Validation of home-based cervical and vaginal self-sampling for the diagnosis of Female Genital Schistosomiasis (FGS) in Zambian women with and without HIV seroconversion. (Version 1.0 Oct 17, 2017)

Introduction

We are doing research on schistosomiasis (bilharzia), which is very common in Zambia. This paper provides information about our research and invites you to participate in our project. If there are words or ideas you don't understand, please ask and we will explain more.

Purpose of the research

Schistosomiasis (bilharzia) is a parasite found in fresh water that can cause problems with a woman's ability to have children. When the eggs from the parasite are in the vagina or cervix, women can have bleeding, discharge, or discomfort. They can also have a hard time getting pregnant and they can be more likely to get infections like HIV. Often doctors need special tests to diagnose this illness. We are studying whether samples you collect in your home are as good as the samples the doctor takes in the clinic. We also want to use a special camera that will be available in local clinics to look at the changes the parasite (bilharzia) causes in your vagina and cervix.

Type of Research Intervention

This research will involve a visit from the BILHIV team. In your own home, you will collect a urine sample, two samples (one vaginal swab and one cervical swab). You will come to the clinic and a nurse will wash the inside of your vagina with some water. At this visit we will use the camera to look at the changes the parasite (bilharzia) causes in your vagina and cervix.

Voluntary Participation

You were chosen for this research because you are a woman who participated in the PopART study. It is your choice whether to participate in this research or not. If you participate, and we find you have schistosomiasis (bilharzia), you will be offered the regular treatment (Praziquantel). You do not have to participate in this study and you may stop at any time without having to give a reason. Choosing not to participate or to withdraw will not affect the care you receive at the health centers in your community.

Duration

This research will involve one visit from the BILHIV team and one visit to your local clinic.

Procedures and Protocol

You will receive the treatment that is standard in Zambia. This means that if you have the parasite, you will get treatment with Praziquantel. We will also request information from PopART about your HIV status. LSHTM ethics committee and other personnel may require access to your information to check compliance with regulations and guidelines. The vaginal swabs and a portion of the vaginal lavage samples will be transported to Leiden University Medical Center, the Netherlands.

What are the possible risks or discomforts?

We will need to use a speculum to see your cervix. This examination can be uncomfortable, but we will do everything we can to make you as comfortable as possible.

What are the potential benefits?

Diagnosis of FGS may benefit the women's health and well-being. All participants will also benefit from treatment of *S. haematobium* infection, cervical cancer screening & greater contact with the medical system may provide an indirect benefit

Confidentiality

All personal information collected in this study will be kept confidential. Your identity will not be revealed in any reports from the study. The results of any testing will be kept confidential and will only be given to you.

People who may review the study data include: The University of Zambia Biomedical Research Ethics committee, local regulatory agencies, LSTHM, study staff, and study monitors. Institutional Review Boards (IRBs) or Ethics Committees (ECs) are committees that watch over the safety and rights of research participants.

What happens if I am injured by participating in this study?

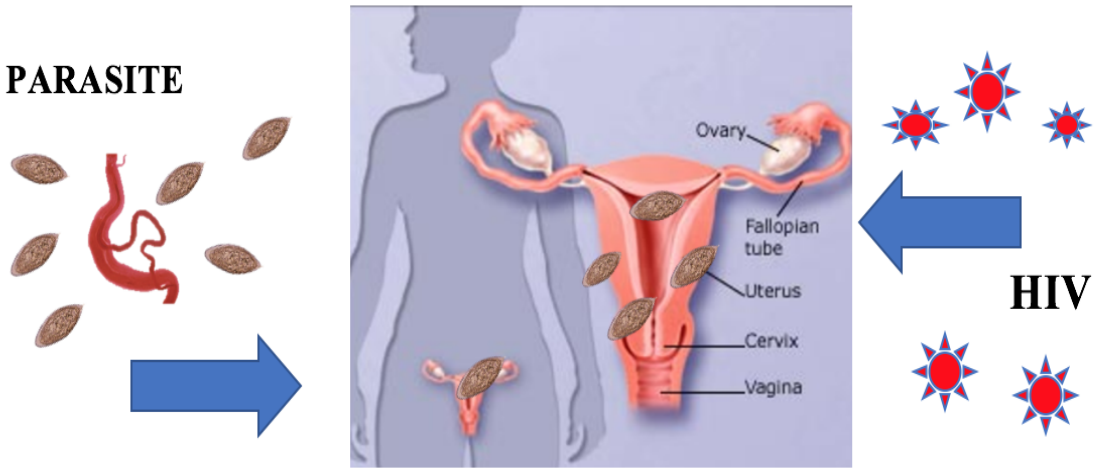
It is very unlikely that you could be injured as a result of participating in this study. However, if you are injured while participating in this study, then we will pause/stop conducting the study procedures so that you can seek medical assistance. The LSHTM holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in

this study, you may be eligible to claim compensation. If you are harmed due to someone's negligence, then you may have grounds for a legal action.

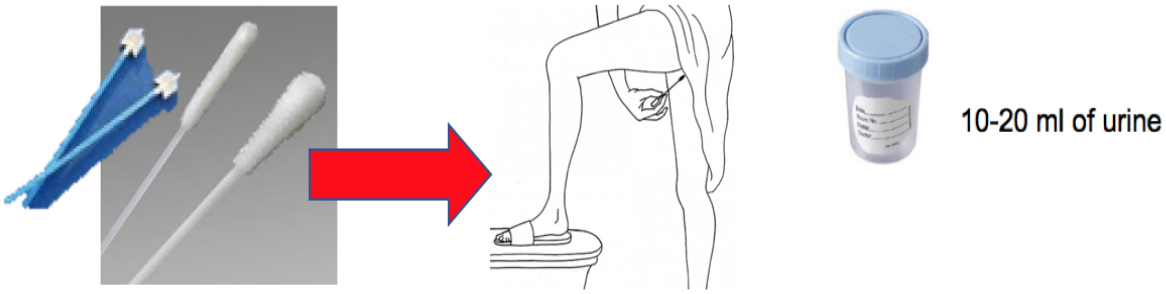
Reimbursements
We will reimburse your travel to and from the clinic

Persons to Contact for Problems or Questions
If you have any questions about your participation in this research study or your rights as a research participant, you may contact or if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of the study then you should immediately contact:

Principal Investigator: Dr. Amaya Bustinduy
Research Site Address (es): *Zambart, School of Medicine, Ridgeway campus, P.O. Box 50697, Lusaka*
Daytime telephone number(s): +260 21 1257215 **Email**: Amaya.Bustinduy@lshtm.ac.uk
Independent Review Board/Ethics Committee: *University of Zambia, Biomedical Research Ethics Committee*
Address of Independent Review Board: *School of Medicine, Ridgeway campus, P.O. 50110, Lusaka*
Daytime Telephone Number: *+ 260 211-256067*



The BILHIV team will come to your home. We will ask you to answer some questions. In your own home, we will ask you to give one urine sample and two vaginal samples (one cotton swab and one cervical brush).



Another day, we will ask you to come to the clinic and a nurse will wash the inside of your vagina with some water (vaginal lavage). The nurse will use a speculum, and then a camera (colposcope) to look at your vagina and cervix. We will take a picture. At the end of this research, we will store any leftover samples.