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Interventional study against Tunga penetrans

Submission date	Recruitment status	[_] Prospectively registered
12/12/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/01/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/01/2010	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Intermittent application of a natural repellent against Tunga penetrans to reduce intensity of infestation and associated morbidity in an endemic area: a randomised controlled trial

Study objectives
1. Compare the efficacy of different schemes of prophylactic application of a natural repellent based on coconut oil to reduce infestation intensity and associated morbidity in a high transmission area
2. Reduce the pathology of tungiasis
3. Identify the frequency of application to effectively reduce tungiasis
4. Open new pathways for cost-effective control of tungiasis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the Federal University of Ceará, Brazil, approved in January 2005

Study design
Randomised (permuted block design) controlled single centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

Interventions
After the admission examination the participants were randomised into three cohorts (A, B and C). In the first phase of the study individuals received a twice-daily application of Zanzarin® for a period of four weeks. It was anticipated that this reduced the number of embedded sand fleas to almost zero. Thereafter participants were examined again and the degree of the tungiasis-associated morbidity was assessed. These data provided the baseline for the subsequent study phase.

During a period of five months members of Cohort A applied the repellent every second week twice daily for one week and members of Cohort B every fourth week for one week. Cohort C served as control group and did not receive any protection.

During the intervention periods Zanzarin® was applied onto the feet by trained community health workers as described previously. The average volume applied was 3 ml per person and day. Prophylaxis was performed in the morning between 6 and 8 a.m. and in the evening between 6 and 8 p.m. The exact time of application was recorded for each study participant. The application of the repellent was regularly checked by random visits to the households of the study participants by one of the investigators.

In addition, at each examination the participants were asked whether the repellent had been applied regularly. This ensured that the repellent was applied exactly as defined in the study protocol, not spilled, given away for money or stolen. The participants were asked not to wash their feet for at least two hours after application of the repellent. However, they were allowed to take a shower whenever they wanted.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Zanzarin®

Primary outcome measure
The whole body surface was examined for the presence of immature, egg-producing or dead fleas and manipulated lesions. Tungiasis lesions were classified according to the Fortaleza Classification. The following findings were considered diagnostic for tungiasis:
1. Flea in statu penetrandi (stage I)
2. A dark and itching spot in the epidermis with a diameter of 1 to 2 mm, with or without local pain and itching (early lesion, stage II)
3. Lesions presenting as a white halo with a diameter of 3 to 10 mm with a central black dot (mature egg producing flea, stage III)
4. A brownish-black circular crust with or without surrounding necrosis of the epidermis (dead parasite, stage IV)

During monitoring the number of viable (stage I to III) and dead (stage IV) sand fleas and the total number of sand flea lesions were determined. Clinical pathology was documented every four weeks. Lesions manipulated by the patient (such as partially or totally eliminated fleas leaving a characteristic crater-like sore in the skin) and suppurative lesions caused by the use of non-sterile perforating instruments such as needles and thorns, were documented as well. The exact topographic localisation of each lesion, its stage, and appearance were documented on a visual record sheet.

Secondary outcome measures
Clinical pathology was assessed in a semi-quantitative manner using a previously elaborated severity score for acute tungiasis (SSAT) and a severity score for chronic tungiasis (SSCT). The SSAT score comprises the following signs and symptoms: erythema, oedema, pain upon pressure or spontaneously, itching, sleep disturbance due to itching, difficulty walking as indicated by an altered gait; abscess and suppuration as indicators of superinfection; fissures and ulcers as characteristic chronic skin defects. The score can take a value from 0 to 24 points. The SSCT ranges from 0 to 33 points and comprises the presence of nail deformation, nail loss, brilliant skin (an indicator of chronic oedema), deformation of toes; hypertrophic nail rim and perilesional

desquamation; the latter two characteristics are indicators of repeated tungiasis experienced in the past.

Overall study start date
01/06/2005

Completion date
18/12/2005

Eligibility

Key inclusion criteria
1. Individuals with tungiasis identified with the assistance of community health workers
2. Aged 1 - 66 years, either sex
3. At least 5 embedded sand fleas in stage 1 to 4 of the Fortaleza Classification or a similar number of sand flea lesions manipulated with a perforating instrument

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
140

Key exclusion criteria
1. Intended to change their place of residence during the next six months
2. Ulcerated lesions necessitating antibiotic treatment
3. Children aged less than one year

Date of first enrolment
01/06/2005

Date of final enrolment
18/12/2005

Locations

Countries of recruitment
Brazil

Germany

Study participating centre

Charite- Campus Benjamin Franklin
Berlin
Germany
12203

Sponsor information

Organisation
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

Sponsor details
Campus Benjamin Franklin
Institute of Microbiology and Hygiene
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Sponsor type
University/education

Website
http://www.charite.de

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Government

Funder Name
DAAD-CAPES PROBRAL program (Germany) (ref: 152/02)

Funder Name
Engelhard Arzneimittel, Niederdorfelden (Germany) - provided the repellent (Zanzarin®) free of charge

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	results	01/01/2007		Yes	No