

# A two-arm interventional study to evaluate the impact of Home and community management of Malaria with Artemisinin Combination Therapy (ACT) on under five childhood mortality in two rural health districts, Burkina Faso

<b>Submission date</b> 12/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/11/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/10/2008	<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

Dr F Pagnoni

### Contact details

World Health Organization  
Special Programme for Research and Training in Tropical Diseases (TDR)  
Av Casai 53  
Geneva-27  
Switzerland  
CH 1211  
+41 (0)22 7911811  
pagnonif@who.int

## Additional identifiers

Protocol serial number

## Study information

### Scientific Title

### Study objectives

1. Home management of malaria with Artemisinin Combination Therapies (ACTs) reduces overall and malaria-specific mortality in children under five years
2. Home management of malaria with ACTs reduces progression of uncomplicated malaria to severe malaria
3. Home management of malaria with ACTs reduces the prevalence of severe anaemia in treated children

Please note that as of 03/10/2008 this record was updated to include an amendment to the study design of this trial from a cluster-randomized controlled trial to a two-arm interventional study (ecological design, 1 zone intervention, 1 zone control). Changes can be found in the study design and title sections; the initial details were as follows:

#### Initial title:

A clustered randomised controlled trial to evaluate the impact of Home and community management of Malaria with Artemisinin Combination Therapy (ACT) on under five childhood mortality in two rural health districts, Burkina Faso

#### Initial study design:

Epidemiological, health systems, randomised trial.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval received on the 10th June 2005.

### Study design

Two-arm interventional study (ecological design)

### Primary study design

Interventional

### Study type(s)

Treatment

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

Uncomplicated malaria

### Interventions

1. Training of community-based drug distributors - Y1
2. Develop and implement a communication for behaviour change strategy - Y1 to Y3
3. Avail pre-packaged unit dosed ACTs (Coartem); ACTs will be deployed at health facility (HF)

and community level in the intervention areas, at HF level only in control areas - Y2 and Y3  
4. Implement a community based vital statistics monitoring system in the study communities  
5. Evaluate the impact of the strategy on overall and malaria-specific mortality in children under five years - Y2 and Y3

**Intervention Type**

Drug

**Phase**

Not Specified

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

Artemisinin

**Primary outcome(s)**

Overall and malaria-specific mortality

**Key secondary outcome(s)**

1. Incidence of severe malaria
2. Prevalence of severe anaemia

**Completion date**

31/10/2008

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

1. Children aged 6 to 59 months with fever (uncomplicated malaria)
2. Signs of severe disease

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 months

**Upper age limit**

59 months

**Sex**

All

**Key exclusion criteria**

1. Known hypersensitivity to the drug
2. Refusal to give informed consent

**Date of first enrolment**

01/11/2005

**Date of final enrolment**

31/10/2008

## 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)

**ROR**

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

## Funder(s)

**Funder type**

Research organisation

**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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration