ISRCTN62801024 https://doi.org/10.1186/ISRCTN62801024

Developing low-cost house floors to control sand flea disease (jiggers) in Kenya

Submission date
29/06/2023

Recruitment status
No longer recruiting

Registration date
07/07/2023

Overall study status
Completed

Last Edited
13/12/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Tungiasis is a neglected tropical skin disease caused by sand fleas, the adult female of which burrows into the skin of the feet. The parasite rapidly expands its body size by a factor of 2000. The growth causes inflammation with immense itching, pain and debilitation. With no good treatment available people cut out the fleas using plant thorns and dirty blades causing more damage and suffering. The embedded flea lays eggs out of the skin into the soil where they develop into larvae and 3 weeks later adults emerge from pupae ready to infect the same person or another person. Several studies have shown that the main source of infection is inside people's homes since they have floors of sand or soil. The best way to control tungiasis is to enable people to build houses with sealed, hard floors in which the flea larvae cannot live. In this project we aim to develop and test a hard floor that is affordable for the poorest families, who are the ones most affected by tungiasis.

Who can participate?
The study enrolled households in Kilifi county in Kenya with an earthen floor and at least two tungiasis cases.

What does the study involve?
Houses were randomly allocated to have either a low-cost floor, a concrete floor, or no additional floor.
Floors were installed in houses in December 2019 and children in all houses monitored for infection once a month for 10 months.

What are the possible benefits and risks of participating?
The benefits of participating in the study were receiving a hard sealed floor in the house and all infected children were treated for tungiasis. The main risk was exposure of the infection status of family members to neighbours.

Where is the study run from?
International Centre of Insect Physiology and Ecology (Kenya)

When is the study starting and how long is it expected to run for?
April 2019 to February 2023

Who is funding the study?
The study was funded with a pump-prime grant from UKRI-MRC through the BOVA Network

Who is the main contact?
Dr Ulrike Fillinger of the International Centre for Insect Physiology and Ecology, Nairobi, Kenya; ufillinger@icipe.org

Contact information

Type(s)
Principal Investigator

Contact name
Dr Ulrike Fillinger

ORCID ID
http://orcid.org/0000-0002-4037-431X

Contact details
International Centre for Insect Physiology and Ecology (icipe)
Duduville Campus
Thika Road
Nairobi
Kenya
00100
+254-791-845259
ufillinger@icipe.org

Type(s)
Scientific

Contact name
Dr Lynne Elson

ORCID ID
http://orcid.org/0000-0003-2264-4459

Contact details
P.O. Box 770
Watamu
Kenya
80202
+254 729338457
lynne.elson@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
KEMRI-SERU-NON-KEMRI 652

Study information

Scientific Title
Developing low-cost house floors to control Tungiasis in Kenya

Study objectives
Sealing house floors will prevent development of off-host stages of Tunga penetrans and therefore transmission

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/02/2019, KEMRI-SERU (PO Box 54840, Nairobi, 00200, Kenya; +254 722205901; ddrt@kemri.go.ke), ref: NON-KEMRI-652

Study design
Feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Prevention of tungiasis among children under 18 years

Interventions

A low-cost floor retro-fitted into 12 houses of families with at least two cases of tungiasis. A second intervention group of 12 houses received a local standard concrete floor and the control group received no floor until the end of the study. The heads of households were randomized to study arms through a public lottery event.
Floors were installed in 24 houses in December 2019 and children in all 36 houses monitored for infection once a month for 10 months.

Intervention Type
Other

Primary outcome measure
Proportion of participating children with live fleas embedded in their feet as detected by eye at midline (4 months) and endline (10 months).

Secondary outcome measures
1. Infection intensity of infected children measured by counting the number of all embedded fleas in both feet of participants at midline (4 months) and endline (10 months).
2. Acute symptom scores of infected children measured by counting the number of zones (9 in each foot) exhibiting each symptom (thermographic hotspot, desquamtation, fissures, ulcers, abscess) at midline (4 months) and endline (10 months).

Overall study start date
11/04/2019

Completion date
12/02/2023

Eligibility

Key inclusion criteria
1. Households with at least two children infected with tungiasis and having at least 5 embedded fleas each
2. House with an unsealed floor
3. Houses with a maximum floor area of 36m²
4. Head of household willing and able to move out of the house while the floor is installed and provide informed consent

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
18 Years

Sex
Both

Target number of participants
36 households

Total final enrolment
36

Key exclusion criteria
1. Households with a concrete sealed floor
2. Houses larger than 36m²
3. Household not willing or able to move out of the house while the floor is installed

Date of first enrolment
09/10/2019

Date of final enrolment
22/11/2019

Locations

Countries of recruitment
Kenya

Study participating centre
Dabaso Tujengane
P.O. Box 770
Watamu
Kenya
80202

Sponsor information

Organisation
International Centre of Insect Physiology and Ecology

Sponsor details
Duduville Campus
Thika Road
Kasarani
Nairobi
Kenya

00100
+254-20-8632000
icipe@icipe.org

Sponsor type
Research organisation

Website
icipe.org

ROR
https://ror.org/03qegss47

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results will be published in a high impact peer-reviewed open-access journal and shared at national conferences and at the BOVA Network meetings.

Intention to publish date
01/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be stored in a publicly available repository associated with the publication.

IPD sharing plan summary

Stored in publicly available repository, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			04/07/2023	No	Yes
Results article		12/12/2023	13/12/2023	Yes	No