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Evaluating a single intervention product to protect people in both indoor and outdoor contexts from multiple vector-borne diseases.

Submission date
16/04/2025

Recruitment status
No longer recruiting

Registration date
24/04/2025

Overall study status
Ongoing

Last Edited
17/04/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Vector-borne diseases are human illnesses caused by parasites and viruses transmitted by a broad range of vectors, including mosquitoes and sandflies. Vector-borne diseases afflict a heavy burden in Ethiopia, with several diseases including dengue, lymphatic filariasis, malaria, visceral leishmaniasis (VL) and other arboviruses overlapping. Malaria is endemic in Sub-Saharan Africa, with 223 million cases and 580,000 deaths annually. Dengue is spreading in Africa, with 90,000 confirmed cases and 900 deaths. Dengue fever had a predominant urban distribution a few decades earlier, but is now also reported from peri-urban as well as rural areas. Other arboviral diseases such as chikungunya, Japanese encephalitis and yellow fever often go unreported. Lymphatic filariasis affects >23 million globally, with 420 million people at risk of acquiring the infection in India. Due to significant investments and efforts of improved vector control of malaria and case detection and treatment the disease dropped in Ethiopia, however, since 2022 the number of cases has again increased and between 1 January and 20 October 2024, over 7.3 million malaria cases and 1157 deaths (CFR 0.02%) were reported, the highest number of annual cases recorded in the last seven years. There is no vector control for the other diseases. Bite Barrier (BB) is an emitter that has been developed and uses the pyrethroid insecticide transfluthrin, which has been available for public health for 20 years. There is the potential to use this tool to target and control several vectors simultaneously. This study aims to investigate the entomological impacts of the BB device against the key vectors: Anopheles, Aedes, and Culex mosquitoes and Phlebotomus sand flies, at the village level.

Who can participate?
Households in the study area who are willing to participate.

What does the study involve?
To estimate the duration of the BB device's effectiveness, standard WHO semi-field experiments will be conducted in Tanzania. These experiments will test the repellent effect on both susceptible and resistant strains of mosquitoes using devices aged in the field every two weeks for 40 weeks. This study will be a prospective observational study within a two-armed cluster randomized control trial with entomological endpoints.

1. Positive Control (LLINs only): Positive control sites will use only the current standard mosquito control method, Long-Lasting Insecticidal Nets (LLINs), which is the current Ethiopian Standard of Care.
2. BB with Standard of Care (LLINs): In other sites, the BB device will be distributed to households for indoor and peri-domestic use, in addition to the standard LLINs.

Standard vector collection methods will be employed, including CDC light traps, BG Sentinel traps, Prokopak aspirators, double-net traps, and both mechanical and mouth aspiration. These entomological collections will be used to determine vector abundance and insecticide resistance to transfluthrin.

To understand the risk of infection, human behavior information regarding sleeping habits will be recorded through a questionnaire. An annual survey will be conducted to assess the acceptability and use of the BB device during entomological collections. Data on the number of people sleeping outdoors, the use of bed nets, fans, or other physical barriers, and the number and species of animals associated with the home will be recorded electronically.

What are the possible benefits and risks of participating?
While there are no direct benefits to participating in the study, individuals will be assisting with the collection of information on control of sand fly and mosquito population within the village, with the results from this study being reported to the National Malaria Control Programme and Ministry of Health that can impact on vector control decision making processes.

Where is the study run from?
The Liverpool School of Tropical Medicine, UK

When is the study starting and how long is it expected to run for?
September 2022 to december 2027

Who is funding the study?
US Department of Defense, USA

Who is the main contact?
Dr Michael Coleman, Michael.Coleman@lstmed.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Evaluating a single intervention product to protect people in both indoor and outdoor contexts from multiple vector-borne diseases.

Acronym
IVC

Study objectives
1. The BiteBarrier will result in significantly lower numbers of each disease vector per household (indoor and semi-outdoor exposure space) when compared to a standard care (LLINs) control
2. Villages where the BiteBarrier is distributed will have a reduction in overall disease incidence

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 16/04/2025, Liverpool School of Tropical Medicine Research Ethics Committee (Pembroke Place, Liverpool, L3 5QA, United Kingdom; +44 (0)151 705 3100; lstmrec@lstmed.ac.uk), ref: 25-028

Study design
Single-centre cross-sectional observation study

Primary study design
Observational

Study type(s)
Prevention, Efficacy

Health condition(s) or problem(s) studied
Visceral leishmaniasis, malaria and dengue

Interventions
BiteBarrier (https://bitebarrier.org/) a spatial emanator for vector control. BiteBarrier contains the insecticide transfluthrin, a pyrethroid.

The interventions are to be hung indoors and semi-outdoor environments by the study team – the impact of this on insect vectors will then be monitored.
This will be done at the beginning of the two malaria seasons and replaced at two month intervals by the study team
Supplied by PIC Corporation US

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
BiteBarrier

Primary outcome(s)
Reduction in visceral leishmaniasis, malaria and dengue vectors measured using CDC-light traps, double net traps and mouth aspiration, form where the BiteBarrier device has been hung inside homes and semi-outdoor spaces in the village, during the two malaria seasons, in 2025 and 2026

Key secondary outcome(s))
Reduction in visceral leishmaniasis, malaria and dengue as measured using health facility data serving the villages where the BiteBarrier device was distributed – monthly data collected pre, during and one month post malaria season

Completion date
20/12/2027

Eligibility

Key inclusion criteria
Household and willing to participate.

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
Not of consent age, do not wish to participate.

Date of first enrolment
01/07/2025

Date of final enrolment
01/08/2025

Locations

Countries of recruitment
Ethiopia

Study participating centre
Armauer Hansen Research Institute
ALERT Compund Zenebework, Jimma Road
Addis Ababa
Ethiopia
1005

Sponsor information

Organisation
Liverpool School of Tropical Medicine

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Government

Funder Name
U.S. Department of Defense

Alternative Name(s)
United States Department of Defense, Department of Defense, U.S. Dept of Defense, US Department of Defense, US Dept of Defense, DOD, USDOD

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. All deidentified data will be made available. Data will be shared in an ongoing process with the national malaria control programme.
The only data that would be entered into a depository is entomological – the depository has not yet been selected.

IPD sharing plan summary
Stored in publicly available repository