

New treatment for tungiasis using a dimeticone of low viscosity

Submission date 19/12/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 18/01/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 05/09/2014	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
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Contact information

Type(s)

Scientific

Contact name

Prof Hermann Feldmeier

Contact details

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Additional identifiers

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 years

Upper age limit

16 years

Sex

All

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)

ROR

<https://ror.org/04xqmb911>

Funder(s)

Funder type

Research organisation

Funder Name

Institute of Microbiology and Hygiene, Berlin (Germany)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration