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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

Registration date
25/11/2005

Last Edited
03/10/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
A41072

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Overall and malaria-specific mortality

Secondary outcome measures
1. Incidence of severe malaria
2. Prevalence of severe anaemia

Overall study start date
01/11/2005

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

Age group
Child

Lower age limit
6 Months

Upper age limit
59 Months

Sex
Both

Target number of participants
5000

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)

Sponsor details
World Health Organization
20 Avenue Appia

Geneva-27
Switzerland
CH 1211
+41 (0)22 791 3909
waylings@who.int

Sponsor type
Research organisation

Website
http://www.who.int

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

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