

Uganda Virus research Institute/Entebbe Hospital

Information parents/Guardian

Blood pressure study among 10 and 11 year old children in the Entebbe Mother and baby study

Introduction

Thank you for taking part in the earlier studies in the Mother and Baby study (EMaBS). This has helped us to collect a lot of information about health of children and their mothers. We are always trying to find new ways to use it to improve people's health.

We now want to use the information that we have collected to help us to study blood pressure in children in developing countries. We will find out if birth weight and other things that happened in early life affect blood pressure in children.

What is blood pressure?

Blood pressure is determined by the amount of blood the heart pumps and the amount of resistance to blood flow in the arteries. The more blood the heart pumps and the narrower the arteries, the higher the blood pressure. A person can have high blood pressure (hypertension) for a long time without any symptom. Uncontrolled high blood pressure increases the chances of serious health problems including death. A child with high blood pressure is likely to have hypertension when they are adults unless they begin treatment or alter their diet and life style.

Why is this study being done?

Hypertension is fast growing problem in developing countries as people change from a rural to an urban life style. Factors that influence blood pressure have been greatly studied in the developed countries. However there is little or no information from developing tropical countries. EMaBS children can help us to find out which factors are associated with high blood pressure among children in Uganda. This will help the Ministry of Health to plan treatment and management of children with hypertension, and the prevention of hypertension in adults.

Who is doing the study?

The EMaBS together with Entebbe Hospital are carrying out this study and it will end in 2016.

Why have you chosen my child?

We have chosen your child because she/he is 10 or 11 years of age and under follow up in the EMaBS. We have collected a lot of information about her/his health from they were in the mother's womb to date. We think that this information together information about the child's blood pressure will help us answers questions about blood pressure in children from developing countries.

What will happen if I allow my child to take part?

Some EMaBS activities will continue, just as before:

- The child will be seen, ask questions about their health and height and weight measurements will be taken when you are 10 or 11 years old.
- Your child will provide a stool sample.
- After giving a stool sample, your child will receive treatment for worms. If the results show that you need special treatment, one of the fieldworkers will come and bring the treatment to your home.

If you agree to your child to take part in this additional study about blood pressure when they are 10 or 11 years of age, this is what will happen.

- As well as height and weight, we will measure the size of your child's waist. We will then take their blood pressure and this will be done three times on the first day. Quite often the reading is high on the first day, just because the child is not used to having their blood pressure measured. If it is high on the first day we will invite you to come back so that the blood pressure reading can be taken again on a second and third day.
- The results of your child blood pressure will be compared to the normal values for his/ her age, sex and height.
- A blood sample (14mls, about three small teaspoons) will be taken.
- Your child will provide a urine sample that will be stored .
- We will combine this information with data we already have about your child including information about your child's genes. We will look for particular genes that may affect blood pressure and other diseases related to your child's heart and blood vessels.
- The transport cost will be refunded. The amount given will depend on where you stay.
- If found with abnormal values of blood pressure on day 3, your child will be investigated further in consultation with a specialist doctor at Mulago Hospital. You will be advised about ways in which the blood pressure can be improved through change in lifestyle, and treatment will be provided if it is required.

What will the stool and blood samples be used for?

The stool and blood samples will be tested for infections. The blood sample will also be tested for chemical changes such as sugar and lipid (fat) levels: high sugar levels and abnormal lipid levels quite often occur along side problems with blood pressure. Some of the blood sample, and the urine sample, will be stored for other tests in the future, including measurement of substances involved in the immune system and nutrition. All the information collected will be linked to information that we already have, including the information about child's genes. This information and results of the test will all be kept confidentially and accessible only for research and to help in treatment of your child. The results of the sugar and lipid levels will be available to you and if they are not normal you will be advised what to do.

Will this cause any problem to my child?

Taking to part in this study is not expected to cause any problems to your child. Measuring blood pressure and taking a blood sample may be uncomfortable to the child. But this is temporary and not expected not to have any danger to your child.

Are there any benefits to taking part in the study?

Because high blood pressure can occur without causing any symptoms, it is likely to be beneficial for your child to have this test done. It is a normal part of good, routine medical care. Results of the blood tests will also be useful for your child's health.

There is a very small possibility that we may discover some genes that increase the risk of your child having high blood pressure or related diseases which may have implications for their health or the health of their children. If we discover that your child has such genes we will make every effort to contact you or your child and provide appropriate guidance with what to do. We think the chances of this happening are very small.

It is your right to refuse or withdraw from the study.

Taking part in this study is voluntary. This means that you or the child can say that you do not what to be involved in the study. You can change your mind about your child's taking part in the study at any time. If you do not wish your child to take part in this study you may still continue under follow up within the EMaBS programme.

You can find out more about this study at any time by asking one of the study doctors, nurses or field workers at the clinic. You can also contact Dr. Elliott (telephone: 0417704000) or the Medical Superintendent of Entebbe Hospital (telephone: 320058), or the Ethics Committee Chairman from Uganda Virus Research Institute on 0414 321962.

Uganda Virus research Institute/Entebbe Hospital

Consent form for parent or guardian

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Child's name..... Child's BIDNO |__|__|__|__|/|__|

My signature below shows that 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 they agree to take part in the study. My questions concerning this study have been answered. My child's participation is voluntary and agrees to participant in this study.

Parent/Guardian's signatures:

- 1. My signature/thumb print indicates that I agree to have my child take part in the blood pressure study

..... or thumb print

- 2. My signature/thumb print indicates that I agree for part of my specimens to be stored for future studies

..... or thumb print

Witness;

.....

Name (Block Capitals)	Signature	Date
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Witness required only for those using a thumb print, or unable to read the information and assent form, or if the person taking the assent does not speak the participant's language. The witness must not be a member of the research team or a study participant but may be a family member or a member of hospital staff who is not involved in the research programme. The witness must be present for the whole consent process.

Person conducting the consent:

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Name (Block Capitals)	Signature	Date
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