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Improving the management of childhood MAlaria: an experiment to bridge the gap between MOthers and health care Providers

Submission date 02/04/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/05/2007	**Overall study status** Completed	
Last Edited 16/08/2011	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ICA4-CT-2001-10010

Study information

Scientific Title

Acronym
MAMOP

Study objectives
This trial will be taking place in Burkina Faso and Tanzania, with slightly different interventions taking place in each area. The differences will be noted under the relevant sections with the title of the country in which the changes are taking place.

Tanzania:
To evaluate the feasibility and effectiveness of an intervention aimed at improving case management of malaria in under-five children through the primary caretakers in collaboration with local women groups and existing health centres.

Burkina Faso:
The study hypothesis is that improved home management of malaria in young children of Sub-Saharan Africa (SSA) will result in earlier treatment with consequently reduced morbidity and mortality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by:
1. The local Ethics Committee in Burkina Faso
2. The Tanzanian Commission of Science and Technology

Study design
Multicentre, interventional, cluster-randomised, controlled, community intervention effectiveness trial with a pre-post design.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Treatment of childhood febrile illness; malaria

Interventions
Tanzania (trial ran from 01/02/2004 to 01/05/2005):
Study children N = 1715 children in baseline, 2169 in follow-up (aim was to enrol one under five from each of a minimum of 1200 households). Health workers were trained to train local women leaders in recognising malaria symptoms, providing first line treatment for uncomplicated malaria (sulfadoxine/pyrimethamine) and referring severe cases. The health workers were also trained to supervise the women groups. The evaluation was through a baseline survey on children aged 6 to 59 months in early 2004 and a follow-up survey in early 2005, i.e. the follow-up was after 10 months.

Burkina Faso (trial ran from 01/09/2002 to 31/10/2004):
Study children N = 2089 (1200 households). The intervention consisted of training of health workers on malaria home treatment, of training of women group leaders on malaria home treatment, of treatment of under five children through their mothers supervised by women group leaders, of supervision of women group leaders by health workers, and of provision of malaria drugs through health workers in form of a revolving fund. Follow up in Burkina Faso was for the two rainy seasons.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome of the study was the proportion of moderate to severe anaemia (haematocrit less than 24%, haemoglobin less than 8 g/L) in children aged six to 59 months.

Evaluation of the trial in Burkina Faso was through a baseline and a follow-up survey.

In the Tanzanian study: Baseline survey Feb-April 2004 and follow-up survey Feb-April 2005.

Secondary outcome measures
1. Fever and malaria prevalence
2. Prevalence of palpable spleens (Hackett score greater than two)
3. Prevalence of other illnesses
4. Mean species-specific number of blood films positive for malaria parasites
5. Mean species-specific malaria parasite densities
6. Mean haematocrit and haemoglobin values
7. Mean weight
8. In vivo chloroquine resistance

Evaluation of the trial in Burkina Faso was through a baseline and a follow-up survey.

In the Tanzanian study: Baseline survey Feb-April 2004 and follow-up survey Feb-April 2005. The number of particants in the follow up survey was 2169.

Overall study start date
01/09/2002

Completion date
01/05/2005

Eligibility

Key inclusion criteria
1. Health workers: all health workers in the district were selected for training
2. Women leaders: all women from the existing women groups in the area were targeted and enrolled if:
2.1. They had completed primary school
2.2. They were a member of an already existing womens group
2.3. They were a resident of the chosen village and expected to live there during the MAMOP study period
This gave 36 women of which 25 were randomly selected for the intervention
3. Households: all households in the randomly sampled villages were included
4. Children: children aged six to 59 months

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
59 Months

Sex
Both

Target number of participants
Burkina Faso N = 2089, Tanzania N = 1715 (at baseline)

Key exclusion criteria
1. Women leaders who were:
1.1. Illiterate
1.2. Not resident in the MAMOP villages
2. For all: those who did not consent to participating
3. Children: aged less than six months or greater than 59 months

Date of first enrolment
01/09/2002

Date of final enrolment
01/05/2005

Locations

Countries of recruitment
Burkina Faso

Tanzania

Study participating centre
Centre de Recherche en Santé de Nouna
Nouna
Burkina Faso
-

Sponsor information

Organisation
Research Centre in Health of Nouna (Centre de Recherche en Santé de Nouna [CRSN]) (Burkina Faso)

Sponsor details
BP 02
Nouna
Burkina Faso
-

Sponsor type
Research organisation

ROR
https://ror.org/059vhx348

Funder(s)

Funder type
Government

Funder Name
European Commission (Belgium) - FP5 (Fifth Framework Programme for Research and Technological Development, Quality of Life and Management of Living Resources Programme) (ref: ICA4-CT-2001-10010)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2007		Yes	No
Results article	results	01/12/2010		Yes	No