PARTICIPANT INFORMATION SHEET AND CONSENT FORM

UNIVERSITY OF CANBERRA

Tea tree oil gel for Tungiasis (Jiggers) Treatment

You are being invited to take part in this research study because your child has been identified with jiggers in his/her feet. We are asking for your willingness to allow your child to take part in this study. Please take time to carefully read the following information. Ask us if there is anything that is not clear or if you would like more information. Consider carefully before you make your decision whether or not you wish to take part. You may also wish to discuss the study with a relative, friend or your friendly clinical staff at the school.

What is the objective of this study?

This study aims to evaluate whether tea tree oil (TTO 5% v/w) gel can kill the embedded jiggers better than the locally recommended potassium permanganate solution followed by Vaseline® application (within a 10-day study period). The study also aims to determine whether the TTO gel can reduce skin inflammation, pain and itching caused by the jiggers better than the potassium permanganate/ Vaseline® treatment. If the proposed treatment is effective, this study might help us improve the treatment outcomes for jiggers.

What would I have to do?

We are asking for your willingness to allow your child to take part in this study. If you agree to proceed, you will be given this information sheet to keep and be asked to sign a consent form.

If we choose to participate, will our participation be kept confidential?

The information gathered about you child during the study will not be shared. All of the people who handle your information will maintain confidentiality and will also comply with NHMRC clinical trial guidelines and local privacy laws.

What will happen to my child if we take part?

Your child will be randomly allocated to either the TTO gel or potassium permanganate treatment. Treatments will be given twice daily on days 1, 4, and 7. In addition, your child will be given a pair of new closed shoes as part of the study. The clinical investigator will then make careful observations about the jiggers on days 5 and 10. The doctor will also ask your child about how much pain and itching he/she is feeling. In summary, your child will be asked to attend the clinics at the school 6 times during the treatment phase (i.e. AM and PM on days 1, 4, and 7), and 2 follow up visits on days 5 and 10. Each clinic-visit will take about 30 mins.

What would be expected from us during study period?

It is **VERY** important that you and your child, **DO NOT** cut out any jiggers from the child's foot during this time.

You should not use any other jigger medicine or any other skin products on the affected skin area during this time (days 1-10). We would like you to maintain the daily diary of events during study participation (1- 10 days).

If your child develops a reaction to the trial medication, you should notify the study clinical team as soon as possible.

What information would be collected?

The study will not be collecting any samples from your child. We will only make observations of the jiggers. If your child is found to have any other disease, we will advise you on the best way to manage it. The information we collect from your child will be entered into a computer system along with information from other study participants. The study team based at University of Canberra, will analyse the data and prepare a report with findings from this study and necessary recommendations. These findings will be communicated with other organizations, the Kisii, and Nyamira counties and National Ministry of Health, Kenya.

What would be the risks of participation for the child?

Tea tree oil (TTO) has been documented as a topical antiseptic (nationally and internationally) for over 90 years and even longer in the indigenous communities in Australia as a bush medicine. The treatment is unlikely to pose any serious health risk to your child. However, the trail medication may have some side effects. It may cause skin discomfort with an allergic or irritant reaction. If your child suffers from these or any other symptoms you should report them immediately to the study team. If you are concerned in any way, you can speak to study team at the school.

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Your Right to Refuse or Withdraw from the study

The decision to participate in the study is entirely voluntary. Clinical examination and treatment will be conducted in the school. This research study has received support and endorsement from the participating school. And you are free to withdraw at any time and without giving a reason.

What is the contact for further information?

If you need any further information or have any concerns, you can speak to the school health officer or study team or Doctor Stanislous Misati (GSP: +254 710 521804).

Consent approval

The undersigned _____ (full name) testifies that she/he is the legal guardian of _____ (name of child) and that she/he has read and understood the consent form which was also read aloud and explained by _____ _____.

I understand the objectives, the necessities, the potential risks and benefits regarding the participation of my child in the study, including the time commitment during the treatment, assessment and follow-up period.

I agree that any living sand fleas remained at the end of the study will be treated with the local government/medical recommendations.

I am aware of the fact that all information which could lead to an identification of my child will be kept strictly confidential. I have the right to withdraw my child from the study at any time without giving any justification for the removal. I voluntarily agree for my child to participate in this study based on these conditions.

School _____ Date: _____/_____/_____
Subject Study ID-No: _____
Parent/Caregiver
Name: _____ Signature: _____
Date: _____/_____/_____
Investigator who provided the information:
Name: _____ Signature: _____
Date: _____/_____/_____
Witness:
Name: _____ Signature: _____
Date: _____/_____/_____

Thank you for your interest in this study.

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