SONAR

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Surveillance Of arteriove Nous fistul Ae using ult Rasound

The SONAR study

We'd like to invite you to take part in our research study. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. Please feel free to talk to others about the study if you wish.

Please ask us if there is anything that is not clear or if you would like more information.

Why have I been invited to take part?

We have invited you to take part because you have failing kidneys and you will be having an arteriovenous fistula (AVF) created in your arm for dialysis.

What is the purpose of the study?

Unfortunately, some fistulas fail within a year despite successful surgery. The reason why this happens and how we can prevent it are largely unknown.

The aim of this study is to see how useful Doppler ultrasound is at checking the growth of your fistula after it has been created. In the future, this may enable us to identify and correct problems with fistulas at an early stage.

What is a Doppler ultrasound scan?

A Doppler ultrasound scan uses soundwaves (ultrasound) to produce pictures of your fistula that allow us to measure the size of your fistula and how fast your blood is flowing through it.

It is safe and painless and does not use any radiation or needles.

How is an ultrasound scan of your fistula performed?

There is no preparation needed and you may eat and drink as usual prior to the scan.

The scan will usually be performed with you lying down or sat on the edge of the couch. During the scan, cold jelly will be applied to your arm and the ultrasound probe will be moved up and down your arm. You will need to roll up your sleeve, remove your arm from your top or change into a gown to allow the sonographer to scan your entire arm. Wearing a loose fitting short sleeved top may be helpful. The lights may be dimmed during your scan to allow us to get the best pictures.

The scan takes approximately 30-60 minutes. During the test, you may hear some "swooshing" noises from the ultrasound machine. These sounds are normal.

What does taking part in the study involve?

Taking part in the SONAR study would involve you:

- Having 4 ultrasound scan visits. The scans would be at about 2, 4, 6 and 10 weeks after your fistula operation. The ultrasound scan results will be shared with the study team.
- Agreeing to share some of your medical history, details of your current medications and some information about your fistula surgery and follow up care, with the study team.

The results of your study scans will not be shared with you or your doctor/nurse. This is so that we can compare what we see in the scans with how well your doctor feels your fistula has grown after 10 weeks.

But at any time during the study, your doctor can decide to do any other tests/scans of your fistula as needed and you will still have all your normal follow up with your clinical team.

What are the possible disadvantages or risks of taking part?

Ultrasound is a very safe method of assessing fistulas. We use sterile probe covers and jelly to minimise any risk of infection while the wound is healing up. Taking part may mean some extra trips to hospital for the study ultrasound scans. As far as possible we will try and arrange for your scans to coincide with other hospital appointments, but if this is not possible we will reimburse your travel expenses.

Where do I go for the ultrasound scans?

Scans will be performed at local hospitals taking part in the study.

What are the possible benefits of taking part?

This research study will not benefit you directly in the short term, but may benefit you and other patients having a fistula made in the future.

The results from this study will improve our knowledge of how fistulas grow and whether ultrasound can predict problems at an early stage.

If during the study, your fistula is found to have a blood clot in it that has completely blocked it, then we would let your doctors know so that they can provide the right care for you.

Who is organising the research?

This study is being run by Mr Gavin Pettigrew at the University of Cambridge and is taking place in hospitals across the UK. The Principal Investigator for this site is [to be localised].

The sponsors of this study are Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge. The sponsors have delegated overall management of this study to the Clinical Trials Unit at NHS Blood and Transplant.

The study is being funded by the National Institute for Health Research Health Technology Assessment programme.

Who has reviewed the study?

The study has been reviewed by the Cambridgeshire and Hertfordshire Research Ethics Committee.

Do I have to take part?

No, it is up to you whether you decide to take part or not. If you decide to take part you will be asked to sign a consent form to say that you agree to take part in the study. You are free to leave the study at any point in time without having to give a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care that you receive.

What if I have a problem?

If you have any concerns regarding your treatment, you can contact the clinical team treating you.

If you have concerns and questions about the study, you should speak with the research team at your hospital who will do their best to answer any questions for you.

If you wish to complain about the treatment you have received as part of the study, you can contact the hospital's Patient Advice and Liaison Services (PALS).

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the NHS Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). The University of Cambridge has an insurance policy to cover harm arising as a result of the design of the study.

Will my taking part in this study be kept confidential?

Yes. All the information about your participation in the study will be kept confidential. The information will be held securely in electronic format under the provisions of the Data Protection Act 2018 and the General Data Protection Regulation.

Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Cambridge University Hospitals NHS Foundation Trust / University of Cambridge will keep identifiable information about you for 25 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at https://www.hra.nhs.uk/information-about-patients/

[NHS site] will collect information from you and your medical records for this research study in accordance with our instructions.

[NHS site] will keep your name, NHS number and contact details confidential and will not pass this information to Cambridge University Hospitals NHS Foundation Trust / University of Cambridge. [NHS site] will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

Certain individuals from Cambridge University Hospitals NHS Foundation Trust / University of Cambridge / NHS Blood and Transplant and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Cambridge University Hospitals NHS Foundation Trust / University of Cambridge / NHS Blood and Transplant will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

[NHS site] will keep identifiable information about you from this study for 25 years after the study has finished.

What will happen to the results of the study?

The results of this study will be submitted for publication in medical/scientific journals, presented at medical/scientific conferences and made publicly available to try and improve the care of people requiring haemodialysis in the future. You will not be identifiable in any publications

Who to contact for further information

You are encouraged to ask any questions you wish before, during or after treatment. If you have any questions about the study, please speak to your study doctor/nurse.

Thank you for taking the time to consider participating in the SONAR study.