

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

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| Submission date 23/04/2008 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| Registration date 25/04/2008 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 21/03/2013 | Condition category Infections and Infestations | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Child

Upper age limit

5 years

Sex

All

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

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Sponsor information

Organisation

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

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

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 |