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New treatment for tungiasis using a dimeticone of low viscosity

Submission date
19/12/2011

Recruitment status
No longer recruiting

Registration date
18/01/2012

Overall study status
Completed

Last Edited
05/09/2014

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Tungiasis is a parasitic skin disease caused by the sand flea Tunga penetrans. In tropical countries tungiasis is associated with symptoms such as lymphoedema (swelling), ulcers, fissures, nail loss, difficulty in walking and bacterial infection. The only efficient treatment is surgical extraction. However, in endemic areas, non-sterile instruments are usually used, which causes more harm than good. The aim of this study is to evaluate a new treatment consisting of the local application of dimeticone to the skin of the feet.

Who can participate?
Children aged five years old and over who have at least two viable lesions on each foot.

What does the study involve?
The feet of each study participant will be randomly allocated to either to dimeticone or to potassium permanganate, the standard treatment of the Ministry of Health of Kenya. The applications will be repeated on three subsequent days. The lesions will be monitored daily for parasites for a total of seven days. At the end of the study, participants will receive a pair of shoes and all pupils of the school who are infected with Tunga penetrans will receive the treatment identified as the most effective.

What are the possible benefits and risks of participating?
Adverse effects of dimeticone are not known.

Where is the study run from?
From two schools in the Gatundu district, Kenya.

When is the study starting and how long is it expected to run for?
From January to February 2012.

Who is funding the study?
The trial is funded by the Institute of Microbiology and Hygiene, Berlin, Germany.

Who is the main contact?
Professor Hermann Feldmeier
hermann.feldmeier@charite.de

Contact information

Type(s)
Scientific

Contact name
Prof Hermann Feldmeier

Contact details
Institute of Microbiology and Hygiene
Campus Benjamin Franklin
Charité - Medical University Berlin
Hindenburgdamm 27
Berlin
Germany
12203

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
New treatment for tungiasis using a dimeticone of low viscosity, in a resource-poor community in Kenya: a proof of principle study

Study objectives
Dimeticone, a silicone oil of extremely low viscosity, has an insecticidal impact on Tunga penetrans as soon as a sand flea has penetrated into the skin. Since clinical pathology is associated with the natural development of the parasite, a second hypothesis is that the application of dimeticone prevents clinical pathology to develop.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ministry of Medical Services Ethics Committee, Kenya, 20/12/2011, ref: NMS/ADM/3/8/VOL.111

Study design
Clinical trial

Primary study design
Interventional

Secondary study design
Non 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
Application of dimeticone or potassium permanganate on the right or left foot, respectively, for 5 minutes. Then the feet will be kept in an upright position to allow the solutions to dry. Shoes will be used thereafter as normal. The applications will be repeated on three subsequent days.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Assess the impact of the different interventions the following outcome measure will be compared every day during a period of 7 days
2. Lesions stage will be assessed according the Fortaleza Classification
3. Number of embedded sand fleas on each foot which loses viability signs and/or for which normal development is interrupted in relation to the number of lesions with a normal development

Secondary outcome measures
The intensity of inflammation of the left and right foot assessed semi-quantitatively using a previously established severity score (SSAT)

Overall study start date
09/01/2012

Completion date
28/02/2012

Eligibility

Key inclusion criteria
1. Ages 5 - 16 years
2. Presence of at least 2 lesions in stage IIa or IIIa (Fortaleza Classification)
3. Presence of at least 2 out of 3 viability signs:
3.1. Expulsion of eggs
3.2. Excretion of faeces
3.3. Characteristic pulsations in the abdomen of the parasite
4. Informed written consent, in the case of children by the caregiver

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
45

Key exclusion criteria
1. Presence of gross inflammation on either foot
2. Presence of abscess/suppuration on either foot
3. Presence of ascending lymphangitis on either foot

Date of first enrolment
09/01/2012

Date of final enrolment
28/02/2012

Locations

Countries of recruitment
Germany

Kenya

Study participating centre
Institute of Microbiology and Hygiene
Berlin
Germany
12203

Sponsor information

Organisation
Institute of Microbiology and Hygiene, Berlin (Germany)

Sponsor details
Hindenburgdamm 27
Berlin
Germany
12203

Sponsor type
Research organisation

Website
http://www.charite.de/imh/

ROR
https://ror.org/04xqmb911

Funder(s)

Funder type
Research organisation

Funder Name
Institute of Microbiology and Hygiene, Berlin (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