ISRCTN59275137 https://doi.org/10.1186/ISRCTN59275137

To assess whether providing Kenyas first line anti-malarial treatment in shops at a subsidised price can increase the share of young children who receive appropriate treatment for malaria

Submission date
23/04/2008

Recruitment status
No longer recruiting

Registration date
25/04/2008

Overall study status
Completed

Last Edited
21/03/2013

Condition category
Infections and Infestations

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SSC 1361

Study information

Scientific Title
The impact of retail sector delivery of artemether-lumefantrine on effective malaria treatment of children under five in Kenya

Study objectives
Null hypothesis:
The provision of pre-packaged, subsidised artemether-lumefantrine (AL) delivered through private sector retailers will have no effect on improving the coverage of prompt effective anti-malarial treatment.

As of 27/01/2009 this record was updated. All updates can be found in the relevant section under the above update date. Please note that as this time the target number of participants was updated from '540 homesteads in each group (target: 79 childhood fevers); 153 shops participating' to the below information. Please also note that the anticipated start date mentioned below is for the start of the evaluation; the anticipated start date for the interventions recruitment was 29/09/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. Kenya Medical Research Institute (KEMRI) Ethical Review Committee (ERC) (Scientific Steering Committee [SSC] ref: 1361) on the 23rd April 2008. Approval was granted from 23rd March 2008 to 23rd March 2009. Application for an approval extension will be done in early 2009.
2. London School of Hygiene and Tropical Medicine (LSHTM) ERC received March 2008 (ref: 5288)
3. Pharmacy and Poisons Board (PPB), Ethical Committee for Clinical Trials (ECCT) received on 12th August 2008 for the duration of a year (ref: PPB/ECCT/08/07)

Special dispensation was granted from the Pharmacy and Poisons Board (Kenya) allowing artemether-lumefantrine to be temporarily deregulated to an over-the-counter medication in the intervention sub locations solely for the purposes of the study.

Study design
Interventional, pre-post randomised cluster controlled 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 below to request a patient information sheet

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

Interventions
This is a pre-post randomised cluster controlled design, with clusters (sub-locations) randomly allocated to 9 intervention and 9 control groups. We will need to collect data on 1,161 homesteads in the intervention and control groups to be able to target a sample size of 79 childhood fevers per group. Potential number of shops participating in the survey: 225 in the intervention arm.

The intervention will consist of the following components:
1. Subsidised, pre-packaged artemether-lumefantrine sold in selected retail outlets in two doses:
1.1. Tablets for 5 kg to less than 15 kg: treatment dose of 20/120 mg twice daily for 3 days
1.2. Tablets for 15 kg to less than 25 kg: treatment dose of 40/240 mg twice daily for 3 days 2. Shopkeepers will be trained on malaria symptoms, clinical diagnosis, treatment and referral of children under the age of five
3. Community promotional/educational activities will be targeted at caregivers of children under five years on malaria symptoms, clinical diagnosis, treatment options and when to seek treatment from a health facility

Total duration of the intervention: one year and six months Follow-up duration in both arms: after 9 months of the intervention, follow-up household and provider surveys will take place in both arms, over a three-month period.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
To determine the impact on the proportion of children under five with fever being treated promptly with appropriate anti-malarial treatment, and adhering to the correct dose.

Timepoints for both primary and secondary outcomes:
At baseline, through household and provider surveys conducted over a four month period prior to the intervention. At follow-up, through household and provider surveys conducted over a three month period, nine to twelve months after the start of the intervention.

Secondary outcome measures
1. To determine if private sector retailers can deliver AL to appropriate standards of quality for the treatment of fever in children under five years (provision)

2. To determine distribution of benefits of retail sector delivery of AL by socio-economic status (equitable coverage)
3. To explore reasons for the impact observed and identify any challenges in the implementation process

Timepoints for both primary and secondary outcomes:
At baseline, through household and provider surveys conducted over a four month period prior to the intervention. At follow-up, through household and provider surveys conducted over a three month period, nine to twelve months after the start of the intervention.

Overall study start date
07/05/2008

Completion date
01/06/2010

Eligibility

Key inclusion criteria
Added as of 27/01/2009:
Please note that the specified minimum amount of time for which the selected retail outlets should have been functioning has been identified as a minimum period of six months prior to the baseline survey.

Initial information at time of registration:
1. All children under five years of age (either sex) from whom care is sought for fever from participating retail shops serving the population in the intervention sub-locations
2. Selected retail outlets either within or serving the intervention sub-locations which are perceived to be well established, respected businesses by the local community, who stock anti-malarials or anti-pyretics and have been functioning for a specified minimum amount of time (time of functioning to be determined following baseline retail census)

Participant type(s)
Patient

Age group
Child

Upper age limit
5 Years

Sex
Both

Target number of participants
1,161 homesteads in each group (target: 79 childhood fevers); 225 shops were identified as potential participants

Key exclusion criteria

Added as of 27/01/2009:
Please note that the specified minimum amount of time for which the selected retail outlets should have been functioning has been identified as a minimum period of six months prior to the baseline survey.

Current information as of 16/04/2010:
1. Children less than 3 months. These children will be referred directly to a health facility.
2. Children 3 - 59 months, suffering from Integrated Management of Childhood Illness (IMCI) danger signs. These children will be referred directly to a health facility.
3. Retail shops serving the intervention sub-locations that do not sell anti-pyretics or anti-malarials, have been functioning for less than the specified amount of time defined from the baseline retail census, and are not perceived to be well established, respected businesses by the local community

Initial information at time of registration:
1. Children under 5 kg suffering from Integrated Management of Childhood Illness (IMCI) danger signs. These children will be referred directly to a health facility.
2. Retail shops serving the intervention sub-locations that do not sell anti-pyretics or anti-malarials, have been functioning for less than the specified amount of time defined from the baseline retail census, and are not perceived to be well established, respected businesses by the local community

Date of first enrolment
07/05/2008

Date of final enrolment
01/06/2010

Locations

Countries of recruitment
Kenya

Study participating centre
KEMRI Wellcome Trust Research Programme
Nairobi
Kenya
-

Sponsor information

Organisation
Kenya Medical Research Institute (KEMRI) Wellcome Trust Research Programme (Kenya)

Sponsor details

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Sponsor type
Research organisation

Website
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ROR
https://ror.org/04r1cxt79

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 077092)

Funder Name
Department for International Development (DFID) (UK)

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	01/05/2011	Yes	No