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

Submission date
13/07/2011

Recruitment status
No longer recruiting

Registration date
28/09/2011

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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21244

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 effacacy 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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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.

Secondary outcome measures

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.

Overall study start date
01/08/2011

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

Age group
Mixed

Sex
Both

Target number of participants
225

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
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21244

Sponsor information

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

Sponsor details
Offenbacher Landstraße 224
60599 Frankfurt am Main
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60599

Sponsor type
Charity

Website
http://www.aerzte3welt.de/

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

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?
Results article	substudy results	15/09/2017	17/12/2020	Yes	No