

Control of sand fleas in the soil using insect growth regulators

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| Submission date 12/05/2025 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 23/06/2025 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 23/06/2025 | Condition category Infections and Infestations | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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;

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Contact information

Type(s)

Public, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention, Efficacy

Participant information sheet

See study outputs table

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 measure

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

Secondary outcome measures

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

Overall study start date

29/11/2021

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

Age group

Mixed

Lower age limit

6 Months

Upper age limit

60 Years

Sex

Both

Target number of participants

105 households

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

Sponsor details

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Sponsor type

Research organisation

Website

<https://www.icipe.org/>

ROR

<https://ror.org/03qegss47>

Funder(s)

Funder type

Research organisation

Funder Name

Deutsche Forschungsgemeinschaft

Alternative Name(s)

German Research Association, German Research Foundation, DFG

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

01/12/2025

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 |