

Uganda Virus Research Institute**Lake Victoria Island Intervention Trial on Worms and Allergies, LaVIISWA****Information for children; main surveys**

We are inviting you to take part in the research study, LaVIISWA. LaVIISWA is finding out about the effects of worms on health.

A lot of people in fishing villages have worm infections. Worm infections can reduce the strength of blood in a person's body. They can damage parts of the body, especially the liver. On the other hand, it is possible that worm infections somehow protect against allergies and diabetes but that is not certain. That might explain why diseases like allergies and diabetes are often more common in cities than in rural communities.

What are worm infections?

Bilharzia is a disease caused by worms called schistosomes. Adult worms live in humans and their eggs pass out in the faeces. The eggs hatch in the lake water and the worms live for a while in snails in the lake. Then the worms are released from the snails into the water. The worms infect people again through the skin when the people are in contact with lake water. People who are infected with schistosomes (Bilharzia) may suffer from anaemia, diarrhoea with blood, and liver disease.

Other worms that occur in fishing villages include hookworm and roundworm. These both live in the human gut and eggs are passed out in faeces. People become infected with hookworm by walking bare-foot in places contaminated by faeces. Hookworm causes anaemia. People become infected with roundworm by eating food contaminated with faeces.

What is diabetes?

Diabetes is a disease that makes a person develop high blood sugar. This happens when the body poorly controls the levels of sugar in blood. This can lead to complications such as poor resistance to infections, eye disease, heart disease and kidney disease. Diabetes often coexists with abnormal levels of fats (lipids) in the blood and high blood pressure. Blood tests can detect diabetes or a tendency towards diabetes, by measuring blood sugar levels and the levels of insulin, which controls blood sugar.

Why is this study being done?

We want to find out the advantages and disadvantages of mass treatment against worm infections for general health outcomes and for diabetes. We also want to find out how worms and other infections protect against diabetes. If we can find this out, we may be able to develop better ways of preventing or of treating diabetes. The study will help the Ministry of Health to plan their worm treatment campaigns, and to plan for improved services to sufferers from diabetes.



What will happen if I take part?

If you agree to take part, this is what will happen:

- You will be asked to sign or thumb-print the consent forms that accompany this information sheet
- The researchers will ask some questions about your health
- You will undergo a physical examination including measurement of height, weight, waist and hip circumference and blood pressure.
- You will be asked to fast overnight before blood samples are taken
- A blood sample (at most 20 ml; just under four teaspoons) will be taken
- You will be asked to provide one stool sample
- The researchers will map the location of your home

What will the stool and blood samples be used for?

Stool samples will be used to test for worms. Blood samples will be used for tests for the level of glucose, insulin and fats (lipids). Counselling and testing for HIV infection will be included if you wish it. Some blood will be used for tests of immunity (the body's defence system against infections). Part of each sample may be stored for other tests in future including genetic studies. All the information collected, and the results of tests, will be completely confidential.

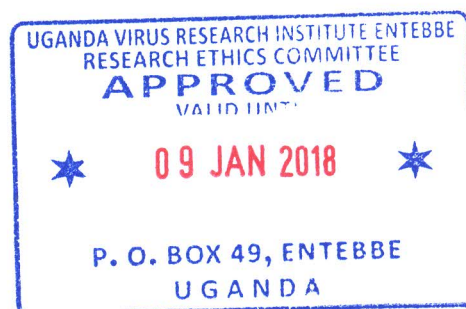
Will this cause any problems to me?

Taking part in the study is not expected to cause any problems for you, apart from the discomfort of fasting overnight. Taking the blood sample will hurt a bit.

Your right to refuse or withdraw from the research study.

Taking part in the study is voluntary. This means that you or the people who look after you can say that you do not want to be involved. You can change your mind about taking part in the study at any time.

You can find out more about the study at any time by asking one of the members of the research team. You may also contact Dr Richard Sanya – telephone: 0417 704000 or Professor Alison Elliott – telephone: 0417 704000 or the Ethics Committee Chairman from Uganda Virus Research Institute on 0414 321962.



Uganda Virus Research Institute

Lake Victoria Island Intervention Trial on Worms and Allergies, LaVIISWAChild Assent form

Village name Participant ID number

Child

I have read and understood (or been read to and understand) the information sheet for this study. My questions have been answered. I understand that taking part in the study is voluntary. I understand that at any time I may withdraw from this study without giving a reason. I agree to participate in this study.

.....
Name of child.....
Signature or thumb print.....
Date

Witness:

.....
Witness name.....
Signature.....
Date

Witness required only for those using a thumb print instead of the final signature, or unable to read the information and consent form, or if the person taking consent does not speak the participant's language. The witness must not be a member of the research staff or a study participant. The witness must be present for the whole consent process.

Person taking the consent:

.....
Researcher name.....
Signature.....
Date

Form to be completed and signed in duplicate. Give one copy to the participant; retain one copy for the study file.

