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Treatment of uncomplicated falciparum malaria in Bobo-Dioulasso, Burkina Faso: comparison of amodiaquine sulfadoxine-pyrimethamine with Coartem

Submission date
24/03/2006

Registration date
05/05/2006

Last Edited
16/02/2007

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

Study objectives
The efficacy of amodiaquine sulfadoxine pyrimethamine and artemether lumefantrine for the treatment of uncomplicated falciparum malaria in Bobo-Dioulasso, Burkina Faso will be equivalent

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Institutional Review Board (IRB) Centre Muraz, University of California San Francisco Committee for Human Research, reference number: H2397-2758-01 and by the IRB Institute for Resource and Security Studies (IRSS), reference number: 019-2005/CE-CM

Study design
Randomized, single-blinded, controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
Subjects will be randomized to receive treatment with amodiaquine sulfadoxine pyrimethamine or artemether lumefantrine. Subjects in amodiaquine group will receive placebo to ensure the same number of doses in the two groups. Repeated therapy will be quinine.

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Amodiaquine sulfadoxine pyrimethamine and artemether lumefantrine

Primary outcome measure
The risk of clinical and parasitological treatment failure after 28 days of follow-up. Pairwise comparisons between regimens will be made on based on a per protocol analysis.

Secondary outcome measures
1. Risk of clinical failure after 14 days of follow-up
2. Risk of rescue therapy after 28 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 versus negative thick blood smears on days 2 and 3
5. Change in mean hemoglobin from day 0 to 28 or day of repeat therapy
6. Proportion gametocytemic: presence versus absence of gametocytes on any follow-up thick blood smear; proportion gametocytemic on days 2, 3, 7, 14, 21, and 28
7. Risk of serious adverse events: proportion of patients experiencing any serious adverse event in each treatment group during the 28-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
02/08/2005

Completion date
22/12/2005

Eligibility

Key inclusion criteria
1. Age ≥6 months
2. Fever (≥37.5 or history of fever in the last 24 hours)
3. Provision of informed consent
4. P. falciparum mono infection
5. Parasite density >2000 microliters and ≥200,000 microliters

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
521

Key exclusion criteria
1. Evidence of severe malaria
2. History of side effects to the investigational product
3. Pregnancy
4. Repeated vomiting of study medication on day 0
5. Hemoglobin <5 g/Dl
6. Evidence of concomitant febrile illness

Date of first enrolment
02/08/2005

Date of final enrolment
22/12/2005

Locations

Countries of recruitment
Burkina Faso

Study participating centre
399 Avenue de la Liberte
Bobo-Dioulasso
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01

Sponsor information

Organisation
Institute of Research in Health Sciences (Institut de Recherches en Sciences de la Sante [IRSS]) (Burkina Faso)

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Sponsor type
Government

ROR
https://ror.org/05m88q091

Funder(s)

Funder type
Government

Funder Name
Fogarty International Center (part of the National Institutes of Health (FIC-NIH), D43 TW01506-05 (subcontract TW/8420599)

Funder Name
National Budget of Institut de Recherches en Sciences de la Sante (IRSS) and International Atomic Energy Agency (IAEA) RAF 6/025

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?
Abstract results		10/02/2007		No	No