

Feasibility, acceptability and costs of diagnosis and management of malaria in the community

Submission date 01/05/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/06/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/07/2023	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Malaria is a serious tropical disease spread by infected mosquitoes. The main victims of malaria infection are African children aged 5 and under. Around 90% of all malaria deaths occur in Africa. If a person is bitten by an infected mosquito, they become infected with parasites (plasmodium species) which multiply in the liver and later infect a person's red blood cells. The symptoms of malaria infection include high temperature, headaches and vomiting. The symptoms usually appear around 2 weeks after being infected, but they can sometimes take much longer to appear. Quick diagnosis and treatment of malaria is very important because malaria can become life-threatening very quickly, and fast treatment most often results in a full recovery. Malaria is categorised as either uncomplicated or severe (complicated); severe malaria is associated with complications such as organ failure or other blood abnormalities. Antimalarial medication is used to treat infection, and there are different types available which are given depending on various factors, such as the type of malaria infection and severity of symptoms. Some progress has been made in the fight against malaria, such as the improved availability of rapid diagnostic test (RDT) kits and artemisinin-based combination therapies (ACTs). The aim of this study is to test a malaria RDT package in the community to see how well it works, how cost-effective it is and whether it could work on a larger scale. The malaria RDT package used in this study aims to diagnose and treat both uncomplicated and severe malaria and will be available from participating community health sites for a 12 month period.

Who can participate?

Children aged 6-59 months with feverish illness in the previous 24 hours.

What does the study involve?

All children aged between 6 and 59 months with fever that attend community health sites during the 12 months of intervention are offered a RDT. Children who are diagnosed positive for uncomplicated malaria are treated with the ACT artemether-lumefantrine. Children with a fever or recent history of fever, and those who are unable to take oral medications, are treated with rectal artesunate for severe malaria.

What are the possible benefits and risks of participating?

Policies in the countries participating in the study are to test, treat and track post-treatment,

and this study is following country policies for uncomplicated malaria. For severe illnesses, there is a risk that patients will not comply with referral advice to proceed to the hospital.

Where is the study run from?

1. Group Health Research in Action (Group de Recherche Action en Sante (GRAS)) (Burkina Faso)
2. Ministry of Health (Uganda)
3. University of Ibadan (Nigeria)

When is the study starting and how long is it expected to run for?

May 2015 to September 2015

Who is funding the study?

European Commission Directorate-General for Research and Innovation (Belgium)

Who is the main contact?

Dr M Gomes

Contact information

Type(s)

Scientific

Contact name

Dr Melba Gomes

Contact details

World Health Organization

Geneva

Switzerland

1211

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

A80550 A80553 A80556

Study information

Scientific Title

Feasibility, acceptability and costs of diagnosis and management of uncomplicated and severe malaria in the community

Study objectives

This is a non-randomised multi-centre community based intervention to assess the feasibility, acceptability and cost-effectiveness of a diagnostic and treatment package for malaria.

Ethics approval required

Old ethics approval format

Ethics approval(s)

World Health Organization Ethics Review Committee, 10/12/2009, refs: A80550-Nigeria, A80553-Burkina, A80556-Uganda.

Study design

Observational study of community based diagnosis and management of malaria.

Primary study design

Observational

Secondary study design

Epidemiological study

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Uncomplicated and severe malaria

Interventions

For the 12 month intervention period:

1. Diagnosis at point of care with a rapid diagnostic test (RDT)
2. Treatment of uncomplicated RDT positive cases with artemeter-lumefantrine (artemisinin combination treatment) and treatment of severe cases with rectal artesunate

Intervention Type

Mixed

Primary outcome measure

Feasibility, acceptability, costs of a diagnosis and treatment package in the community. Severe malaria cases are followed up (to monitor compliance with referral advice, and vital status /wellbeing at follow up), and uncomplicated cases are monitored for diagnosis and treatment.

Secondary outcome measures

Treatment seeking behaviour and promptness of access to diagnosis and care.

Overall study start date

01/05/2015

Completion date

30/09/2015

Eligibility

Key inclusion criteria

Febrile children aged 6 months 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

Unspecified. This is an observational study and the number of participants will depend upon malaria transmission.

Key exclusion criteria

Age below 6 months or above 59 months

Date of first enrolment

01/09/2015

Date of final enrolment

30/09/2015

Locations

Countries of recruitment

Burkina Faso

Nigeria

Uganda

Study participating centre

Group Health Research in Action (Group de Recherche Action en Sante (GRAS))

Ouagadougou

Burkina Faso

-

Study participating centre

Ministry of Health

Plot 6/P.O. Box 7272 Lourdel Rd

Kampala

Uganda

-

Study participating centre

University of Ibadan

College of Medicine

Ibadan

Nigeria

-

Sponsor information

Organisation

World Health Organization

Sponsor details

1211 Avenue Appia

Geneva

Switzerland

Geneva 27

Sponsor type

Other

ROR

<https://ror.org/01f80g185>

Funder(s)

Funder type

Government

