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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

Protocol serial number
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.

Primary study design
Observational

Study design
Observational study of community based diagnosis and management of malaria.

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
Treatment seeking behaviour and promptness of access to diagnosis and care.

Completion date
30/09/2015

Eligibility

Key inclusion criteria
Febrile children aged 6 months to 59 months

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
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

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

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
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