Informed Consent Form (ICF) in English

CHEW MEB PEMBA

NTC03995680

24.12.2018

Study participant information and consent sheet (will be translated into Kiswahili)

Name of study: Efficacy and safety of a new chewable tablet of mebendazole versus the solid, standard tablet of mebendazole hookworm infections in children: a randomized controlled trial

This study is a collaboration of researchers from the following institutions:
Public Health Laboratory-Ivo de Carneri, 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** (Director Public Health Laboratory-Ivo de Carneri), **Mr. Shaali Ame** (Public Health Laboratory-Ivo de Carneri), **Prof. Dr. Jennifer Keiser** (Swiss TPH) and **Ms. Marta Palmeirim** (Swiss TPH).

Why is this study being done? In many parts of the world people have worms in their bellies, especially children. On Pemba, most children have different types of worms in their bellies. These worms are bad for children's health because they can cause anemia, malnutrition and other diseases, they can keep the child from growing well and they may make the child do less well at school. This is the reason why children are regularly given drugs to kill these worms. The problem is that some of the drugs are too big for small children too swallow, or they do not taste good and children do not take them. If children do not take them, the worms in their bellies do not die and this is bad for their health.

What is the aim of this study? In this study we want to test a new type of pill of mebendazole and compare it with the old pill of mebendazole. This new pill tastes better and is made to be chewed by the children. We want to know if children like better the chewable pill and if it kills more worms than the old pill. Approximately 400 children with worms will be treated (3-12 years of age). This is a research project, not just treatment.

Does my child have to do this? No. It is completely up to you if you want your child to participate or not. Nobody will force you to accept this, it is completely voluntary.

What will my child have to do if he/she participates? First, we will give your child a cup and ask him/her to give us one stool sample. If he/she is positive for hookworm we will ask for a second sample the next day. We will bring these samples to the laboratory in Chake Chake to check if your child has worms and we will count the eggs of these worms. If he/she has a worm called hookworm, your child will be invited for treatment. Before receiving treatment a doctor and nurses will check your child's health. To check if he/she has anemia the nurse will take a small finger blood sample. If your child is a girl (10 years old or above) she will be asked for a cup of urine because we have to check if she is pregnant. If she is pregnant, it may not

be safe to receive the treatment so she will not be included in the study. Then, your child will, by chance, receive either the new mebendazole tablet (chewable mebendazole) or the old mebendazole tablet (solid mebendazole).While your child is receiving treatment we will check how he/she reacts when taking the medication. Also, we will ask him/her a few questions about the medication to understand whether he/she liked it or not. On the treatment day we will give your child water, biscuits and lunch. During and after treatment a medical team will monitor your child and will do a physical examination. Your child will be asked about how he/she is feeling 3h and 24h after treatment. Two of three weeks after the treatment we will ask your child again to provide two stool samples to check whether all worms have been killed. Finally, all children who remain infected with worms will receive a dose of albendazole and ivermectin (current standard treatment) at the end of the study. All this should not take more than 10 weeks.

What will I have to do in this study? As the participant's caregiver you will be in one of four groups of caregivers: if you are in group 1 we will ask you some questions before you receive any information about this study, if you are in group 2 we will ask you those same questions after you have attended an oral information session, if you are in group 3 we will ask you the questions after you have attended an oral information session with some projected pictures and sentences, and if you are in group 4 you will be asked the questions after you have attended an oral information session and watched a theatre about the study. We can then check which caregivers understood better the information about this study and next time we know the best way to transmit this information.

What do I gain if my child participates in the study? A doctor will check your child's health and give him/her free treatment if he/she has belly worms.

Is participating in the study bad or dangerous for my child? Mebendazole is safe but may have some mild side effects such as feeling dizzy, belly ache or headache.

What are the costs for me? If your child participates in this study you will have no costs. The treatment for any of the diagnosed worms is free.

Will I receive any payment? You will not be paid any money other than the transport reimbursement to come for the information session (3,000 TZS).

Once I have signed the document allowing my child to participate, can I change my mind and take him/her from the study? Yes. Your child can leave the study whenever you want without any consequence. If you decide to leave the study we will not use your child's data for this study but if we found that he/she has worms then he/she will still receive the standard treatment (albendazole plus ivermectin).

Is everyone going to know about my child's results in this study? No. Only you, the research team and the monitor will be able to see if your child has worms. All the information we collect about your child will be locked and nobody else will be able to see it. Also, your child will have a code number which is always used instead of his name and only the researchers will know which number is your child's.

Contact person for further questions and complaints: Any questions or complaints can be directed at the fieldworkers who will try to answer them or transfer them to one of the principal investigators. You may contact directly **Mr. Said Ali** (CEO Public Health Laboratory-Ivo de Carneri, Tel 0777 416 867), **Dr. Shaali Ame** (Public Health Laboratory-Ivo de Carneri, Tel 0777 432 094).

ID ___ ___ ___ ___

Informed Consent Form (Parent/caregiver)

If parent/caregiver can READ: **I have read and got an explanation about** the information sheet, I understand what will be done during the study, how it will be done, what my child needs to do and the constraints associated with the study. I got answers to all my questions. I also know that I can stop the participation of my child at any time without disadvantage or explanation.

Therefore,
□ ***I agree, that my child participates in this study***
□ ***I agree to participate in the interview about caregiver knowledge***

Complete parent's/caregiver's name:

_____

Date___/___/2019 Place _____ Signature _____

If parent/caregiver CANNOT READ: 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 my child needs to do and the constraints associated with the study. I got answers to all my questions. I also know that I can stop the participation of my child at any time without disadvantage or explanation.

Therefore,
□ ***I agree, that my child participates in this study***
□ ***I agree to participate in the interview about caregiver knowledge***

Complete parent's/caregiver's name:

_____

Date ___/___/2019 Place _____ Signature _____ or thumbprint.

Name of witness: _____

Date___/___/2019 Place _____ Signature _____

Name of investigator: _____

Date ___/___/2019 Place: _____ Signature: _____

ID ___ ___ ___ ___

Informed Consent Form (co-PI)

If parent/caregiver can READ: **I have read and got an explanation about** the information sheet, I understand what will be done during the study, how it will be done, what my child needs to do and the constraints associated with the study. I got answers to all my questions. I also know that I can stop the participation of my child at any time without disadvantage or explanation.

Therefore,
□ ***I agree, that my child participates in this study***
□ ***I agree to participate in the interview about caregiver knowledge***

Complete parent's/caregiver's name:

_____

Date___/___/2019 Place _____ Signature _____

If parent/caregiver CANNOT READ: 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 my child needs to do and the constraints associated with the study. I got answers to all my questions. I also know that I can stop the participation of my child at any time without disadvantage or explanation.

Therefore,
□ ***I agree, that my child participates in this study***
□ ***I agree to participate in the interview about caregiver knowledge***

Complete parent's/caregiver's name:

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Date ___/___/2019 Place _____ Signature _____ or thumbprint.

Name of witness: _____

Date___/___/2019 Place _____ Signature _____

Name of investigator: _____

Date ___/___/2019 Place: _____ Signature: _____