

PART I: Information Sheet

Introduction

I am Dr Joyce Sande, a Senior Instructor in the department of Radiology of Aga Khan University Nairobi. We are doing research on the diagnosis and quantification of liver fibrosis. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.

Purpose of the research

Liver fibrosis is a common finding in patients with liver disease. It is important to know the state of the liver as this affects choice of medication and follow up. A new technique for assessing for liver damage using ultrasound scan has been developed. This technique is called elastography. The purpose of this study is to establish the role of elastography in the diagnosis and accurate quantification of liver fibrosis as compared to the current gold standard which is biopsy. Biopsy is not perfect and it has attendant risks of morbidity and mortality due to its invasive nature, which can be avoided by elastography.

Type of Research Intervention

This research will involve having an additional measurement done during the ultrasound scan of the liver that will be performed in the radiology department of Aga Khan University Hospital as before you undergo the ultrasound guided liver biopsy that your primary physician has referred you for.

Participant selection

We are inviting all adults referred for an ultrasound guided liver biopsy to participate in this study.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the procedure and treatment that is routinely offered in this radiology department. You may change your mind later and stop participating even if you agreed earlier.

Description of the Process

Participation involves being interviewed by one of the researchers and then undergoing an additional measurement during your liver ultrasound scan. The additional liver scan measurement will be carried out at the radiology department and takes approximately 20 minutes. The scan measures the stiffness of the liver to evaluate presence or absence of damage.

Risk and Side Effects

There are no risks or side effects associated with having the liver ultrasound measurement done.

Benefits

If you participate in this research, you will have a free elastography measurement performed that will inform on the presence of any damage to your liver. Your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

Confidentiality

With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is.

The scope of information collected in relation to fulfilling study objectives are specifically for this study and not any other.

Sharing the Results The knowledge that we get from doing this research will be shared with you through your doctor before it is made widely available to the public. Confidential information will not be shared. We will publish the results in order that other interested people may learn from our research.

Right to Refuse or Withdraw. You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact:

Dr. Joyce Sande, Department of Radiology, Aga Khan University Hospital,

P. O. BOX 30270, Nairobi.

MOBILE: 0704624756.

Email: joyce.sande@aku.edu

This research has been reviewed and approved by the Aga Khan University Hospital Research Ethics Committee.

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Name of Participant: _____

Signature _____ Date _____

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands what the study entails.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this consent form has been provided to the participant.

Name of Researcher: _____

Signature: _____ Date _____