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Can improved housing provide additional protection against clinical malaria over current best practice?

Submission date
05/09/2014

Recruitment status
No longer recruiting

Registration date
23/09/2014

Overall study status
Completed

Last Edited
13/04/2021

Condition category
Infections and Infestations

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

Malaria is a life-threatening infection that people can get though bites by infected mosquitoes (malaria mosquitoes). It is one of the greatest threats to global public health; in 2012 there were 207 million cases of the condition resulting in 627,000 deaths with some 80% of those deaths occurring in Africa. Most cases of infection happens indoors at night, so its important to try and prevent, or at least reduce, the number of malaria mosquitoes entering peoples homes. In previous research, we have shown that closing the eaves (the gap between the top of the wall and the roof) and using screening can reduce dramatically the number of malaria mosquitoes entering a house. Here, we want to find out if we can protect children against malaria by modifying houses so that they have a metal roof, closed eaves, screened doors and windows and screened air bricks which allow the warm air to rise out of the house, but not let any mosquitoes indoors. We will see how successful these measures are by looking at how many children become infected in these houses compared to those living in houses with thatched roofs and open eaves. Over the past thirty years a silent revolution in house design has been happening across Africa. The traditional thatched-roofed houses are being replaced steadily by metal-roofed houses as the continent develops. We hope to ride this wave of cultural change and further improve the design of houses to make them healthier to live in. Improved housing has the potential to improve the lives of millions of people across sub-Saharan Africa.

Who can participate?

Children aged 6 months to 13 years who live in single-story homes with thatched roofs, walls without cracks, open eaves, have no more than 4 rooms, no ceiling and no screening.

What does the study involve?

Households in eligible housing are randomly allocated into one of two groups. Those in the intervention group have their homes modified to have metal roofs, closed eaves, screened-air bricks and screening on the doors and windows. Those in the control group do not have their homes modified.

What are the possible benefits and risks of participating?
The study participants will benefit from the intense follow up as any illness, including clinical malaria, will be diagnosed and treated. Most importantly, participants will benefit by having a better quality house at the beginning or end of the study, i.e. those in the control group will be offered the modifications at the end of the study. There is a low risk that well-sealed houses may increase the risk of respiratory disease in children. However, we will monitor this during the study. Children with respiratory disease will be referred to local health facilities for treatment.

Where is the study run from?
The study will take place in The Gambia, but run from Durham University (UK)

When is the study starting and how long is it expected to run for?
November 2014 to February 2017

Who is funding the study?
Global Health Trials (MRC-DfID-Wellcome Trust) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 0.1

Study information

Scientific Title
Can improved housing provide additional protection against clinical malaria over current best practice? A household-randomised controlled study

Acronym
RooPfs

Study objectives
Improved housing will reduce house entry by malaria mosquiotes and thereby reduce the incidence of clinical malaria in children living in these houses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Gambia Government/MRC Joint Ethics Committee, 29/10/2014, SCC 1390v3
2. Durham University School of Biological and Biomedical Sciences Ethics Committee, 01/12/2014, Ref: SBBS/EC/1401/RooPfs 12 09 14

Study design
Two-armed household clustered-randomised controlled study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Home

Study type(s)
Prevention

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
All study houses will be provided with a sufficient number of LLINs to be able to cover all sleeping places and we will follow national guidelines to encourage their correct use as this is the current best practice at the beginning of the study. In the intervention arm, representing modern housing, we propose to modify existing thatched roof houses so that they will have

metal roofs, closed eaves, screened-air bricks, and screening on the doors and windows (n=400) and the control arm, representing traditional houses, will be left with thatched roofs and open eaves (n=400) until the end of the study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To assess whether improved housing reduces the burden of clinical malaria where coverage of LLINs is high. Incidence of clinical malaria determined by active case detection (ACD) and defined as body (axillary) temperature of ≥37.5oC, together with the presence of Plasmodium falciparum parasites detected by microscopy. Incidence will be measured from June to December in 2015 and 2016.

Secondary outcome measures
1. To determine whether improved housing reduces the rate of parasite infection, parasite density and anaemia in children. Prevalence of malaria infection, splenomegaly and anaemia determined by cross-sectional surveys at the beginning (June) and end of each rainy season (November /December) in 2015 and 2016. The presence of malaria parasites will be determined by microscopy, the presence of an enlarged spleen by palpation and anaemia quantified by measuring haemoglobin using a HemoCue.
2. To find out whether improved housing is associated with a rise in respiratory infections. Measure cough and either a respiratory rate of above the age specific cut-off or chest indrawing during twice weekly visits from June to December in 2015 and 2016.
3. To assess whether improved housing reduces vector density inside houses when compared with LLIN alone. Mean number of female Anopheles gambiae s.l./light trap/night. Estimated entomological inoculation rate (EIR) in each study arm (i.e. mean number of sporozoite infective bites/child/season) from June to December in 2015 and 2016. Collections will be made indoors using CDC light traps and the presence of vectors with sporozoites determined using an ELISA.
4. To determine whether improved housing is acceptable to the residents and sufficiently durable
5. To find out whether these interventions are cost effective
6. To develop a strategy for potential scale-up of improved housing

Overall study start date
01/11/2014

Completion date
01/02/2017

Eligibility

Key inclusion criteria
Houses must meet the following criteria to be selected:
1. Thatched roofs
2. Intact walls (no cracks)
3. Be single-storey square buildings
4. Open eaves

5. No more than four rooms
6. No ceiling (which is equivalent to closed eaves)
7. No screening
8. At least two resident children aged six months to 13 years old (needed in case the study child leaves the study)

Children must be:
1. Aged 6 months to 13 years old
2. Resident in houses enrolled in the study
3. Whose parents/carers give written, informed consent for their child to be included in the study

Assent will also be sought from eligible children >11 years old after the purpose of the study and what is required has been explained to them according to their capability. In the case of school-age children, only those who live in their village during term-time will be eligible for enrolment. In order for the results from this study to be as generalizable as possible, no distinctions will be made in terms of medical condition or physical health.

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
6 Months

Upper age limit
13 Years

Sex
Both

Target number of participants
800 children; 400 in each arm

Total final enrolment
805

Key exclusion criteria
1. Children for whom informed consent is not or cannot be provided
2. Children aged under 6 months or over 13 years on 1st June for the year of survey
3. Children expected to be non-residence during several month of the transmission season

Date of first enrolment
01/01/2015

Date of final enrolment
01/06/2016

Locations

Countries of recruitment
England

Gambia

United Kingdom

Study participating centre
Durham University
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Sponsor information

Organisation
Durham University (UK)

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Sponsor type
University/education

ROR
https://ror.org/01v29qb04

Funder(s)

Funder type
Research organisation

Funder Name
Global Health Trials (MRC-DfID-Wellcome Trust). MR/M007383/1 (UK)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/06/2016		Yes	No
Results article		01/04/2021	13/04/2021	Yes	No