Study participant information and consent sheet

Efficacy and safety of moxidectin and albendazole compared to ivermectin and albendazole co-administration in adolescents infected with *Trichuris trichiura*: a randomized controlled trial

Version 1.0**, Date:** 15th June 2020

This study is jointly undertaken by researchers from the following institutions:
- Public Health Laboratory-Ivo de Carneri (PHL-IdC), Pemba, Tanzania
- Swiss Tropical and Public Health Institute (Swiss TPH), Basel, Switzerland

Principal investigators: The following persons are directly responsible for the design and the implementation of the study: **Mr. Said Ali** (CEO PHL-IdC), **Mr. Ghanil Mohamed Khatib** (PHL-IdC), **Prof. Dr. Jennifer Keiser** (Swiss TPH), **Dr. Daniela Hofmann** (Swiss TPH), **Ms. Sophie Welsche** (Swiss TPH) and **Mr. Emmanuel Mrimi** (Swiss TPH).

Why is this study being done? Parasitic worms are living in the bellies and can cause poor nutrition, slower development of the body and the mind, and reduced work performance. On Pemba Island most children are infected with one or several different types of parasitic worms. Since children suffer the most from having these worms in their bellies, they receive drugs to kill these worms at school. However, the most widely used drug does not work very well. We would like to find out whether giving the current drug together with a second drug kills the worms in your/your child's body better and how you/your child feel/feels shortly after taking this drug combination.

What is the aim of this study? The aim of this study is to look at how well the currently used drug (albendazole) in combination with another drug (ivermectin or moxidectin) kills the worms in the people's bodies. 540 adolescents (12-19 years of age) going to schools on Pemba Island and with worms will be treated and then revisited three times over a period of three months to see if the participant's health improved.

Can I decide if I/my child participate/s? Yes. You are free to decide, whether you/your child participate/s in this study.

What will I/my child have to do if I/he/she participate/s? You/your child will be asked to provide 2 stool samples in the morning to check if you/he/she has the worm *Trichuris trichiura* or other worms. If you/your child have/has *T. trichiura* and are/is willing to participate in the study, you/your child will be assigned by chance to one of the different treatment groups (ivermectin-albendazole, moxidectin-albendazole, albendazole alone, ivermectin alone, moxidectin alone). You/your child will not know to which treatment you/your child will be receiving.

Before treatment, a doctor and nurses will check your/your child's health. For this, they will check that you/your child are healthy enough to participate and ask for a small finger blood sample to ensure that you/your child are/is not suffering from a lack of blood. To avoid accidental treatment of pregnant girls/women, we will ask all female participants to provide a urine sample to do a pregnancy test. Before giving the treatment, we will provide you/your child with a meal so nobody who takes the pills will have an empty stomach. Since you/ your child will spend several hours with our team on the day of treatment, we will provide all participants with another meal.

During and after treatment a medical team will monitor your/your child's condition, which includes a physical examination. The medical team will ask you/your child about symptoms and discomfort before treatment and 3 hours, 24 hours and 3 weeks after treatment. Three weeks, 5-6 weeks and 3 months after the treatment, we will ask you/your child again to provide 2 stool samples to check whether all worms have been killed.

We will ask 60 willing people to provide a few drops of blood from the fingertip. We will ask each of these participants to give us 4 blood samples. The blood sample is given by finger prick and done by a medical team member between the day of treatment and 7 days after. Your blood sample will help us see how the drug behaves in your body and can help to find the best treatment to kill the worms. If we still find worms in your/your child's stool at the end of the study, you/your child will receive the standard treatment again. We would also like to store a small portion of your stool sample for further analysis to improve our understanding and treatment of parasitic worm infections.

What are the risks and benefits of this study? The drug dose you/your child will receive might cure or reduce worm infections. The drugs can sometimes have some unwanted effects for your well-being, however, until now, researchers have reported only mild effects that usually go away/resolve within a few hours. The drugs might cause you/your child to feel dizziness, headache, stomachache or itching skin. If we detect other types of worms in your/your child's belly or if we find abnormal medical conditions, you/your child will get the appropriate care after the clinical examination. Before taking your/your child's blood sample from the fingertip, we will always disinfect the skin and only use sterile disposable finger pricks to avoid any risk of infection. This procedure is well tolerated too. The results of this study will help to identify better treatment options for all populations in the world who suffer from worm infections.

Who will have access to the personal information of myself/my child? Doctors and scientists from the institutions organizing and coordinating the research (Swiss TPH, Public Health Laboratory Ivo de Carneri or from Health Authorities) may review the results of this research, including your/your child's patient files. However, your/his/her personal information (name, birth date, health conditions, etc.) will not be shared with anybody else. The data will be coded with an identification number (encryption). This number replaces your name and date of birth so that nobody can identify your person. Data and related material will be kept for 15 years so that everything that was done is still understandable later.

Participation/withdrawal: Participation in this study is entirely voluntary. You are free to withdraw yourself/ your child from the study at any moment without further obligations. You/your child will not lose any benefit and will receive free treatment (albendazole and ivermectin).

What are the costs to me? Will I receive any payment? Participation in this study will not result in any costs to you. The treatment for any of the diagnosed worms including retreatment, if necessary, is free. Participants will not receive any money or other compensation except the free treatment of all diagnosed worms.

Contact person for further questions and complaints: If you have any questions or complaints or if you want to know the health status of yourself/ your child, you can ask the fieldworkers who will try to answer them or transfer them to one of the principal investigators. You may contact any time directly **Mr. Said Ali** (PHL-IdC), **Tel 0777 416 867.** For any ethical inquiries, please contact **ZAHREC Secretariate** (Zanzibar Health and Research Ethical Committee, Phone number: **0776 264 880**).

Informed Consent Form
(Kept by caregiver / adult participant)

ID _____ _____ _____ _____

I have read and got an explanation about/ Somebody has read and translated for me the information sheet. I understand what will be done during the study, how it will be done, what I/my child will do and I know of the risks and benefits associated with the study. I got answers to all my questions. I also know that I can stop my participation or that of my child at any time without any disadvantage or explanation.

Therefore,

☐ ***I agree, that my child participates in this study (if participant is < 18 years old)***

☐ ***I agree to participate in this study (if participant is 18 - 19 years old)***

☐ ***I agree that my/my child's stool sample may be stored for further analysis***

Name of caregiver or adult participant:

_____

Signature _____ or thumbprint

If Illiterate: I have witnessed the accurate reading of the consent form to the caregiver/ adult participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness: _____ Signature _____

Assent of minor participant:
I have read this information/ I have had the information read to me. I understand the meaning of this information. I have had my questions answered and know that I can ask questions later if I have them. By signing this form, I agree to participate in the study. I also understand that I am free to withdraw from the study at any time without any disadvantage or explanation.

Name of minor participant:

_____

Signature _____ or thumbprint

If Illiterate: I have witnessed the accurate reading of the consent form to the caregiver/ adult participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness: _____ Signature _____

Date _____/_____/20___

Name of study team member: _____

Date _____/_____/20___ Signature _____

Informed Consent Form
(Kept Co-PI)

ID _____ _____ _____ _____

I have read and got an explanation about/ Somebody has read and translated for me the information sheet. I understand what will be done during the study, how it will be done, what I/my child will do and I know of the risks and benefits associated with the study. I got answers to all my questions. I also know that I can stop my participation or that of my child at any time without any disadvantage or explanation.

Therefore,

☐ ***I agree, that my child participates in this study (if participant is < 18 years old)***

☐ ***I agree to participate in this study (if participant is 18 - 19 years old)***

☐ ***I agree that my/my child's stool sample may be stored for further analysis***

Name of caregiver or adult participant:

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Signature _____ or thumbprint

If Illiterate: I have witnessed the accurate reading of the consent form to the caregiver/ adult participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness: _____ Signature _____

Assent of minor participant:
I have read this information/ I have had the information read to me. I understand the meaning of this information. I have had my questions answered and know that I can ask questions later if I have them. By signing this form, I agree to participate in the study. I also understand that I am free to withdraw from the study at any time without any disadvantage or explanation.

Name of minor participant:

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Signature _____ or thumbprint

If Illiterate: I have witnessed the accurate reading of the consent form to the caregiver/ adult participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness: _____ Signature _____

Date _____/_____/20___

Name of study team member: _____

Date _____/_____/20___ Signature _____