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Efficacy of mobile phone short message service (SMS) on malaria treatment adherence and post-treatment review

Submission date
19/11/2013

Recruitment status
No longer recruiting

Registration date
22/01/2014

Overall study status
Completed

Last Edited
27/01/2017

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
Artemisinin-resistant malaria has been detected in south East Asia, with possible malaria cases in Western Cambodia, Western Thailand and Myanmar. This poses a major global public health threat, with the greatest potential effects in sub-Saharan Africa where the disease burden is greatest and systems for monitoring resistance to malaria treatment and control of malaria are weakest. A public health disaster is imminent, unless early warning and early detection measures are urgently set up. Poor patient adherence to treatment and drug misuse are among the causes of resistance. Recent evidence suggests that the traditional approaches (provider counselling and caregiver aids) for improving patient adherence in routine settings are not enough. There is a need to investigate new approaches to address this problem. Mobile phone short messaging services (SMS) have been investigated in health information reporting, provider performance, drug and diagnostic stock management and patient adherence to treatment for chronic diseases. However, their role in improving patients adherence and post-treatment review for acute diseases has not been investigated. The aim of this study is to investigate if text messaging can improve patient adherence to malaria treatment and to find out whether text messaging can bring back more patients for post-treatment review.

Who can participate?
Caregivers of male and female children aged < 5 years old with uncomplicated malaria.

What does the study involve?
Participants will be randomly allocated to one of two study groups: 1) the current standard of care based on provider counselling and health education alone, and 2) the current standard of care plus SMS reminders. Within each group participants will be further equally allocated to three different categories. Category 1 will be visited at home on day 1 of follow-up to measure appropriate timing of the second Artemether-Lumefantribe (AL) dose; category 2 will be visited on day 2 to measure adherence and timing of AL doses 2, 3 and 4; category 3 will be visited on day 3 to measure adherence for the full AL course.

What are the possible benefits and risks of participating?
If successful, the results of the planned study could improve malaria case management and offer new strategies for mitigation of antimalarial drug resistance in Africa. This is a minimal risk study, the text messages will be designed in English and local languages (Dholuo and Kiswahili), and except for small needle pricks to get blood samples we do not anticipate major risks to the safety of patients in the study. Home visits are likely to cause some inconvenience but we will ensure that they are fairly convenient to the study participants. Psychological risks could occur if caregivers receive the wrong text messages or receive text messages when the patient has died. We will limit such risks by carefully designing the intervention and pre-testing it, and we will conduct the study among patients with uncomplicated malaria where the risk of death is lower. There are no other risks, costs or individual benefits for those involved in the study, beyond getting health care.

Where is the study run from?
The study will be conducted at four sites in the greater Bondo area in Nyanza Province, Kenya, at Bondo and Madiany District Hospitals representing two urban areas and Ndori and Got Agulu Health Centres representing two rural areas.

When is the study starting and how long is it expected to run for?
April 2014 to September 2015

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr Ambrose Talisuna
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
SSC 2554

Study information

Scientific Title
Efficacy of mobile phone SMS reminders on malaria treatment adherence and post-treatment review (SMS-RES-MAL) in Kenya: a randomized controlled trial

Acronym
SMS-RES-MAL

Study objectives
Mobile phone SMS text messaging has no effect on malaria treatment adherence and post treatment review.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Kenya Medical Research Council Research Ethics Committee (ERC), 17/06/2013, ref:KEMRI/RES/7/3/1

Study design
Randomized controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Malaria treatment adherence and post treatment review

Interventions
Caregivers of eligible children with uncomplicated malaria will be randomly assigned using the automated system to two different arms:
1. The current standard of care based on provider counselling and health education alone
2. The current standard of care plus SMS reminders

Within each arm participants will be further equally randomly assigned to three different categories for the measurement of adherence. In category 1, 300 caregivers will be visited at home on day 1 of follow-up to measure appropriate timing of the second AL dose. In category 2, another 300 caregivers will be visited at home on day 2 to measure adherence of and timing of AL doses 2, 3 and 4. In category 3, a final 400 caregivers will be visited at home on day 3 after they have completed the full treatment course to measure adherence for the full course of AL. The 600 caregivers per arm in category 1 and 2 will not be visited again to avoid biases in the subsequent measures of adherence. This group will also present the study group for the day 3 post-treatment review.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Adherence to a complete AL course (doses 2-6) measured in category 3 only and defined as: a) adherent, if they present blister packs with the appropriate number of pills used and report taking the medications as recommended (± 1 hour for dose 2 and ± 2 hours for doses 3-6); b) probably adherent if they do not present blister packs but report taking the medications as recommended, c) probably non adherent if they do not present blister packs and do not report taking the medications as recommended, and d) non adherent if they present blister packs with at least one tablet not used
2. The proportion of patients in the intervention and control arms reporting to the health facility for post treatment review and subsequent evaluation of clinical and parasitological cure at day 3 (only category 1 and 2) and at day 28 (all categories)

Key secondary outcome(s))
1. Adherence and timing outcomes for individual AL doses measured in category 1 for AL dose 2 and category 2 for AL doses 3 and 4, and category 3 for AL doses 5 and 6
2. Loss to follow up at day 3 defined as unable to return to the facility 24 hours after the scheduled appointment and loss to follow up at day 28 defined as unable to return to the facility 48 hours after the scheduled appointment

Completion date
30/09/2015

Eligibility

Key inclusion criteria
1. Caregivers of male and female children aged < 5 years old
2. Body weight eligibility for artemether-lumefantrine (AL)
3. Microscopically confirmed, mono-infection of Plasmodium falciparum (parasitaemia ≥ 500/µL to 200,000/µL)
4. History of fever in the last 24 hours or presence of fever (axillary temperature ≥ 37.5 °C)
5. Network coverage at patients household
6. Owning a mobile phone or have shared access to a mobile phone in household
7. Ability to access a mobile phone on a daily basis for the period of follow up
8. Ability to open and read short message service (SMS)
9. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
5 years

Sex
All

Key exclusion criteria
1. Caregivers not owning a mobile phone and have no shared access to any phone in the household
2. Severe malaria
3. Danger signs: not able to drink or breast-feed, vomiting (> twice in 24hours), recent history of convulsions (>1 in 24h), unconscious state, unable to sit or stand
4. Presence of concomitant illness or any condition which in the judgement of the investigator would place the subject at undue risk or interfere with assessment
5. Severe malnutrition (weight for height < 70 % of the median NCHS/WHO reference)
6. Ongoing prophylaxis with drugs having antimalarial activity such as cotrimoxazole for the prevention of pneumocysti carini pneumonia in children born to HIV+ women
7. Having taken AL in the previous one month

Date of first enrolment
01/04/2014

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
Kenya

Study participating centre
University of Oxford-KEMRI-Wellcome Trust Programme
Nairobi
Kenya
00100

Sponsor information

Organisation
University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK) (MR/K007351/1)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	25/01/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes