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Evaluation of patient adherence to artemether-lumefantrine (AL) obtained from public and private drug outlets in Tanzania

Submission date
15/12/2012

Recruitment status
No longer recruiting

Registration date
16/01/2013

Overall study status
Completed

Last Edited
29/11/2019

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Malaria is still a major health problem in Tanzania and many other parts of Africa. Many people with malaria do not get appropriate treatment, and at the same time, people that do not have malaria continue to get treated with antimalarial drugs. Not receiving the recommended treatment can be dangerous, as older medicines that contain sulfadoxine-pyrimethamine (SP) and chloroquine are no longer very effective at killing the parasites that cause malaria. Taking antimalarial drugs when malaria has not been confirmed can also be dangerous, as many other illnesses have symptoms similar to malaria and require different treatments. In addition, widespread use of antimalarial drugs can cause the parasites to get used to the drug and develop resistance, so that they are no longer killed by the medicine.
The latest and most effective antimalarial drugs are called artemisinin-based combination therapies (ACTs), which are combinations of drugs, and have been shown to be very effective at killing all the malaria parasites. The ACT that is recommended by the government in Tanzania is called artemether-lumefantrine (AL). Recently, the government has been promoting cheaper AL with a green leaf on the package; the cost of these medicines is subsidized by international donors. These drugs can be sold in drug shops called Duka la Dawa Muhimu (DLDM). Dispensers at DLDM are supposed to receive special training on dispensing AL.
Patient adherence, the extent to which patients promptly and correctly take the full course of a drug, is a key component in ensuring drug effectiveness. As ACTs become more widely available in the private sector, monitoring their use is critical to their success. This study in Mtwara region, Tanzania will be comprised of two major activities: (1) a trial to assess adherence to AL among patients obtaining AL at Duka la Dawa Muhimu (DLDM) and those obtaining AL at DLDM where dispensers will receive a text message reminder intervention and an observational assessment of patient adherence to AL obtained from public health facilities.

Who can participate?
Patients of all ages attending one of the 36 randomly selected public health facilities and who are dispensed AL provided by the study, or those that purchase AL at one of the 72 randomly

selected DLDM during the time of the study. Patients living more than 10 km away will not be eligible to participate.
Dispensers at any of the study DLDM can also participate in interviews.

What does the study involve?
Beginning one month prior to data collection, dispensers at half of the DLDM will receive text message reminders of appropriate advice to provide when dispensing AL. The content of these messages will be based on materials used by the government to train dispensers at DLDM. Patients who are prescribed an ACT in public health facilities or who want to purchase ACTs at DLDM will be given age or weight-appropriate blister packs of AL supplied by the study. Half of the patients from each group will receive normal blister packs and half will receive blister packs containing electronic labels that measure the day and time each blister is opened. These patients will be visited at their homes a minimum of 75 hours after they obtain treatment, and they will be asked to consent to an interview about their visit to the drug outlet and how each dose of medication was taken. A pill count will be conducted and blister packs will be collected. Dispensers at DLDM will also be interviewed about their characteristics and knowledge of advice to give patients when dispensing AL.

What are the possible benefits and risks of participating?
Costs associated with transport or additional treatment for such patients will be provided by the research study, in order to ensure that recommended referrals are completed as promptly as possible.
Participants will undergo a finger stick, and blood will be collected for a blood smear and filter paper sample for the measurement of lumefantrine levels. Patients or clients encountered at follow-up visits or during exit interviews that exhibit signs of severe disease or severe febrile illness will be referred immediately for health facility level care, in accordance with national treatment guidelines. There are no other benefits or risks of participating in the study.

Where is the study run from?
The study will be run from Ifakara Health Institute in Tanzania.

When is the study starting and how long is it expected to run for?
The study will begin in September 2011, with data collection expected to finish in December 2012, and data entry, cleaning, and analysis to take place in 2013.

Who is funding the study?
The Bill and Melinda Gates Foundation is funding the study.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
QA393

Study information

Scientific Title
Evaluation of patient adherence to artemether-lumefantrine (AL) obtained from public and private drug outlets in Tanzania: a cluster-randomised trial

Study objectives
The null research hypotheses of the study are:

1. There is no difference in patient adherence to AL among patients who obtained AL from dispensers who received text message reminders compared to patients who obtained AL from dispensers who did not receive text message reminders.
2. There is no difference in patient adherence to AL from public health facilities compared to accredited drug shops (DLDM)
3. There is no difference in patient adherence to AL as measured by electronic blister packs compared to self-report.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. London School of Hygiene and Tropical Medicine, 24 July 2012, reference number 6205, A346
2. Ifakara Health Institute, 5 June 2012

Study design
Interventional cluster-randomised trial

Primary study design
Interventional

Study type(s)
Screening

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

Interventions
Text message reminder arm: Daily text messages reminding providers of national guidelines for treatment of malaria with artemether-lumefantrine (AL) have been developed based on training materials used by the government for training dispensers at accredited drug shops (DLDM). These messages will be summarised and pretested by the study team. To improve the probability that dispensers will read the messages, a unique quote, interesting saying, or a question requesting a response in exchange for free airtime will be included at the end of each message.

DLDM that have been randomized to receive the text message intervention will be visited prior to the study to invite all staff members who dispense drugs to register their numbers for receipt of text messages about AL. Text messages will be sent to all providers on the list, once a day for five days per week beginning one month prior to the study until data collection is complete.

No text message reminder arm: This would involve 36 control DLDM, where dispensers do not receive any messages. Patients will be followed-up in the same way from both arms.

In addition, we also have a group of patients who attend 36 health facilities. This "arm" isn't really part of the trial, but a separate evaluation not involving the intervention, but following up patients according to the same procedures as in the two DLDM arms: the Text message reminder arm and the No text message reminder arm.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Artemether-lumefantrine

Primary outcome(s)
Patient adherence to AL is the primary outcome indicator and will be reported in two ways:
1. Patient took all expected doses of AL in three to four days
2. Patient took all expected doses of AL at six time points at different times of day between three and four times of day

Key secondary outcome(s))
Score of dispenser knowledge of advice to provide when dispensing AL (from dispenser interviews)

Completion date
31/12/2012

Eligibility

Key inclusion criteria

Male and female patients of all ages attending health facilities and drug stores during the week of the study will be eligible for inclusion (i.e. follow-up visit) if they are seeking treatment for fever or malaria for themselves or on behalf of someone else, and they are dispensed AL (health facilities) or purchase AL (drug shops).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
1014

Key exclusion criteria
Patients will be excluded from follow-up if they reside further than 10 km away from the drug outlet or if another family member was previously followed-up and interviewed by the study team.

Date of first enrolment
13/09/2012

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Tanzania

Study participating centre
Ifakara Health Institute
Dar es Salaam
Tanzania
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Sponsor information

Organisation
London School of Hygiene and Tropical Medicine (UK)

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation (USA) ref E-2972

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2014	29/11/2019	Yes	No