

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

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Contact details

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Additional identifiers

Protocol serial number

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)

Primary study design

Interventional

Study design

Non-randomised controlled trial

Study type(s)

Not Specified

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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)

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

Funder(s)

Funder type
Charity

Funder Name
Mandacaru Foundation (Brazil)

Results and Publications

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?
Results article	Results	01/11/2008		Yes	No