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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

Registration date
25/05/2007

Overall study status
Completed

Last Edited
10/09/2007

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

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Additional identifiers

Protocol serial number
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.

Primary study design
Interventional

Study design
Open randomised, controlled, clinical trial

Study type(s)
Diagnostic

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Months

Upper age limit
59 Months

Sex
All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration