

# Role of rapid diagnostic testing in the context of home management of childhood fever with Coartem®: an open randomised controlled trial in a rural and seasonal malaria transmission area of Burkina Faso

**Submission date**

17/04/2007

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

25/05/2007

**Overall study status**

Completed

☐ Statistical analysis plan

☐ Results

**Last Edited**

10/09/2007

**Condition category**

Infections and Infestations

☐ Individual participant data

☐ Record updated in last year

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Franco Pagnoni

**Contact details**

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## **Secondary identifying numbers**

A60486

# **Study information**

## **Scientific Title**

### **Study objectives**

Community level treatment of malaria and/or acute respiratory infections guided by malaria Rapid Diagnostic Testing (RDT) and respiratory rate counting improves clinical recovery rate of children with febrile disease.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approval received from the Comité dethique pour la Recherche en Santé du Burkina (CERS-B) on the 15th February 2007.

### **Study design**

Open randomised, controlled, clinical trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Diagnostic

## **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Malaria, acute respiratory infection

### **Interventions**

Patients were randomised between:

1. Treatment with Coartem® and/or cotrimoxazole based on rapid diagnosis test results and respiratory rate count
2. Presumptive treatment with Coartem®, on day three after the onset of the treatment

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**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Coartem®, cotrimoxazole

**Primary outcome measure**

Clinical recovery rate at 72 hours after treatment (defined as apyrexia and axillary temperature less than 37.5°C).

**Secondary outcome measures**

1. Evaluate influence of the seasonal variation of malaria transmission on the impact, measured at eight days post onset of the treatment
2. Assess the cost-effectiveness of RDT in the context of the HMM strategy with Coartem®, measured at the end of the study
3. Describe the operational feasibility and acceptability of RDT in the context of the HMM strategy with Coartem®, measured at the end of the study

**Overall study start date**

01/05/2007

**Completion date**

01/05/2008

**Eligibility****Key inclusion criteria**

1. Written informed consent from parent/guardian
2. Aged 6 to 59 months
3. Weight equals 5 kg
4. Willing to comply with the study procedures
5. History of fever within the last 24 hours or documented fever (axillary temperature equals 37.5°C)

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

6 Months

**Upper age limit**

59 Months

**Sex**

Both

**Target number of participants**

1200

**Key exclusion criteria**

1. Severe malaria
2. Danger signs (unable to drink or eat, incoercible vomiting, convulsions, prostration)
3. History of allergic reaction to the study drugs
4. History of treatment with artemisinin derivatives in the past seven days
5. Previous participation in this study

**Date of first enrolment**

01/05/2007

**Date of final enrolment**

01/05/2008

**Locations****Countries of recruitment**

Burkina Faso

Switzerland

**Study participating centre**

World Health Organization

Geneva-27

Switzerland

CH-1211

**Sponsor information****Organisation**

UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR)

**Sponsor details**

World Health Organization

20 Avenue Appia

Geneva-27

Switzerland  
CH-1211

**Sponsor type**

Research organisation

**Website**

<http://www.who.int/tdr/topics/mim/default.htm>

**ROR**

<https://ror.org/01f80g185>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Multilateral Initiative on Malaria (MIM)

**Funder Name**

United Nations Children's Fund (UNICEF)/United Nations Development Programme (UNDP)  
/World Bank/World Health Organization (WHO) - Special Programme for Research and Training  
in Tropical Diseases (TDR)

## **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