

# Controlling Tungiasis in an Impoverished Community

**Submission date**

16/07/2008

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

12/09/2008

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

13/11/2008

**Condition category**

Infections and Infestations

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Hermann Feldmeier

**Contact details**

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Germany  
12203

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

195/02

# Study information

## Scientific Title

Controlling tungiasis in an impoverished community: an intervention study

## Acronym

CTIC

## Study objectives

The implementation of various control measures will result in a drop of prevalence and intensity of infestation of tungiasis.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethical Review Board of the Federal University of Ceará. Date of approval: 25/10/2002 (ref: 195/02)

## Study design

Non-randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Non randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Not Specified

## Participant information sheet

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

Tungiasis (Tunga penetrans [sand flea] infestation)

## Interventions

One village served as the intervention village and the other served as the control village.

Target number of recruitment: 597 individuals in the intervention village and 234 individuals in the control village (total 831). The actual number of people living in the villages was 630 for the intervention village and 281 for the control village.

Intervention village: From November 2002 through January 2003, from all infested individuals, embedded sand fleas were extracted every two to three weeks by experienced health care professionals under sterile conditions. The remaining sore was treated with an antibiotic ointment. During the same period all cats and dogs were treated with trichlorphone 97% in oily

solution (Neguvon®, Bayer do Brasil, Brazil) or neck collars impregnated with propoxur and flumethrin (Kiltix®, Bayer Bayer do Brasil, Brazil). In February 2003, deltamethrin was used for focal premise treatment. Focal spraying was performed by trained personnel of the Health Secretariat of Cascavel Municipality. The insecticide was sprayed on the ground next to the houses targeting areas in which off-host development of *T. penetrans* was suspected to occur, such as preferred whereabouts of dogs and cats, and shady places under trees, or inside houses in the case of a sandy floor. Focal premise treatment using insecticides was repeated twice during a period of six weeks.

No intervention took place in the control village.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

Proportion of individuals infested with *Tunga penetrans* (Prevalence of tungiasis), measured 10 times during the 12 months study period in equal intervals. Reduction of prevalence was measured through comparison with the baseline level.

### **Secondary outcome measures**

Number of embedded sand fleas per infested individual, measured 10 times during the 12 months study period in equal intervals. This intensity of infestation was measured in terms of categories and total number, both compared to baseline levels.

### **Overall study start date**

14/11/2002

### **Completion date**

20/11/2003

## **Eligibility**

### **Key inclusion criteria**

1. Inhabitants of all age groups, both males and females, were eligible for the study, provided they had spent at least four days per week in the village during the last three months
2. Informed written consent obtained from study participant and carers

### **Participant type(s)**

Patient

### **Age group**

Other

### **Sex**

Both

### **Target number of participants**

**Key exclusion criteria**

1. Absence from the study area for more than 4 days per week
2. Unwillingness to participate

**Date of first enrolment**

14/11/2002

**Date of final enrolment**

20/11/2003

**Locations****Countries of recruitment**

Brazil

Germany

**Study participating centre**

Institute for Microbiology and Hygiene

Berlin

Germany

12203

**Sponsor information****Organisation**

Mandacaru Foundation (Brazil)

**Sponsor details**

Rua José Vilar de Andrade 257

Fortaleza

Brazil

CE 60833-830

**Sponsor type**

Charity

**Website**

<http://www.mandacaru-foundation.org>

**ROR**

<https://ror.org/05h876969>

# Funder(s)

## Funder type

Charity

## Funder Name

Mandacaru Foundation (Brazil)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Results	01/11/2008		Yes	No