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Treatment of uncomplicated falciparum malaria in Bobo-Dioulasso, Burkina Faso: comparison of artemether/lumefantrine, dihydroartemisinin /piperaquine, and amodiaquine/sulfadoxine-pyrimethamine

Submission date	Recruitment status	[_] Prospectively registered
09/02/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/04/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/09/2021	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Treatment of uncomplicated falciparum malaria in Bobo-Dioulasso, Burkina Faso: comparison of artemether/lumefantrine, dihydroartemisinin/piperaquine, and amodiaquine/sulfadoxine-pyrimethamine

Study objectives
We hypothesize that Artemether/Lumefantrine (AL) and Dihydroartemisinin/Piperaquine (DP), each of which is a promising new artemisinin-based combination antimalarial therapy, and Amodiaquine/Sulfadoxine-Pyrimethamine (AQ/SP), an older regimen, will provide outstanding and equivalent efficacy for the treatment of uncomplicated malaria. To test this hypothesis, our aim will be to compare the antimalarial efficacy of these three regimens. The study will be a randomized comparison at three sites in Bobo-Dioulasso. A secondary aim will be to compare the safety and tolerability of the study regimens.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. UCSF committee on Human Research (California, USA), approved on 25 July 2006. Ref: CHR # H2397-29335-01
2. Centre Muraz / IRSS Institutional Review Board (Burkina Faso), approved in July 2006. Ref: 012-2006/CE-CM

Study design
Randomized, single-blind trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Interventions

This trial compares three therapies for uncomplicated malaria, conducted at three locations in the city of Bobo-Dioulasso, Burkina Faso. The design will closely follow two studies that we conducted in 2004 and 2005 in Burkina Faso (UCSF CHR H2397-25259 and H2397-27158) following guidelines of the World Health Organization (WHO) for assessment of therapeutic efficacy of antimalarial agents in areas of intense transmission, with slight modifications. The target population is residents of three catchment areas within Bobo-Dioulasso, with care at dispensaries at Sarfalao, Colsama and Ouezzin-ville. The available population is residents aged 6 months and older who present to one of the study clinics with symptoms suggestive of malaria and who have a positive screening thick blood smear. Subjects who meet the inclusion criteria and are enrolled in the trial will be randomized to treatment with one of the three study regimens and will be followed for 42 days. The study regimens will be AL (Coartem), DP (Duocotexcin), and AQ/SP, each administered for three days. Repeat evaluations will be performed on days 1, 2, 3, 7, 14, 21,28, 35 and 42 and will include assessment for the occurrence of any serious adverse events. Treatment efficacy outcomes will be assessed using modifications of WHO clinical and parasitological classification criteria.

Patients will be randomized to receive:
1. Artemether-lumefantrine (Novartis, 20 mg artemether/120 mg lumefantrine tablets, 1 [5 - 14 kg], 2 [15 - 24 kg], 3 [25 - 34 kg], or 4 [> 35 kg] tablets twice daily for 3 days) or
2. Amodiaquine (Parke-Davis, 200 mg tablets, 10 mg/kg on days 0 and 1, and 5 mg/kg on day 2) + sulfadoxine-pyrimethamine (Roche, 25 mg/kg of sulfadoxine and 1.25 mg/kg pyrimethamine administered on day 0) or
3. Dihydroartemisinin/piperaquine once daily for 3 days in the morning given in fixed dose tablets (40 mg dihydroartemisinin + 320 mg piperaquine) according to weight-based guidelines consisting of a total dose of 6.4 and 51.2 mg/kg of dihydroartemisinin and piperaquine, respectively.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Primary outcomes will be based on the risk of clinical and parasitological treatment failure after 28 days of follow-up either adjusted or unadjusted

Secondary outcome measures

1. Risk of clinical failure after 14 days of follow-up
2. Risk of rescue therapy after 42 days of follow-up
3. Risk of fever during the first 3 days of follow-up: presence or absence of objective fever (axillary temperature > 37.5°C) or patient report of fever on days 1, 2, 3
4. Risk of parasitemia on follow-up days 2 and 3: proportion of positive vs. negative thick blood smears on day 2 and day 3
5. Change in mean hemoglobin from day 0 to 42 or day of repeat therapy
6. Proportion gametocytemic: presence vs. absence of gametocytes on any follow-up thick blood smear; proportion gametocytemic on days 2, 3, 7, 14, 21, 28, 35 and 42
7. Risk of serious adverse events: proportion of patients experiencing any serious adverse event

in each treatment group during the 42-day follow-up period, excluding treatment failures
8. Risk of adverse events of moderate or greater severity, at least possibly related to the study medications, excluding treatment failures

Overall study start date
01/08/2006

Completion date
31/01/2007

Eligibility

Key inclusion criteria
1. Age 6 months and above
2. Fever (> 37.5°C axillary) or history of fever in the previous 24 hours
3. Absence of any history of serious side effects to study medications, including allergy to sulfa drugs
4. No evidence of a concomitant febrile illness in addition to malaria
5. Provision of informed consent and ability to participate in 42-day follow-up (patient has easy access to health unit)
6. No history of treatment with any antimalarial (other than chloroquine) in the past 2 weeks.
7. No danger signs or evidence of severe malaria defined as:
7.1 Unarousable coma (if after convulsion, > 30 min)
7.2 Repeated convulsions (> 2 within 24 h)
7.3 Recent convulsions (1-2 within 24 h)
7.4 Altered consciousness (confusion, delirium, psychosis, coma)
7.5 Lethargy
7.6 Unable to drink or breast feed
7.7 Vomiting everything
7.8 Unable to stand/sit due to weakness
7.9 Severe anemia (hemoglobin < 5.0 g/dL)
7.10 Respiratory distress (labored breathing at rest)
7.11 Jaundice (yellow coloring of eyes)

Patients fulfilling these criteria will be assigned a study number and referred to the study nurse for treatment allocation and treatment with the study medications. Patients must also meet the following criterion:
8. Absence of repeated vomiting of study medications on day 0

After treatment with the study medications, patients will be referred to the laboratory. A fingerprick blood sample will be obtained to prepare thick and thin blood smears, and for measurement of hemoglobin. Patients will be excluded from the study on day 1 if the following inclusion criteria are not met.
9. P. falciparum mono-infection
10. Parasite density > 2000/ul and < 200,000/ul
11. Hemoglobin > 5.0 g/dL

Participant type(s)
Patient

Age group

Not Specified

Sex
Not Specified

Target number of participants
528

Key exclusion criteria
1. Signs of severe malaria/danger signs
2. Known Allergy to the study medications
3. Inability to participate in 42 days follow up
4. Concommittant febrile illness
5. Severe anemia < 5g/dL
6. Absence of provision of informed and signed consent
7. Previous antimalarial use (other than chloroquine [CQ]) in the previous 14 days
8. Mixed infection

Date of first enrolment
01/08/2006

Date of final enrolment
31/01/2007

Locations

Countries of recruitment
Burkina Faso

Study participating centre
399, Avenue de la Liberte
Bobo-Dioulasso
Burkina Faso
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Sponsor information

Organisation
Institut de Recherche en Science de la Sante (IRSS) (Burkina Faso)

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399 Avenue de la Liberte
PO BOX: 545

Bobo-Dioulasso
Burkina Faso
-

Sponsor type
Government

ROR
https://ror.org/05m88q091

Funder(s)

Funder type
Charity

Funder Name
Doris Duke Charitable Foundation (USA)

Alternative Name(s)
Doris Duke Charitable Foundation, Inc., DDCF Trust, Doris Duke Foundation, DDCF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Funder Name
Beijing Holley-Cotec Pharmaceuticals Co. Ltd (China)

Funder Name
International Atomic Energy Agency (Austria)

Alternative Name(s)
IAEA

Funding Body Type
Private sector organisation

Funding Body Subtype

International organizations

Location
Austria

Funder Name
National Budget of Institut de Recherche en Science de la Sante (IRSS)/ Direction Regionale de l'Ouest (DRO) (Burkina Faso)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2007	23/09/2021	Yes	No