Title of Research Study: Chronic hepatitis B virus infection in Zambia: a prospective clinical cohort study
Protocol: Version 1.3, dated 4 April 2017
Principal investigators: Dr. Edford Sinkala, University Teaching Hospital and University of Zambia (UNZA) and Dr. Michael J. Vinikoor, University of Alabama at Birmingham (UAB) and UNZA
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Sponsor: University of Alabama at Birmingham (UAB), U.S.A.
Study contact telephone number: +260 972921285/955884088
UAB Institutional Review Board Protocol #: F151224005

Purpose of the Research:
You are being asked to take part in a research study. The purpose of this research study is to learn about Zambians who have chronic hepatitis B virus (HBV) infection. For example, in patients with HBV we want to learn how common is liver disease and how well current treatments control the infection. This research study will enroll 500 adults. You are being asked to be in the study because you are at least 18 years old and are HBV positive according to your test result.

Explanation of Procedures:
At your first visit we will do the following:

- Ask you information about behaviors which could also make you at risk of liver problems, such as drinking large amounts of alcohol or beer.
- Ask you whether your partners and household members have also been tested for HBV.
- Take 15 ml (3 teaspoons) of blood to measure the amount of HBV in your body and to check for liver disease and take a urine sample to check levels of alcohol in your body.
- Take two types of liver ultrasound. The first is to check for liver cancer and the second, called Fibroscan, checks the health of the liver by measuring its stiffness.

Not all people with HBV need treatment. Sometimes the HBV is “inactive” and you do not need medicines. However, if the results of your tests indicate that HBV is “active” and causing a liver problem, we will prescribe you a medicine that is recommended by the Ministry of Health to treat HBV. This medicine is the same one we recommend in the clinic for other patients with HBV.

Whether or not you are prescribed medicine, after the first visit, you will have follow-up visits every 3-6 months for 5 years to repeat the procedures listed above. It is possible that you may not need treatment at the first visit but will need it later on. If you start taking medicine, during follow-up visits we will check your adherence to the medicine. At some of these visits, we will again collect up to 15 ml of blood to monitor your liver, to check the amount of HBV, to check medication levels in the body, and to ensure that you receive the routine laboratory tests for HBV. We will also periodically repeat the urine alcohol test, the ultrasound, and the Fibroscan test.

Incidental Findings:
The liver ultrasound for the study is checking for signs of liver cirrhosis and/or cancer; however, it is possible that the radiographer may find that something else is unusual. If something unusual is found, we will inform you and we will refer you for appropriate medical care.

Risks and Discomforts:
Having blood taken may cause some discomfort, light headedness, bleeding, swelling, or bruising where the needle enters the body, and in rare cases, fainting, or infection. People taking blood will be trained and will try hard to avoid these problems. Ultrasound and Fibroscan® are painless tests.

Benefits:
You may not receive any direct benefit from being in this research study, but we believe it will increase our understanding of problems caused by HBV and the outcomes of HBV treatment in Zambia. You may benefit from being checked every 6 months for a 5 year period for the possible development of liver problems.

Alternatives:
The alternative to participating in this study is for you to receive regular HBV treatment in the clinic according to local guidelines.

Confidentiality:
Every effort will be made to keep your personal information confidential. It will be your decision whether you share the results of your tests with others in your home or community. We will not share them. Your study information and blood samples will be identified by a code to protect your privacy. When the results of the study are disseminated, we will not use your name or identify you personally.

Your records may be reviewed by representatives of the University of Zambia Biomedical Research Ethics Committee, the UAB Institutional Review Board, the study sponsor (UAB), the Zambian Ministry of Health, or the Office for Human Research Protections. However, this information will be kept confidential and will only be used to ensure that the study is being conducted properly and that your records are being stored appropriately.

Voluntary Participation and Withdrawal:
To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher or the clinic staff. If you are a patient with an illness, you do not have to be in the research study in order to receive care and treatment.

You can leave this study at any time, without losing your regular medical care. The investigators also have the right to stop your participation at any time. This could be because you failed to follow instructions or because the entire study has been stopped.

Cost of Participation:
It will not cost you anything to participate in this study.

Payment for Participation in Research:
You will be given transport reimbursement at the end of the first visit and every 6 months at your scheduled follow-up study visits. The amount of reimbursement will be based on the price of bus fare from your home to and from the clinic.

Significant New Findings:
You will be given any new information learned during the study that might affect your willingness to continue your participation.

Questions:
If you have questions, concerns, or complaints about the research you may contact Drs. Sinkala and Vinikoor who will be glad to answer any of your questions. Dr. Vinikoor's phone number is 0972921285 and Dr. Sinkala's is 0955884088.

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research participant, or if you would like to obtain information or offer input, you may contact the Chairperson of the University of Zambia Biomedical Research Ethics Committee, Ridgeway Campus, Nationalist Road, Lusaka, at phone number 0211 256 067.

Informed consent for blood storage after the study ends

After the study ends, we would like to store a leftover portion of your blood specimens to measure additional substances that may help us develop the best treatments for HBV. The blood specimens will be stored at University Teaching Hospital for up to 10 years. Your blood will not be identified by name. It will be stored with the usual protectors of identity. If you allow us to store the blood now and change your mind later, you can inform us at any time (at phone numbers 0972921285 or 0955884088) and we will destroy your stored samples. No research will be undertaken on your stored blood specimens without prior approval from the University of Zambia Biomedical Research Ethics Committee.

Please initial or thumbprint AND date beside your choice(s) below:

_____ I agree to allow my sample to be
Initials/Thumbprint of Participant and Date stored for future HBV research.

_____ I do not agree to allow my sample to
Initials/Thumbprint of Participant and Date be stored for future HBV research.

Informed consent for shipping blood samples abroad for testing if unable to perform tests in Zambia

In this study, we intend to perform all blood testing within local laboratories, including several tests that are new in Zambia. In case we are are unable to do these tests in Zambia, for example due to equipment breakdown, we would like your permission to ship your samples abroad to be tested at recognized laboratories. If there is a need to test you samples abroad, we will inform you, and only tests related to HBV infection and liver disease will be done. Your blood samples will be identified with a code to protect your identity and will not be identified by name.

Please initial or thumbprint and date beside your choice below:

_____ I agree to allow my blood
Initials/thumbprint of participant and date sample to be shipped abroad
for testing if necessary.

_____ I do not agree to allow my
Initials/thumbprint of participant and date sample to be shipped abroad
for testing. I only want my blood
tested in Zambia.

Informed consent form signature page

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Participant's agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature/thumbprint of research participant Date

_____
Printed name of research participant

_____ _____
Signature of research team member obtaining consent Date

_____
Printed name of research team member obtaining consent

_____ _____
*Signature of witness Date

_____
*Printed name of witness

***Note: Witness name, signature and date are required on this consent form only when the consenting volunteer is not able to read and/or is illiterate**