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

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

# 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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# 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/amodiaguine (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**

# **Results and Publications**

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

**Study outputs** 

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet
Participant information sheet
11/11/2025 No Yes