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

**Submission date**
01/05/2015

**Recruitment status**
No longer recruiting

**Registration date**
10/06/2015

**Overall study status**
Completed

**Last Edited**
10/07/2023

**Condition category**
Infections and Infestations

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

**Funder Name**
European Commission Directorate-General for Research and Innovation

**Alternative Name(s)**
EC DG Research

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
International organizations

**Location**

# Results and Publications

**Publication and dissemination plan**
To be confirmed at a later date.

**Intention to publish date**
30/12/2016

**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 | 15/12/2016 | 22/01/2019 | Yes | No |
| Other publications | | 15/12/2016 | 10/07/2023 | Yes | No |
| Other publications | | 15/12/2016 | 10/07/2023 | Yes | No |
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| Other publications | | 15/12/2016 | 10/07/2023 | Yes | No |
| Other publications | | 15/12/2016 | 10/07/2023 | Yes | No |