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Evaluating the impact of eave tubes plus house screening on malaria transmission

Submission date
31/01/2017

Recruitment status
No longer recruiting

Registration date
01/02/2017

Overall study status
Completed

Last Edited
09/05/2023

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 deadly disease caused by infection with malaria parasites. Every year, millions of people become infected with malaria parasites and hundreds of thousands of people die from the infection. The biggest burden of disease is in children, and particularly children who live in Africa. Malaria parasites are transmitted through the bite of a female malaria mosquito. Many of these infectious bites happen at night, when people are sleeping inside their homes. To protect themselves from malaria mosquitoes, people can sleep under an insecticide treated bed net or have their walls sprayed with insecticides. Although these tools have contributed substantially to the recent reductions in malaria cases, they face various challenges, such as the resistance of mosquitoes to he insecticides used for malaria control and the practical difficulties associated with spraying houses. Eave tubes are a new control tool that addresses these challenges. The basic principle of the eave tube technology is to limit mosquito access into the house by screening or blocking as many openings as possible, and adding tubes containing insecticide-treated netting into the eaves of the house. Heat and odors rise out of the house and through the tubes, and these cues attract mosquitoes in search of a blood meal. The insecticide-treated netting inside the tubes provide a focal point to kill mosquitoes as they try to enter or exit through the openings. The advantages of this approach include the fact that eave tubes and window screening protect an entire household without any additional effort by the occupants, and that the eave tubes require only a small amount of insecticide, and the insecticide is placed in a location that is inaccessible to children. The aim of this study is to investigate the effectiveness of the eave tube approach in reducing malaria.

Who can participate?
Children between 6 months and 10 years old living in houses that are suitable to the eave tube modification.

What does the study involve?
Eligible villages (a minimum of 100 houses and 50 children in the village) are randomly assigned to one of two groups: treatment or control. All householders in the treatment group, are offered the opportunity to have their houses screened and modified with eave tubes. Villages in both groups receive insecticide-treated bed nets.

What are the possible benefits and risks of participating?
The study participants will benefit from close monitoring and treatment of any illness, including malaria. In the treatment arm, participants will benefit from improvements to their house including screening of their windows and sealing any cracks or holes in their walls. All participants will benefit from new, insecticide-treated nets. There is a small risk that improving the condition of the houses will decrease airflow and increase the risk of respiratory diseases, but this will be monitored throughout the study and any children with respiratory disease will be referred to a local health facility (a practice already followed by the resident community health workers).

Where is the study run from?
The study is run from Institut Pierre Richet and takes place in villages within an approximately 50km radius of Bouake (Cote d'Ivoire)

When is study starting and how long is it expected to run for?
November 2015 to March 2019

Who is funding the study?
Bill and Melinda Gates Foundation (USA)

Who is the main contact?
Professor Matthew Thomas
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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

BMGF Grant # OPP1131603

Study information

Scientific Title
Evaluating the impact of eave tubes plus house screening on malaria transmission: A randomized controlled trial in central Cote d'Ivoire

Study objectives
Installing eave tubes plus associated house screening will prevent mosquito entry into the house and kill mosquitoes attempting to enter houses at eaves level. This will reduce the incidence of malaria infection in children living in villages where houses have been modified with eave tubes and associated screening.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Cote d'Ivoire Ministry of Health, National Committee for Ethics and Research (Comite National d'Ethique et de la Recherche), 04/08/2015, ref: 039/MSLS/CNER-dkn
2. Penn State University Institutional Review Board (IRB), 27/10/2016, ref: STUDY00004815
3. London School of Hygiene and Tropical Medicine (Pending)

Study design
Two-arm cluster randomized controlled trial (RCT)

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

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

Interventions
Villages (clusters) will be allocated to one of two treatments through restricted randomization based on village size and malaria prevalence in children between the ages of 6 months in 10 years. There will be 20 villages in each trial arm with 100-200 houses per village.

Control arm treatment: at the start of the trial, each household will receive the number of long lasting insecticidal nets (LLINs) necessary to achieve universal bed net coverage (1 bed net for ever 2 people in the household. Houses will not be modified in the control arm.

Treatment (eave tube) arm treatment: at the start of the trial, each eligible household will be offered the option of having their house modified with eave tubes. This consists of installing eave tubes, screening windows, and sealing any large cracks in the walls. A house is eligible for the intervention if it has a metal roof (as opposed to thatch) and the walls are in sufficiently good condition to support drilling to install the eave tubes. The eave tubes will then be fitted with screened inserts treated with a 10% formulation of beta cyflutherin. After the installation of the eave tubes, each household will also receive LLINs as in the control arm.

A subset of study participants in both arms (50 children per village, 2,000 children total) will be enrolled in the epidemiological monitoring, which will involve monthly (November - April) or fortnightly visits (May - October). Every 3 months there will be a "walk through" of all study villages to check the condition of the houses. Participants in the treatment arm will also be informed that they can contact the study team at any point for repairs relating to the eave tube intervention. A sample of insecticide treated inserts will be taken from the treatment villages each month to test for persistence of the insecticide. Inserts will be replaced once post-exposure mortality in mosquitoes falls below 50% (expected to be every 3-4 months).

Intervention Type
Other

Primary outcome measure
Malaria incidence will be monitored in cohorts of children (6 months through 10 years old) through active case detection (ACD) with monthly visits during the dry season (November – April) and fortnightly visits during the rainy reason (May – October). Clinical malaria will be defined as a positive malaria rapid diagnostic test (RDT) and an axillary body temperature of ≥37.5oC. Malaria infections will be confirmed by PCR of blood samples for malaria parasite DNA.

Secondary outcome measures
1. Clinical malaria incidence in all children will be measured by clinic visits throughout the course of two year monitoring period. Malaria diagnosis will be defined as any child presenting with an axillary body temperature of ≥37.5oC and a positive Rapid Diagnostic Test (RDT).
2. Prevalence of anemia and respiratory infections in the study cohort, measured twice yearly (April and November) for two years. Anemia will be testing using blood samples and the Hemocue Hb system and defined as moderate (7 – 9.9 g/dL hemoglobin) to severe (<7 g/dL hemoglobin) anemia. Respiratory infections will be diagnosed based on clinical symptoms including coughing, and either a raised age-specific respiratory rate or chest indrawing.
3. Malaria vector densities will be measured by CDC light traps for two nights every month, and by human landing catches for 2 nights every two months. Mosquito species identification will be done based on morphology and confirmed by PCR. Parity rates will be measured through a visual inspection of ovaries and sporozoite prevalence will be measured by ELISA in a subset of the mosquito catches. Prevalence of kdr and ace1 resistance alleles will also be measured through PCR in a subset of the catches.
4. Data loggers will be used to record hourly temperature and relative humidity in a subset of study houses in each village to determine whether house modifications affect indoor microclimate. A commercial air sampler will be used to assess whether house modifications

affect indoor air quality every month from baseline to two years
5. Public attitudes about malaria, its prevention, and whether eave tube technology is acceptable to the residents will be measured through surveys from baseline to two years

Overall study start date
20/11/2015

Completion date
01/03/2019

Eligibility

Key inclusion criteria
1. Aged 6 months – 10 years old
2. Resident in houses enrolled in the study
3. Whose parents/guardians give written, informed consent for their child to be included in the study
4. In the case of school-aged children, only those who live in their villages throughout the school term will be eligible for enrollment
5. For the results to be as generalizable as possible, no distinctions will be made in terms of medical condition, physical health, gender or ethnic group

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
6 Months

Upper age limit
10 Years

Sex
Both

Target number of participants
2,000 children, 1,000 in each arm.

Total final enrolment
2560

Key exclusion criteria
1. For whom informed consent is not or cannot be provided by a parent or guardian
2. Who are under 6 months or over 10 years at any point in the study
3. Expected to be non-resident during a significant part of the transmission season

Date of first enrolment
15/02/2017

Date of final enrolment
15/02/2019

Locations

Countries of recruitment
Côte d'Ivoire

Study participating centre
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Sponsor information

Organisation
The Pennsylvania State University

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Sponsor type
University/education

ROR
https://ror.org/04p491231

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal within a year of the end of the trial period.

Intention to publish date
01/03/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/07/2018	09/09/2019	Yes	No
Results article	results	27/02/2021	01/03/2021	Yes	No
Results article	results	04/05/2023	09/05/2023	Yes	No