

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/01/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/01/2017	Condition category Infections and Infestations	<input type="checkbox"/> 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-Lumefantrine (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?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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

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 measure

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)

Secondary outcome measures

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

Overall study start date

01/04/2014

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 $\geq 500/\mu\text{L}$ to $200,000/\mu\text{L}$)
4. History of fever in the last 24 hours or presence of fever (axillary temperature $\geq 37.5^\circ\text{C}$)
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

Age group

Child

Upper age limit

5 Years

Sex

Both

Target number of participants

2000

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
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Sponsor information

Organisation

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Sponsor type

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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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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