

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

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

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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