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Improving the test, treat and track (T3) malaria strategy in the informal sector

Submission date
04/11/2019

Recruitment status
No longer recruiting

Registration date
04/11/2019

Overall study status
Completed

Last Edited
07/11/2022

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The World Health Organization (WHO) has said that anybody who is suspected to have malaria should be tested before treated and followed up. This is to ensure that malaria medicines are given to only people who truly have malaria. In Africa, many people with symptoms that look like malaria visit drug shops, and are not tested but given malaria medicines. This means that people with other diseases that look like malaria are given malaria medicines when they do not need them. This study aims at improving the way drug sellers take care of people who visit their shops with signs and symptoms that look like malaria. The study findings will help the National Malaria Control Programme (NMCP) and other partners adopt measures that will ensure that only people with confirmed malaria receive malaria medicines in drug shops

Who can participate?
There are three types of participants: 1) selected Over The Counter Medicine Sellers (OTCMS) 2) children below ten years old 3) persons above 6 months (excluding pregnant women) visiting the selected drug shops with signs and symptoms that look like malaria

What does the study involve?
During the study, we will train selected drug sellers on how to test their patients for malaria using RDT kits, help the patients to pay for the test at a reduced cost, assist the drug sellers to overcome challenges during regular visits to their shops, and collect data on how they attend to their malaria patients

What are the possible benefits and risks of participating?
There will be no direct benefits to those taking part in this study. Participants will, however, help determine how to improve on the work of drug sellers when it comes to taking care of malaria patients, and also determine the accuracy of the malaria tests they do. The main risk in participating in this study is a little pain at the site of the finger prick during the malaria test

Where is the study run from?
The study is being run by the Noguchi Memorial Institute for Medical Research and takes place in four selected communities in the Fanteakwa North district in the Eastern region of Ghana

When is the study starting and how long is it expected to run for?
September 2019 to November 2020

Who is funding the study?
The World Health Organization / Special Programme for Research and Training in Tropical Diseases (WHO/TDR), Switzerland

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
STC Paper 6(6)2018-19 version 2

Study information

Scientific Title
Evaluating interventions to improve test, treat and track (T3) malaria strategy among over the counter medicine sellers (OTCMS) in some rural communities of Fanteakwa North district, Ghana: study protocol for a cluster randomized controlled trial

Acronym
ETTTOMS

Study objectives
Provision of artemisinin-based combination therapies (ACTs) and other antimalarials without confirmed malaria frequently results in overtreatment of malaria and reduces the availability of ACTs for true malaria cases. Hence, this study is aimed at improving the implementation of the T3 strategy in the informal healthcare sector using a number of intervention tools that could be scaled-up easily at the national level. This will help to achieve universal access to prompt parasite-based diagnosis, reduce overprescribing of antimalarial to malaria-negative clients, and promote the tracking of malaria cases

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/08/2019, Institutional Review Board (IRB) of Noguchi Memorial Institute for Medical Research (University of Ghana, P.O.Box LG581, Legon, Accra, Ghana; +233 302 916438; nirb@noguchi.ug.edu.gh), ref: NMIMR-IRB CPN 086/18-19

Study design
Single-centre interventional cluster randomized trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Malaria

Interventions
Intervention clusters have been randomly selected from one district while non-intervention clusters have been randomly selected from an adjacent district. An urban sub-district in the intervention district will act as a buffer between the two arms.

Intervention activities for this study will be:
1. Facilitating acquisition of subsidized mRDT kits
2. Training OTCMS operators on malaria diagnosis, treatment, and tracking of cases
3. Quarterly supportive visits to OTCMSs after training

4. Community sensitization on malaria focusing on the T3 strategy
5. Introduction of malaria surveillance tool for use by OTCMS operators

he methods for measuring the primary outcome will include mystery client surveys (monthly from March 2020 to November), assessment of OTCMS surveillance register (January 2020, April 2020, July 2020, and October 2020), mRDT quality survey (May - October 2020), and end-line household survey (November 2020)

Intervention Type
Other

Primary outcome measure
Proportion of patients attended to by OTCMS operators with report of fever or suspected malaria that receive a diagnostic test (using RDT). The methods for measuring the primary outcome will include mystery client surveys (monthly from March 2020 to November), assessment of OTCMS surveillance register (January 2020, April 2020, July 2020, and October 2020), mRDT quality survey (May - October 2020), and end-line household survey (November 2020)

Secondary outcome measures
1. Proportion of children under 10 years who received an antimalarial drug from an OTCMS operator without testing (method of assessment will be baseline household survey in October 2019 and end-line household survey in November 2020)
2. Adherence to treatment guidelines:
2.1. Percentage of clients/patients testing negative or not tested receiving ACT or other antimalarial drug (method of assessment will be an assessment of surveillance registers in January 2020, April 2020, July 2020, and October 2020)
2.2. Percentage of clients/patients referred to the public health facility by the OTCMS operator for further care (method of assessment will be an assessment of register in January 2020, April 2020, July 2020, and October 2020)
2.3. Percentage of OTCMS operators who could accurately perform an RDT, interpret results and dispose of waste (method of assessment will be monthly mystery client surveys from March 2020 to November 2020)
3. Adherence to RDT retail price: percentage of OTCMS operators who adhered to the recommended RDT retail price (method of assessment will be monthly mystery client surveys from March 2020 to November 2020)
4. The sensitivity, specificity, and predictive values of mRDTs used in the study (method of assessment will be mRDT quality survey from May 2020 to October 2020)

Overall study start date
17/09/2019

Completion date
30/11/2020

Eligibility

Key inclusion criteria
1. In-depth interviews: OTCMS operators within the selected clusters/communities
2. Household surveys: Children less than 10 years old
3. mRDT quality survey: Suspected uncomplicated malaria cases 6 months and above

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
OTCMS operators: 12 from 8 clusters; Children less than 10 years old: 776 from 8 clusters; Suspected malaria cases in intervention arm only: 591 from 4 clusters

Key exclusion criteria
mRDT quality survey: pregnant women; signs and symptoms of severe malaria

Date of first enrolment
17/09/2019

Date of final enrolment
30/11/2020

Locations

Countries of recruitment
Ghana

Study participating centre
Fanteakwa North District
c/o District Health Directorate
Begoro
Ghana
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Sponsor information

Organisation
World Health Organization (WHO) Special Programme for Research and Training in Tropical Diseases (TDR)

Sponsor details
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Sponsor type
Other

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ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
World Health Organization

Results and Publications

Publication and dissemination plan
Baseline data (perception on malaria, testing rate and barriers to implementation of test before treatment) will be published in PLOS ONE journal in June, 2020.
Intervention phase data will be published in BMJ in April, 2021.
Results of the study will be disseminated to WHO/TDR through biannual progress reports.
At the end of the study, study outcome will be disseminated to Ghana Health Service through the National Malaria Control Programme, and also presented at the institutional seminar of Noguchi Memorial Institute of Medical Research and two international conferences.

Intention to publish date
30/04/2022

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/07/2020	10/07/2020	Yes	No

Results article	05/11/2022	07/11/2022	Yes	No