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Artemisinin Combination Therapies (ACTs) efficacy for uncomplicated falciparum malaria treatment in Burkina Faso

Submission date
29/09/2011

Recruitment status
No longer recruiting

Registration date
30/01/2012

Overall study status
Completed

Last Edited
21/04/2017

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Malaria is a serious tropical disease spread by mosquitoes. It can be prevented and treated with antimalarial drugs. The aim of this study is to assess the effectiveness and side effects of the antimalarial drug combinations artemether-lumefantrine and amodiaquine-artesunate for the treatment of malaria in Burkina Faso.

Who can participate?
Patients aged over 6 months with malaria

What does the study involve?
Participants are randomly allocated to be treated with either artemether-lumefantrine or artesunate-amodiaquine. Participants who fail to respond to initial treatment are given quinine, the standard treatment for malaria in Burkina Faso. Participants are followed up for 42 days and are asked to return for assessment on days 1, 2, 3, 7, 14, 21, 28 and any unscheduled day that they feel ill.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
The study is conducted at public health facilities in Sarfalao, Dori and Gaoua (Burkina Faso)

When is the study starting and how long is it expected to run for?
September 2011 to December 2012

Who is funding the study?
1. Ministry of Health (Burkina Faso)
2. National Malaria Control Program (Burkina Faso)

Who is the main contact?
Prof. Jean Bosco Ouedraogo

Contact information

Type(s)
Scientific

Contact name
Prof Jean Bosco Ouedraogo

Contact details
BP 545
Bobo Dioulasso
Burkina Faso
150000

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Efficacy and tolerability of artemether lumefantrine and amodiaquine artesunate for the treatment of uncomplicated falciparum malaria in Burkina Faso

Study objectives
Artemether-lumefantrine (AL) and artesunate-amodiaquine are equally effective in the treatment of malaria in Burkina Faso.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Centre Muraz Ethics Committee

Study design
Randomized controlled open trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Malaria

Interventions
Subjects will be randomized to receive either artemether-lumefantrine (AL) or artesunate-amodiaquine (ASAQ). Subjects who fail initial therapy will receive quinine which is the standard treatment for recurrent malaria in Burkina Faso.

Subjects will be followed for 42 days and will be asked to return for follow-up

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Risk of treatment failure unadjusted and adjusted by genotyping at day 28 and tolerability

Key secondary outcome(s))
1. Prevalence of fever on days 1-3
2. Prevalence of parasitemia on days 2 and 3
3. Change in mean hemoglobin level between days 0 and 28 (or day of treatment failure)
4. Prevalence of gametocytes during follow-up
5. Risk of serious adverse events during follow-up
6. Risk of adverse events of moderate or greater severity, at least possibly related to the study medications, excluding patients requiring quinine therapy
7. Selection of molecular markers associated with drug resistance

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Age > 6 months
2. Weight > 5 kg
3. Fever (> 37.5°C axillary) or history of fever in the previous 24 hours
4. Absence of any history of serious side effects to study medications
5. No evidence of a concomitant febrile illness
6. Provision of informed consent and agreement to follow-up for 28 days
7. No evidence of severe malaria or danger signs
8. Absence of repeated vomiting of study medications on day 0
9. P. falciparum mono-infection
10. Parasite density > 2000/ul and < 200,000/ul

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Severe malaria
2. Unable to respect the follow-up schedule
3. Known allergy to the study medication
4. Other chronic disease requiring care

Date of first enrolment
29/09/2011

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Burkina Faso

Study participating centre
BP 545
Bobo Dioulasso
Burkina Faso
150000

Sponsor information

Organisation
National Malaria Control Program (Burkina Faso)

Funder(s)

Funder type
Government

Funder Name
Ministry of Health (Burkina Faso)

Funder Name
National Malaria Control Program (Burkina Faso)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration