

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

<b>Submission date</b> 09/10/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/06/2010	<b>Condition category</b> 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

Prof Jean Bosco

### Contact details

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Bobo-Dioulasso  
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## Additional identifiers

## 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 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(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