Uganda Virus Research Institute

Lake Victoria Island Intervention Trial on Worms and Allergies, LaVIISWA

Information for parents/ guardians of child household members; main surveys

We are inviting your child to take part in a survey that is part of the research study, LaVIISWA. LaVIISWA is investigating the effects of worms on health, and the advantages and disadvantages of regular treatment of the whole community for worm infections.

The worm infection called schistosomiasis (Bilharzia) is still a problem among fishing communities. In 2013, over 70% of residents surveyed in Koome sub-county had schistosome infection.

Worm infections can cause health problems such as anaemia (which is often described as having little blood) and poor growth. They can damage parts of the body, especially the liver and gut. It is possible that they can also reduce the body's defences against other infections, such as hepatitis (which also damages the liver) and it is possible that they can reduce the benefits of immunisation, but this is not certain.

On the other hand, it is possible that worm infections somehow protect against allergies and related diseases such as asthma. This might help to explain why asthma, eczema and allergies are often commoner in cities than in rural communities.

What are Bilharzia and 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. Children may have poor growth and it is possible that they may also perform poorly at school.

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 are asthma, eczema and allergies?

Asthma is a disease that affects the lungs. People with asthma have attacks of difficulty in breathing which come and go. Different things can trigger asthma attacks – such as exercise, cold weather, and "flu". When someone has an asthma attack their breathing makes a whistling noise called wheezing.

Eczema is an itchy skin rash which comes and goes. Usually the rash occurs around the eyes, around the neck, inside the elbows or behind the knees.

Allergies are a reaction to substances in the environment which should not normally cause any problem. Allergic reactions are sometimes triggered by foods or insect bites, and sometimes by substances in dusts and in the environment. When the person gets into contact with the substance they are allergic to, they may have diarrhoea (if it is a food) or may start itching, sneezing or wheezing.

Allergy-related conditions are becoming commoner in countries like Uganda. It is thought that living in clean, modern environments may increase the risk of allergies and related conditions.

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What is Hepatitis B infection?

Hepatitis B is a disease caused by the Hepatitis B virus and it affects the liver. The virus is transmitted through contact with the blood or other body fluids of an infected person. In Uganda, 10% of the adult population has this infection. Long standing infection with the virus can result in permanent damage to the liver (liver cirrhosis) and liver cancer. We shall test the blood of your child for the presence of this virus if the child is aged 16 years and above.

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 asthma, eczema and allergies.

We also want to find out how worms and other infections protect against asthma, eczema and allergies. If we can find this out, we may be able to develop better ways of preventing or of treating asthma, eczema and allergies.

The study will help the Ministry of Health to plan their worm treatment campaigns, and to plan for improved services to sufferers from asthma, eczema and allergies.

Why has my child been chosen to take part in this study?

There are 26 villages taking part in the study, and samples are needed from people of all ages in each village, in order to find out what the effects of mass treatment for worms are. Households to give samples are chosen using a computer. The process of choosing households is like the choice of a number in a lottery. All members of a chosen household, including children, are being asked to take part.

What will happen if I agree for my child to take part?

If you agree for your child to take part this is what will happen:

- You will be asked to sign or thumb-print the consent form that accompanies this information sheet
- If your child is aged 8 and 17 years, he or she will also be asked to sign or thumb-print an "assent" form to show that he or she agrees to take part
- The researchers will ask some questions about your child's health
- Your child will be asked to provide one stool sample
- Your child will be asked to provide a urine sample
- Your child will be asked to undergo an ultrasound scan of the abdomen. This is to test whether bilharzia has affected the liver and spleen.
- If your child is aged one year or above, he or she will be tested for his or her reaction to substances that commonly cause allergies, by skin prick testing
- If your child is aged one year or above a blood sample will be taken. The sample will be 10 ml (two teaspoons) for children aged 1 to 4 years, 12 ml (just over 2 teaspoons) for children aged 5 to 12 years, 18 ml (just under four teaspoons) for children aged 13 to 17 years.
- If your child is found to have hepatitis B infection he/she will be asked to provide an additional blood sample of up to 20ml (four teaspoons) for tests that will help us to advise you about hepatitis treatment, and that will help us to understand the effects of Bilharzia and hepatitis on each other.
- People with hepatitis B infection, and a comparison group of people without hepatitis B infection, will be selected to undergo an ultrasound scan of the abdomen. This is to test whether hepatitis or bilharzia has affected the liver and spleen.
- If your child is found to have hepatitis B, the researchers will visit you and your child again after six months. This is to follow up on whether or not your child might need treatment 6 months later. This visit will also help to assess the effects of bilharzia treatment on resolution or progression of the hepatitis B infection in your child. During this visit, your child will be asked to provide a blood sample of up to 8 ml (just under 2 teaspoons).

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What will the stool, urine and blood samples be used for?

Stool and urine samples will be used to test for worms and other intestinal infections. Blood samples will be used for tests for anaemia, malaria, and other infections, and for allergy tests. If your child is aged 16 years and above, his/her blood will also be used to test for hepatitis B virus. Among infections, counselling and testing for HIV infection will be included if you or your child 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. Some of the stored samples may be used for genetic studies. All the information collected, and the results of tests, will be completely confidential. We will contact you with the results if they will be useful for your child's health. For example, the results of tests for malaria will be given to you if your child has a fever and needs immediate treatment. The results of the hepatitis test will be given to you and, if necessary, you will be advised about where you should take your child for treatment, and given a letter to the doctors at the treatment centre. We will not contact you with results from stool samples, because everyone will be offered treatment for worms as soon as the survey ends.

What are genetic studies?

Genetic studies are studies that test whether inherited differences between individuals and families, resulting from differences in ancestry, have an effect on resistance to infections or diseases. Genetic studies on the stored samples of blood will test whether inherited differences explain why some people are more resistant to certain infections (such as worm infections), and whether inherited differences explain why some people are more likely to develop diseases like asthma, eczema and allergies. These inherited differences can be identified by studying the chemicals (DNA) in the blood. It may also be possible to conduct studies on the DNA to find out how worms modify the risk of other diseases, like asthma, eczema and allergy. If you agree we will store some of your child's blood for future genetic studies. These studies will be conducted at specialised laboratories in Uganda or outside Uganda. Storage could be for many years. We will not contact you with the results of this future genetic testing because the work is for research purposes and not for identifying illnesses. If you allow your child's blood to be used we may be able to find out information that will help to provide better services for people in Uganda and elsewhere in the future.

Are there any risks or disadvantages to my child of taking part?

Taking part in the study is not expected to cause any problems for your child, apart from the discomfort of having blood samples taken and the smaller discomfort of skin prick testing. Skin prick testing involves placing about five drops of liquid, containing the substances to be tested, on the skin, and gently scratching through the liquid. In some cases there is an itchy reaction, like the reaction to a mosquito bite. Very rarely a person may over-react to a skin prick test and may need urgent treatment. The research team is ready to treat such a reaction, but it is very unlikely to happen.

Are there any benefits to my child of taking part?

There are no direct benefits to your child of taking part, but your child, and all the members of your village, will benefit from the regular provision of treatment for worm infections. Treatment will be provided at least as often as recommended by the government, and in some villages more often. Also we will work with the Health Centres to promote regular provision of outreach health services, such as immunisation in the village. Your child will be provided with a soft drink or a simple snack when procedures have been completed.

What happens if I refuse for my child to participate?

Taking part is voluntary. You are free to refuse for your child to participate or to withdraw your child at any time. This will not affect your right to the provision of treatment for worms within the study. It will not affect your right to health care provided by the government services.

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Who will have access to information from this research?

All our research records are stored securely in rooms with restricted access and on password protected computers. Only research staff trained to keep the information confidential will have access to the records. The names of individual participants will not appear on any reports on this research. After all your child's samples have been collected, his/ her name will be removed from the records, so no-one will be able to find out information about him/ her from our records.

Who has allowed this research to take place?

An independent national committee (the Uganda National Council for Science and Technology) and a committee at the Uganda Virus Research Institute have looked carefully at this work and agreed that the research is important, that it will be conducted properly, and that participants' safety and rights have been respected.

What if I have any questions?

If you have any questions about your child's participation in this study, please feel free to ask any member of the research team at any time. If you prefer, you may speak to the principal investigator for this study (Professor Elliott, telephone 0417 704000).

What if we want to ask someone independent anything about this research, or have any questions about our rights as research participants?

You may speak with the Ethics Committee Chairman from Uganda Virus Research Institute on 0414 321962.

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Uganda Virus Research Institute / Entebbe Hospitals

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Consent form for child household members; main surveys

Village name ..... **Child's ID number** .....

Child's name .....

Parent or Guardian

	Initial or thumbprint each box
1. I have read and/or been fully explained the information sheet concerning my child's participation in this study and I understand what will be required if he or she takes part. I understand that my child's participation is voluntary. My questions concerning this study have been answered. I understand that at any time I may withdraw my child from this study without giving a reason and without affecting his or her entitlement to government health care. I understand that a part of each specimen may also be stored for other tests in future. I agree for my child to take part in this study.	
2. I agree for my child to undergo skin prick testing to assess his or her response to substances that can cause allergy.	
3. I agree for part of my child's specimens to be stored for future studies.	
4. I agree for part of my child's specimens to be stored for genetic studies.	

.....	.....	.....
Name of parent or guardian	**Signature or thumb print**	**Date**

Relationship to child (mother, father, guardian) .....

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.

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