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Control of sand fleas in the soil using insect growth regulators

Submission date	Recruitment status	[_] Prospectively registered
12/05/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/06/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
23/06/2025	Infections and Infestations	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Tungiasis is the disease caused by the sand fleas, often referred to as "jiggers" in Kenya. Jiggers burrow into the skin of people's feet, causing much pain and itching. When the jiggers produce eggs, they drop to the floor as a person walks or rests. The eggs then hatch into a larva and develop into an adult in the soil. The adult female then seeks a person and burrows into the foot. The best method to control the jiggers is to prevent people from getting infected. Flea control products in animal medicine often include an ingredient that prevents the insect to grow and develop, which is called an insect growth regulator. Such an ingredient is, for example, pyriproxyfen. This study aims to test the effectiveness of pyriproxyfen as a potential control tool.

Who can participate?
The study enrolled households with natural earthen floors and at least 2 infected family members in Kwale County.

What does the study involve?
Households were randomly allocated to three groups, each with 34 houses: 1) water-based emulsified pyriproxyfen solution, 2) water only, and 3) no treatment at all. Treatment of floors was done every 5 days for groups 1 and 2. Group 3 were only recruited at the end of the trial. Soil samples were collected from all enrolled houses (group 1-3) at day 29 after the start of the trial. All participants were examined by trained community health volunteers, and treatment was provided as per county guidelines.

What are the possible benefits and risks of participating?
The benefits of this study are that all infected individuals during the study are referred to the nearest health facility for treatment. The risks of participating are that it would have been time-consuming.

Where is the study run from?
International Centre for Insect Physiology and Ecology (icipe), Muhaka field station in Kwale County, Kenya

When is the study starting and how long is it expected to run?
October 2022 to December 2022

Who is funding the study?
The German Research Foundation

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

Contact information

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Public, Principal investigator

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
KEMRI-SERU-NON-KEMRI 4383

Study information

Scientific Title
Testing insect-growth regulators to control off-host stages of Tunga penetrans

Study objectives
The insect growth regulator, pyriproxyfen, will inhibit the development of Tunga penetrans eggs, larvae and pupae in the soil of unsealed earthen house floors, reducing the population of the parasitic adult females and the prevalence of tungiasis.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 02/03/2022, Kenya Medical Research Institute Scientific and Ethics Review Unit (SERU) (P.O Box 54840, Nairobi, 00200, Kenya; +254 2722541; director@kemri.org), ref: NON-KEMRI 4383

Study design
Household-based single-center randomized controlled open-label intervention study

Primary study design
Interventional

Study type(s)
Prevention, Efficacy

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

Interventions
A household randomized controlled study with three arms:
1. Water-based emulsified pyriproxyfen solution (0.06 ppm)
2. Water only
3. No treatment at all

The households enrolled on arms 1 and 2 had their house floors sprayed once a week for 4 weeks. For all three study arms, household members were examined for embedded fleas at baseline and week 5, and soil samples were collected from the floors of sleeping rooms of households in all three study arms at week 5.

Intervention Type
Other

Primary outcome(s)
Proportion of households containing off-host stages of the sand flea Tunga penetrans measured using count data of the flea larvae extracted in the laboratory at baseline and week 5

Key secondary outcome(s))
1. The flea abundance (number of larvae per unit of soil) measured using count data of the flea larvae extracted in the laboratory at baseline and week 5
2. Any potential change of tungiasis infection in household members measured using a comparison of standard rapid assessments of feet at baseline and end-line

Completion date
09/02/2023

Eligibility

Key inclusion criteria
1. Households with a natural earthen floor
2. Total floor area of households less than 72 square meters. A maximum size limit was set to limit the amount of product that needed to be prepared
3. Households with at least two members with more than 5 embedded fleas
4. The head of the household provided signed consent to participate

Participant type(s)
Resident

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
6 months

Upper age limit
60 years

Sex
All

Total final enrolment

102

Key exclusion criteria
Households that were in very poor condition and considered likely to collapse within the timeframe of the study

Date of first enrolment
24/10/2022

Date of final enrolment
15/12/2022

Locations

Countries of recruitment
Kenya

Study participating centre
International Centre for Insect Physiology and Ecology
Muhaka Field Station, Msambweni Sub-County, Kwale County.
Kenya
80400

Study participating centre
Kwale County
Kenya
80403

Study participating centre
Msambweni Sub-County
Kenya
80400

Sponsor information

Organisation
International Centre of Insect Physiology and Ecology

ROR
https://ror.org/03qegss47

Funder(s)

Funder type
Research organisation

Funder Name
Deutsche Forschungsgemeinschaft

Alternative Name(s)
German Research Association, German Research Foundation, Deutsche Forschungsgemeinschaft (DFG), DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

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

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			28/05/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes