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

| Submission date | Recruitment status | Prospectively registered |
|-------------------|-----------------------------|--------------------------------------------|
| 29/09/2011 | No longer recruiting | ☐ Protocol |
| Registration date | Overall study status | Statistical analysis plan |
| 30/01/2012 | Completed | Results |
| Last Edited | Condition category | Individual participant data |
| 21/04/2017 | Infections and Infestations | 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)

Contact information

Type(s)

Scientific

Contact name

Prof Jean Bosco Ouedraogo

Contact details

BP 545 Bobo Dioulasso Burkina Faso 150000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

Risk of treatment failure unadjusted and adjusted by genotyping at day 28 and tolerability

Secondary outcome measures

- 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

Overall study start date

29/09/2011

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

Age group

Adult

Sex

Both

Target number of participants

780 patients

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)

Sponsor details

BP 7009 Ouagadougou Burkina Faso 01

Sponsor type

Government

Funder(s)

Funder type

Government

Funder Name

Ministry of Health (Burkina Faso)

Funder Name

National Malaria Control Program (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