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The United Kingdom
UKAGS
Aneurysm Growth Study

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This information sheet has been sent to you since you have told us that you ***do*** have an aneurysm. If this is incorrect please contact us.

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you.

Talk to others about the study if you wish.

Part 1 of this information sheet tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Please contact us if there is anything that is not clear.

If after reading this information you wish to take part in the study please complete the enclosed consent form and return it to us in the postage-paid envelope.

Part 1: Study Overview

What is the purpose of the study?

This research aims to find out more about abdominal aortic aneurysms, and in particular how and why they grow in size over time. This knowledge will be used to develop new treatments for aneurysms which will be able to save lives in the future.

This research is not designed to directly help those people who are taking part in the study. Rather, it should give future patients with aneurysms a better chance of being successfully treated.

Why have I been invited?

You have been invited to take part in this research since you indicated your interest to us at the time you attended the aneurysm screening clinic and had a scan of your abdomen. The only information we have for you is that which you provided to us. If you decide that you do not want to take part in the research study just let us know using the enclosed envelope. If we do not hear from you within 6 months we will delete your details from our database.

Do I have to take part?

No. Your participation is entirely voluntary. If you decide not to take part in the study this will have no effect on the care you receive now, or in the future.

What is involved if I decide to take part?

Taking part in this research would involve:

- Completing a brief questionnaire that we will send you
- Visiting your general practitioners surgery and having a small blood sample taken and giving a sample of your urine.

We would ask you to repeat this process once, in one year's time unless you decide you do not want to or if you end up having an operation to fix your aneurysm.

Part 2: Detailed Study Information

1. What is the purpose of the study?

Arteries are blood vessels that take blood away from the heart. The aorta is the main artery in the body. An aneurysm occurs when the wall of the artery becomes weak and it stretches. Although aneurysms usually affect the aorta, they can also occur in other blood vessels such as the leg arteries.

We do not know why some people develop aneurysms and others do not. We do know however, that aneurysms are more common in some families. This may suggest a genetic cause. We also know that certain types of chemical in the body can weaken the walls of blood vessels and cause them to stretch, resulting in an aneurysm

Protein levels in the blood are controlled by genes (chemicals that contain genetic information). We know that some people have genes that cause high or low levels of circulating proteins. A recent study has suggested that patients who produce a low level of one protein may be more likely to develop aneurysms. We aim to do a similar study in more detail to clearly see whether there is a link between aneurysms, proteins and genes. We will compare a group of patients with aneurysms to a group without aneurysms.

You have been invited to participate in this study since you have attended the NHS Abdominal Aortic Aneurysm Screening Programme and it has found that you do have an aneurysm. We would like to compare people such as yourself with patients who do not have an aneurysm. Your help would be greatly appreciated.

2. What will be involved if I take part in the study?

We will ask you to make an appointment at your general practitioners surgery to have a blood test and give a urine sample. This study looks at the levels of naturally occurring proteins in the blood and urine, and peoples genes. In order to do this we need to take a blood sample from a vein in your arm and obtain a sample of your urine. You will probably have had both tests before as part of your medical care. We will only need 15-20ml (about two tablespoons) of blood and the same amount of urine. From this we can analyse protein levels and genes. Your genes will be examined by extracting and analysing DNA and RNA (which contains genetic information) from your blood sample. This *is not* genetic fingerprinting. Any genetic material that is analysed will not be traceable back to you. Your identity will be protected at all times.

The samples that you donate will be stored anonymously for use by the research team in future research. Such future research may involve examining diseases other

than aneurysms and may involve research teams from organizations other than the University of Leicester and outside of the UK. Where this occurs, your identity will not be passed on (samples will be anonymised prior to dispatch). All samples and data transfer will be subject to approval by the project steering committee and formal transfer agreements between the University of Leicester and the receiving institution will be established prior to the transfer. This ensures that the samples will only be used for the purposes specified here.

As well as obtaining the above samples we will also ask you to fill out a short questionnaire about your general health and also your attitudes towards the process of having attended the NHS Abdominal Aortic Aneurysm Screening and Surveillance Programmes. Once you have provided us with your samples and completed the questionnaire we will ask you to repeat this process in one year's time, and to complete a follow-up questionnaire for the following 4 years. At any point if you decide that you no longer wish to take part in the study then you are under no obligation to continue. If you decide to withdraw from the study we will write to you and ask if you would like any samples that you have donated to be destroyed or if you would be willing to allow us to continue to study these samples.

All participants in the study will be followed up for up to ten years by obtaining data from the Health and Social Care Information Centre. This organization controls research access to information obtained from the national register of births and deaths and any admissions to hospitals. In addition, the Health and Social Care Information Centre holds some data for a number of General Practices (about 8% as of December 2014). Access for General Practice data is controlled by the Clinical Practice Research Datalink, part of the NHS National Institute for Health Research. We will also obtain data about the results of any scans you have on your aneurysm from the NHS Abdominal Aortic Aneurysm Screening Programme.

3. Will the information obtained in the study be confidential?

All details recorded in the study will be treated in the strictest confidence. The researchers involved in the study will keep your contact details in a secure database so that you can be contacted in the future should the need arise and to ensure you are not asked to take part in the study on multiple occasions. This data will be held in compliance with the Data Protection Act 1998. Any data obtained from questionnaires and the blood and urine samples will be stored without any information regarding your identity.

4. What if I am harmed by the study?

Medical research is covered for mishaps in the same way as for patients undergoing treatment on the NHS ie compensation is only available if negligence occurs.

5. What happens if I do not wish to participate in this study or wish to withdraw from the study?

If you do not wish to participate in this study or if you wish to withdraw from the study you may do so without justifying your decision and your future clinical care will not be affected.

6. Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Leicestershire Northamptonshire and Rutland Research Ethics Committee.

7. Further information

If you require further information about this research study or wish to ask us any questions please contact us at the address given on the front page of this information sheet.