

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

Submission date 09/10/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/06/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/06/2010	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Bobo-Dioulasso
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Malaria

Interventions

Artemether/lumefantrine (Coartem®) versus artesunate/amodiaquine (Coarsucam®). The drugs will be administered 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 measure

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

Secondary outcome measures

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

Overall study start date

12/10/2009

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

Age group

Other

Sex

Both

Target number of participants

197

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)

Sponsor details

Direction Régionale de l'Ouest (DRO)
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Sponsor type

Government

ROR

<https://ror.org/05m88q091>

Funder(s)**Funder type**

Government

Funder Name

National Malaria Control Programme (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