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First line therapy for uncomplicated falciparum malaria with Coartem® and Coarsucam® in Burkina Faso

Submission date
09/10/2009

Recruitment status
No longer recruiting

Registration date
28/06/2010

Overall study status
Completed

Last Edited
28/06/2010

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
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Assessment of first line therapy for uncomplicated falciparum malaria with artemether /lumefantrine (Coartem®) and artesunate/amodiaquine (Coarsucam®) in Bobo-Dioulasso, Burkina Faso: a randomised controlled trial

Study objectives
Artemether/lumefantrine (Coartem®) and artesunate/amodiaquine (Coarsucam®) remain effective and well tolerated for the treatment of uncomplicated falciparum malaria in Burkina Faso.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Muraz Centre (Comite d'Ethique Institutionnelle du Centre Muraz), approval pending as of 09/10/2009

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Artemether/lumefantrine (Coartem®) versus artesunate/amodiaquine (Coarsucam®). The drugs will be administrated over three days orally. The dose will be calculated based on the child's weight.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Artemether/lumefantrine (Coartem®), artesunate/amodiaquine (Coarsucam®)

Primary outcome(s)
The following will be assessed at 28 days:
1. Risk of recurrent malaria
2. Risk of recurrent parasitaemia
3. Risk of clinical treatment failure
4. Risk of parasitological treatment failure

Key secondary outcome(s))

1. Prevalence of fever (defined as both subjective fever in the previous 24 hours and measured axillary temperature greater than 37.5°C) on follow-up days 1, 2, and 3
2. Prevalence of parasitaemia on follow-up days 2 and 3
3. Change in mean haemoglobin from day 0 to 28 (or day of rescue therapy for patients classified as late clinical failure [LCF] or late parasitological failure [LPF])
4. Prevalence of gametocytaemia and gametocyte density on follow-up days 2, 3, 7, 14, 21, 28
5. Risk of serious adverse events: proportion of patients experiencing any serious adverse event in each treatment group during the 28-day follow-up period (both including and excluding patients classified as early treatment failure [ETF] or LCF, as recurrent malaria can be confounding)
6. Risk of adverse events of moderate or greater severity, at least possibly related to the study medications (both including and excluding patients classified as ETF or LCF)
7. Change in the prevalence of molecular markers associated with drug resistance from day 0 to the day of recurrent parasitaemia

Completion date
31/01/2010

Eligibility

Key inclusion criteria
1. Not previously enrolled in this study
2. Both males and females, aged greater than 6 months
3. Weight greater than 5 kg
4. Fever (greater than 37.5°C axillary) or history of fever in the previous 24 hours
5. Absence of any history of serious side effects to study medications
6. No evidence of a concomitant febrile illness in addition to malaria
7. Provision of informed consent and ability to participate in 28-day follow-up (patient has easy access to health unit)
8. No danger signs or evidence of severe malaria defined as:
8.1. Unarousable coma (if after convulsion, greater than 30 minutes)
8.2. Repeated convulsions (greater than two within 24 hours)
8.3. Recent convulsions (one to two within 24 hours)
8.4. Altered consciousness (confusion, delirium, psychosis, coma)
8.5. Lethargy
8.6. Unable to drink or breast feed
8.7. Vomiting everything
8.8. Unable to stand/sit due to weakness
8.9. Severe anaemia (Hb less than 5.0 g/dL)
8.10. Respiratory distress (laboured breathing at rest)
8.11. Jaundice
9. Plasmodium falciparum mono-infection
10. Parasite density greater than 2,000/ul and less than 200,000/ul

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Other

Sex
All

Key exclusion criteria
1. Severe malaria
2. Unable to comply with planned follow up
3. Pregnancy

Date of first enrolment
12/10/2009

Date of final enrolment
31/01/2010

Locations

Countries of recruitment
Burkina Faso

Study participating centre
Institut de Recherche en Sciences de la Santé - Direction Régionale de l'Ouest (IRSS-DRO)
Bobo-Dioulasso
Burkina Faso
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Sponsor information

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

ROR
https://ror.org/05m88q091

Funder(s)

Funder type
Government

Funder Name

National Malaria Control Programme (Burkina Faso)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration