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Development of a simple protocol to enhance compliance in home management of malaria

Submission date	Recruitment status	[_] Prospectively registered
22/10/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/10/2007	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/10/2007	Infections and Infestations	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Malaria is a disease caused by the protozoan plasmodium falciparum. It is still rampant in sub-Saharan Africa and endemic in Nigeria with perennial transmission. It causes febrile illness which could be severe in children accounting for 25% of infant mortality and 8-12% of death under age of five years. Malaria is responsible for 40-60% of out patient consultation. It presents in two clinical types - uncomplicated and severe malaria.

Study Domain: Parasitic infection; child care and health education/behaviour change

Study hypotheses:
1. There will be no significant difference in the outcome of malaria in children whose mothers or caregivers used treatment protocol to treat malaria at home and those whose mothers did not use the protocol.
2. There will be no significant difference in the correctness of use of chloroquine by mothers who used the treatment protocol and those who did not use the protocol.
3. There will be no significant difference in the correctness of use of chloroquine by trained mothers and mothers who were not trained.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The joint University of Ibadan/University College Hospital Institutional Ethical Review Board. Date of Approval: 29th June 2000

Study design
Single-centre, single-blind, randomised controlled field study.

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
Malaria

Interventions
Randomisation of the communities to the intervention and control groups was done by ballots.

Interventions carried out at the intervention site:
1. Training of 'mother trainers' and community members about cause, symptoms and signs of the clinical types, treatment and prevention of malaria including referral.

2. Development of a treatment protocol using participatory approach and distribution of the protocol to households. The development of the protocol was done in phases using modified focus group sessions with several community checks at different stages of development. The participants were the 'mother trainers', selected community members, research team and a graphic artist. The treatment protocol consists of treatment guidelines for each of the clinical types of malaria compiled together on a cardboard. The protocol illustrated the presentation of clinical types of malaria, the appropriate steps to take for each type and the correct dose and schedule of treatment of uncomplicated malaria using chloroquine according to the age of the child. The protocol was in cartoon format and the local language was used.

Mothers/caregivers in both arms of the study were requested to purchase the chloroquine used for treatment from their regular source which in most instances are the drug hawkers and patent medicine sellers.

Control arm of the study:
They were passive controls. The communities in the control arm of the study were left to continue their usual treatment practice for malaria in their children. No training or guideline was provided.

Duration of intervention: One year

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The mothers/caregivers were asked about the treatment given to the child during visits by the research assistants. The mothers/caregivers were asked to record these details in their diary, which was checked on Day 7 from recruitment at the time of collecting Day 7 blood sample for microscopy examination. These data were used to assess the following:

1. Correct use of chloroquine, measured in terms of dose, frequency and duration
2. Timeliness of commencing treatment (commencing treatment within 24 hours of noticing fever in child)
3. Treatment outcome, measured by mean parasite clearance time, fever clearance time, and progression of illness as reported by mothers/caregivers
4. Use of the protocol. Proportion of mothers who referred to the treatment protocol in the treatment of last episode of malaria in children

Secondary outcome measures
1. Attack rate of malaria over a period of one year
2. Sensitivity and specificity of presumptive diagnosis of malaria by mothers/caregivers

Overall study start date
16/06/2004

Completion date
30/06/2005

Eligibility

Key inclusion criteria
1. Mothers with children 10 years or less who have febrile illness presumed to be malaria
2. Willingness of mothers to allow their child remain in study for a period of 14 days
3. Mothers who consent to their child having finger prick to collect blood for blood smears

Participant type(s)
Patient

Age group
Child

Upper age limit
10 Years

Sex
Both

Target number of participants
152 children (76 in each arm)

Key exclusion criteria
1. Child with severe illness or requiring parenteral medication
2. Child with other diseases, co-morbid with febrile illness

Withdrawal Criteria:
1. Parents of children choosing not to continue with the study
2. Progression of illness in child

Date of first enrolment
16/06/2004

Date of final enrolment
30/06/2005

Locations

Countries of recruitment
Nigeria

Study participating centre

Department of Epidemiology
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Sponsor information

Organisation
University of Ibadan (Nigeria)

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Sponsor type
University/education

Website
http://www.ui.edu.ng/

ROR
https://ror.org/03wx2rr30

Funder(s)

Funder type
Other

Funder Name
Investigator funded (Nigeria)

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