National d'Ethique des Sciences de la vie et de la Terre (National Ethics Committee for Life Science and Health, Ivory Coast; +225 (0)69 285 753; cnesvs@gmail.com), ref: 082-21/MSHP/CNESVS-km

## Study design
Implementation study

## Primary study design
Interventional

## Study type(s)
Prevention

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

## Interventions
As part of routine treatment, participants are treated with seasonal malaria chemoprevention (SMC) drugs (unique dose of sulfadoxine-pyrimethamine and one dose of amodiaquine on the first day and two further doses of amodiaquine on the second and third days over 5 months).

Acceptability and feasibility studies are carried out along with the drug distribution. Before and after the SMC distribution, surveys will be done to assess parasitemia (parasites in the blood) and molecular markers.

## Intervention Type
Drug

## Phase
Phase III/IV

## Drug/device/biological/vaccine name(s)
Sulfaodoxine-pyrimethamine, amodiaquine

## Primary outcome(s)
Proportion of children aged 3 - 59 months (at the time of first SMC cycle) who received five monthly treatments of SMC measured using patient records one month after the last round of treatment (in December)

## Key secondary outcome(s))
All measured one month after the last round of treatment (in December) unless otherwise noted:
1. The proportion of children 3 - 59 months (at the time of SMC first cycle) who received 1, 2, 3, 4 or 5 monthly treatments of SMC measured using patient records through coverage survey
2. Logistics of delivery including the number of health workers, the time required per month, the average number of children treated per health worker team measured using qualitative and quantitative surveys
3. Timeliness of delivery measured using individual interview
4. Quality of delivery (adherence to guidelines) measured using using individual interview
5. Adherence to supervised and unsupervised doses measured using coverage survey

6. Acceptability to caregivers and to health staff measured using qualitative acceptability questionnaire
7. Prevalence of parasite carriage on baseline and at the end of the fifth cycle measured using epidemiological survey
8. Prevalence of molecular markers conferring resistance to SMC drugs (codons at dhfr, dhps, pfmdr-1 and pfcrt T76) measured using epidemiological survey

### Completion date
31/03/2022

## Eligibility

### Key inclusion criteria
1. Both sexes
2. Resident of the study area
3. Willingness to remain in the study area during the study
4. Age between 3 and 59 months
5. Provision of signed informed consent
6. Absence of severe malnutrition or severe condition

### Participant type(s)
Mixed

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
3 months

### Upper age limit
59 months

### Sex
All

### Total final enrolment
1701

### Key exclusion criteria
1. Absence of provision of informed consent
2. Age less than 3 months and more than 59 months
3. Presence of severe malnutrition or other severe condition
4. Residing outside the study area

### Date of first enrolment
06/07/2021

**Date of final enrolment**
31/12/2021

# Locations

**Countries of recruitment**
Côte d'Ivoire

**Study participating centre**
**National Institute of Public Health Malaria Research and Control Center**
BP V 47
Abidjan
Côte d'Ivoire
225

# Sponsor information

**Organisation**
Institut de Recherche en Sciences de la Santé

**ROR**
https://ror.org/05m88q091

# 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 (EDCTP), 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 (orpheekouakou@yahoo.fr)

### IPD sharing plan summary
Available on request