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

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

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
/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

Secondary study design
Non randomised study

Study setting(s)
Community

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
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 measure

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)

Secondary outcome measures
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

Overall study start date
01/01/2021

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

Age group
Child

Lower age limit
3 Months

Upper age limit
59 Months

Sex
Both

Target number of participants
1700

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
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Sponsor information

Organisation
Institut de Recherche en Sciences de la Santé

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Sponsor type
Research organisation

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

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, 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
31/12/2022

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