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To determine whether a targeted application of dimeticone has a higher efficacy to cure tungiasis (sand flea disease) than wetting the whole feet

Submission date
29/01/2014

Recruitment status
No longer recruiting

Registration date
18/02/2014

Overall study status
Completed

Last Edited
16/03/2017

Condition category
Infections and Infestations

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and summary
Tungiasis (sand flea disease) is a neglected tropical parasitic disease. It occurs in many countries in South America and sub-Saharan Africa and effects the poorest of the poor. 99% of the parasites penetrate into the skin of the feet. Parts of the body which are particularly affected are the toes, the sole, the lateral rim and the heel. In the endemic areas, prevalences are up to 70% in children and 30% in the general population. Sand fleas burrowed in the skin elicit an intense inflammatory response. Acute and chronic inflammation results in fissures, ulcers, pain and difficulty walking. Repeated infections are debilitating and eventually lead to mutilation of the toes. In a previous study it was shown that wetting the skin of the feet three times within 10 minutes with a combination of two dimeticones with a very low viscosity killed 78% of the parasite. It is assumed that a repeated targeted application of dimeticone to the site where parasites are burrowed in the skin will increase the efficacy of the treatment to ≥ 95%. Since the application of dimeticone can be performed with minimal input from the health sector, this treatment will become the core measure in national control programs against tungiasis currently being developed by the Ministries of Health in several East African countries. The study will be performed in Busoga Region, Uganda, north of Lake Victoria, an area which is notoriously affected by tungiasis.

Who can participate?
55 school children between 6 and 15 years with tungiasis

Who does the study involve?
Every day, 3 - 4 school children are admitted to the study and are followed up daily during 7 days. (on the basis of having at least two viable parasites on each foot). The left and the right foot of each participant are randomly allocated to one of two treatments: either the standard treatment (wetting the foot with dimeticone 3 times during 10 minutes) or the targeted treatment (application of the dimeticone directly on the abdominal cone of the parasite which protrudes through the skin with the help of a syringe). At the end of the study, the following are

compared between left and right feet:
- % of viable parasites that died after the application of dimeticone
- % of parasites that did not develop in a normal manner
- regression of the intensity of local inflammation

What are the possible benefits and risks of participating?
A direct benefit for the participants is that they are relieved from a parasitic skin disease for which there is currently no effective treatment. As dimeticones are wholly non-toxic, the treatment does not pose any health risk.

Where is the study run from?
The study has been set up by the Institute of Microbiology and Hygiene of the Charité University Medicine, Berlin, Germany, together with the Ministry of Health, Kampala, Uganda. It will take place in Bugiri, Busoga region, Uganda.

When is study starting and how long is it expected to run for?
March 2014 to April 2014

Who is funding the study?
German Doctors e.V., a non-governmental organization, as well as by private donations

Who is the main contact?
Prof. Hermann Feldmeier
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Contact information

Type(s)
Scientific

Contact name
Prof Hermann Feldmeier

Contact details
Hindenburgdamm 27
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Germany
12203

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Dimeticone II

Study information

Scientific Title
Treatment of TUNGiasis (jiggers) with a targeted Application of a two-component DIMETicone

Acronym
TUNGADIMET

Study objectives
It is assumed that a repeated targeted application of dimeticone to the site where parasites are burrowed in the skin has a higher efficacy in killing embedded sand fleas than simply wetting the skin of the feet with dimeticone (the standard procedure).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee, the Ministry of Health, Kampala, Uganda, 29/01/2013

Study design
Randomized trial using the left and the right foot of the participants as units of randomization

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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 (sand flea disease)

Interventions
The left and the right foot of each participant are randomized to either receive the standard treatment (wetting the foot with dimeticone 3 times during 10 minutes) or the targeted treatment: application of the dimeticone directly on the abdominal cone of the parasite (which protrudes through the skin) with the help of a syringe.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dimeticone

Primary outcome measure
1. % of viable parasites that died after the application of dimeticone. Viability is determined with a portable digital video microscope.
2. % of parasites that did not develop in a normal manner

Followed up daily during 7 days

Secondary outcome measures
Regression of the intensity of local inflammation

Overall study start date
01/03/2014

Completion date
30/04/2014

Eligibility

Key inclusion criteria
1. School children between 6 and 15 years with at least two viable sand fleas in the skin of each foot
2. Care-takers are requested to sign an informed written consent form for the participant before admission

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
55

Key exclusion criteria

Children with severe bacterial superinfection of tungiasis lesions are not eligible and will be referred to the next primary health care center for antibiotic treatment

Date of first enrolment
01/03/2014

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
Germany

Uganda

Study participating centre
Hindenburgdamm 27
Berlin
Germany
12203

Sponsor information

Organisation
German Doctors e.V. (Germany)

Sponsor details
Löbestraße 1a
Bonn
Germany
53173

Sponsor type
Not defined

ROR
https://ror.org/001m0em47

Funder(s)

Funder type

Charity

Funder Name
German Doctors e.V., a non-governmental organization (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	results	10/03/2017		Yes	No