World Health Organization

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Main

Note: This record shows only 22 elements of the WHO Trial Registration Data Set. To view changes that have been made to the source record, or for additional information about this trial, click on the URL below to go to the source record in the primary register.

Register:	ANZCTR
Last refreshed on:	10 December 2019
Main ID:	ACTRN12619001610123
Date of registration:	21/11/2019
Prospective Registration:	Yes
Primary sponsor:	University of Canberra
Public title:	Exploring a tea tree oil (TTO)-based skin treatment for tungiasis in children
Scientific title:	Treatment of tungiasis using a proprietary tea tree oil (TTO)-gel formulation in children: Protocol for a randomised, controlled, proof-of principle trial
Date of first enrolment:	03/02/2020
Target sample size:	88
Recruitment status:	Not yet recruiting
URL:	https://anzctr.org.au/ACTRN12619001610123.aspx
Study type:	Interventional
Study design:	Purpose: Treatment; Allocation: Randomised controlled trial; Masking: Blinded (masking used);Assignment: Parallel;Type of endpoint: Safety/efficacy;
Phase:	Phase 2

Countries of recruitment

Kenya

Contacts

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Key inclusion & exclusion criteria

Inclusion criteria: 1. Children aged 6-15 years with at least 1 viable (stage II and Stage III) lesions according to the Fortaleza classification and a maximum of 2 viable sand flea lesions will be targeted.
2. Children whose legal guardians are willing to give informed written consents after having been oral and written informed about benefits and potential risks of the trial
Exclusion criteria: 1. Children with cluster lesions and manipulated lesions.
2. Children with complicated lesions requiring antibiotic treatment. They will be referred to the nearby health facilities for appropriate clinical management.
3. Children whose guardian/parents intend to change their place of residence during the study period
4. Children with known history of allergy to any of the study medications (Tea Tree Oil or other essential oils and potassium permanganate)
5. Individuals have/had systemic or topical drugs or medications, including systemic antibiotics, which may interfere with the study results (based on clinical team's assessment).

Age minimum: 6 Years
Age maximum: 15 Years
Gender: Both males and females

Health Condition(s) or Problem(s) studied

Infection - Other infectious diseases

Public Health - Other public health

Skin - Dermatological conditions

Tungiasis (sand flea disease) ;
Tungiasis (sand flea disease)

Intervention(s)

Test group- treatment of tungiasis with a 5% (v/w), proprietary tea tree oil (TTO) gel

The feet of the participants will be washed with water and non-medicated soap, dried with a clean towel, and the participants' toenails will be clipped to enable easier application of the test medication. Then, the test medication will be applied twice daily on days 1, 4 and 7 by trained study personnel (concerned case officers from participating schools). The mode of administration of the test medication is by taking the required amount of the gel on the palms (up to 8g/day) and spreading it over the infested skin areas until it provides a full coverage of the affected area (skin surface of the feet up to the ankle) and the feet will then be left for 15 minutes to allow the medication to dry.

Primary Outcome(s)

Proportion of non-viable fleas

Determination of viability of the sand flea lesions will be performed using a handheld digital video microscope, assisted with pictorial flipcharts. Expulsion of eggs, excretion of faecal threads, excretion of faecal liquid, and pulsations/contractions in the abdomen of the embedded flea will be considered as four viability signs and lesions with 2 out of 4 viability signs will be recorded viable. Lesions will be considered dead (non-viable) if their viability signs are not detected during the 10 min follow-up examinations. Differences in the proportion of non-viable lesions between test and control groups will be compared and presented with their respective confidence intervals at 95% and p-values. [Day 10 (9 days after the first treatment).]

Secondary Outcome(s)

Acute morbidity evaluation

The severity score for acute morbidities (SSAT; which includes typical signs of local inflammation, the presence of suppuration, ulcers and fissures) will be assessed using a validated scoring system designed for tungiasis morbidity assessment.
In addition to SSAT, a visual analogue scale (VAS) called the 'Itch-man scale'-- a 5-point pictorial Likert scale, validated for paediatric burn survivors, will be adopted to evaluate itching. Finally, a 4 point pictorial scale, validated in paediatric tungiasis patients will be adopted to assess the pain, as well as pain-related and itching related sleep disturbances (QoL assessment).
[Days 0 (baseline), 5 and 10 (post treatment)]

Participant acceptability of the trial intervention/s

Participants/caregivers will be asked to rate the acceptability of the treatment in terms of effectiveness, side effects, convenience, and overall satisfaction on a 0-5 visual analogue scale. [Day 10 (9 days after the first treatment).

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Proportion of participants with side effects (adverse events)

Safety will be assessed through evaluation of treatment related adverse events and skin irritation.
Participants/caregivers (in person or on the phone) will be asked about the occurrence of any solicited or unsolicited adverse reactions to the treatment during each follow-up visit. The trial team (clinical officer and health officers) will also carefully follow-up the trial participants on a regular basis at the trial site, until the end of trial period. This will be done using a pre-specified list of possible AEs, including local adverse reactions (swelling, stinging/burning, itching, induration, erythema) and systemic adverse reactions (fever, nausea and headache). Caregivers of participants will also be given a diary card to record ongoing solicited adverse events. The severity of the adverse events will be categorized as mild, moderate and severe according to common terminology criteria for adverse events (CTCAE) v5.0 guideline[Days 1 (PM), 4, 5, 7 and 10 (post-treatment)

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Secondary ID(s)

None

Source(s) of Monetary Support

University of Canberra

Secondary Sponsor(s)

Ethics review

Status: Approved
Approval date:
Contact:
University of Canberra Human Ethics Research Committee

Results

Results available:
Date Posted:
Date Completed:
URL: