

PARTICIPANT INFORMATION SHEET AND ASSENT FORM**Tea tree oil gel for Tungiasis (Jiggers) Treatment*****What the study is about?***

We are testing whether tea tree oil (TTO)-based gel can kill the jiggers in your feet without causing you any pain or discomfort compared to the purple medicine called potassium permanganate, in a 10-day treatment period.

What would I have to do?

If you agree to be a part of the study, you will be asked to sign this form and to:

1. Allow the study team to wash and carefully examine your feet using a handheld digital microscope
2. Allow the study team to take photographs of your feet
3. Allow the study team to apply the treatment on days 1, 4, and 7
4. Wear a pair of new closed shoes throughout the study period (which we will be provided on day 1)
5. Attend the clinic for treatment and examination on Days 1, 4, 5, 7 and 10
6. Avoid applying any other medicine or skin products on the jiggers affected skin area during the study period (1-10 days).
7. Avoid cutting your jiggers affected skin during the study period
8. Follow the study instructions explained to you by the study team

What are the side effects of taking part?

TTO has long been used as a medicine by indigenous communities in Australia and internationally and the likelihood for developing severe skin reactions are minimal. However, the trial medication may have some side effects. It may cause skin discomfort with an allergic or irritant reaction. If you suffer 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. As for the purple medicine, it will not hurt you, but it will change the colour of your feet. This colour will go away after a few days. However, the provided closed footwear will adequately mask this skin colouration – and this is likely to prevent other students from giving you a hard time.

What happens if something goes wrong during the trial?

The risk of serious side effects is small compared to the risk you face as a result of having jiggers. If you do experience side effects as result trial medications, you will be referred to the nearby health facility for appropriate treatment and medical care.

What would I benefit from the participation?

We hope that the TTO gel will help you, but this cannot be guaranteed. The information we get from this study may help us to improve the treatments available for jiggers in the future.

Will my taking part in this study be kept confidential?

The information gathered about you by the investigator or obtained during the study will be held by the investigators in strict confidence. All the people who handle your information will adhere to traditional standards of confidentiality and will also comply with all relevant privacy legislation, in Australia and Kenya.

If needed, summary data without your name attached will be made available, to government regulatory bodies in Kenya and Australia.

Do I have to take part?

You do not have to be in this study if you do not want to be, even if your parents and teachers said it is okay for you to be in the study. If you decide to stop after we begin, that's okay too. Your parents know about the study too.

Version 2.0 dated 20/08/2019

PARTICIPANT INFORMATION SHEET AND ASSENT FORM**Consent approval**

1. I have been given clear information, both verbally and in writing, about this study and, having had time to consider it, am able to make an informed decision to participate.
2. I have read and understood the Patient Information Sheet and have retained a copy of it.
3. I have been given the opportunity to ask the investigator questions about the study.
4. I have been told about the possible benefits and risks of taking part and I understand what I am being asked to do.
5. I understand that I may withdraw from the study at any time without affecting any future medical treatment, or the treatment of the condition which is the subject of the trial.
6. I agree to take part in this research and for the data obtained to be published provided that my name or other identifying data is not used.
7. I understand that if I leave the study for any reason, the information and samples collected will still be used unless I specifically ask for them to be removed from the study at the time I leave.
8. I understand that the investigators of the trial will adhere to usual standards of confidentiality in the collection and handling of my personal information.

I, _____, agree to participate in the above study. I have read and understood the Participant Information Sheet and I have been given a copy of it. I have been given the opportunity to ask questions about the study. I understand that I may withdraw from the study at any time without affecting my future medical treatment, or the treatment of the condition which is the subject of the trial.

Participant Name: _____ Signature: _____

Date: ____/____/____

Investigator Name: _____ Signature: _____

Date: ____/____/____

Thank you for your interest in the study.

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