

Prevention of tungiasis - associated morbidity in a resource-poor community in Madagascar

Submission date 13/07/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/09/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 17/12/2020	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Tungiasis is a parasitic skin disease caused by the sand flea. It occurs in economically deprived communities such as in Madagascar. It is associated with considerable illness, such as chronic lymphoedema (swelling), ulcers, fissures, nail loss, difficulty in walking and gripping and infection. The only efficient measure against is surgical extraction with generally non sterile material causing further illness. The aim of this study is to test preventive measures to reduce tungiasis-related illness.

Who can participate?

Patients aged 5 and over with tungiasis

What does the study involve?

Participants are randomly allocated to one of three groups. In the first group Zanzarin (an insect repellent) is applied twice daily on the feet and ankles for 3 months, in the second group participants receive sport shoes, and the third group receive no treatment. The number of tungiasis lesions are counted every two weeks during the 3-month study. At the end of the study after 3 months all participants receive sport shoes, and if there are remaining tungiasis lesions these are extracted at the local health center, and local antibiotics and tetanus vaccinations are given.

What are the possible benefits and risks of participating?

Not provided at time of registration

When is the study starting and how long is it expected to run for?

August to October 2011

Where is the study run from?

Villages in the area of Andasibé in Moramanga district in Madagascar

Who is funding the study?

Doctors for the Third World (Ärzte für die dritte Welt) (Germany)

Who is the main contact?
Prof. Hermann Feldmeier

Contact information

Type(s)
Scientific

Contact name
Prof Hermann Feldmeier

Contact details
am Rain 7
Buchholz in Nordheide
Germany
21244

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Morbidity prevention of tunga penetrans in a resource-poor community in Madagascar: a randomized controlled trial

Study objectives
The regular application of Zanzarin®, a coconut oil-based plant repellent, protects against morbidity associated with Tunga penetrans. The trial will evaluate the efficacy Zanzarin® compared to the wearing of shoes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Health Ministry of Madagascar, 05/05/2011

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied

Tungiasis

Interventions

Three cohort groups:

1. Zanzarin® (active ingredients: capric acid, cocos nucifera, citronellol) : topical application 5 ml twice daily on the feet and ankles for 3 months
2. Wearing sports shoes
3. Control group, no intervention

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Zanzarin®

Primary outcome(s)

To assess the impact of the different interventions the following outcome measures will be compared every two weeks during three month. Lesion stage will be assessed according the Fortaleza Classification.

1. Total number of lesions located at the feet
2. Number of viable lesions (stage 1-3)
3. Number of non-viable lesions (stage 4)
4. Ratio of viable lesions (stage 1 to 3) divided by total number of lesions
5. Ratio of non-viable lesions (stage 4) divided by total number of lesions
6. Percentage of participants without viable lesions at the end of the study
7. Severity score for acute and chronic tungiasis-associated morbidity

To assess the impact of the different interventions the outcome measures will be compared every two weeks during three months. Lesion stage will be assessed according the Fortaleza Classification.

Key secondary outcome(s)

To assess the impact of the different interventions the following outcome measures will be compared:

1. Percentage of participants without viable lesions at the end of the study
2. Modified severity score for acute and chronic tungiasis-associated morbidity

To assess the impact of the different interventions the outcome measures will be compared every two weeks during three months. Lesion stage will be assessed according the Fortaleza Classification.

Completion date

30/10/2011

Eligibility

Key inclusion criteria

1. More than or equal to 10 tungiasis lesions
2. Aged more than or equal to 5 years
3. 4-5 days of permanence in the village per week
4. Permanence in the village during next 4 months
5. The participants or their legal guardian have signed the informed written consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

1. Less than or equal to 10 tungiasis lesions
2. Aged less than 5 years
3. Less than 4-5 days of permanence in the village per week
4. Less than 4 months permanence in the village
5. The participants or their legal guardian have not signed the informed written consent

Date of first enrolment

01/08/2011

Date of final enrolment

30/10/2011

Locations**Countries of recruitment**

Germany

Madagascar

Study participating centre

am Rain 7

Buchholz in Nordheide

Germany

21244

Sponsor information

Organisation

Doctors for the Third World [Ärzte für die dritte Welt] (Germany)

ROR

<https://ror.org/001m0em47>

Funder(s)

Funder type

Charity

Funder Name

Doctors for the Third World [Ärzte für die dritte Welt] (Germany)

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	substudy results	15/09/2017	17/12/2020	Yes	No