SONAR-12M

Participant Information Sheet

Trust logo to be added

Surveillance Of arteriove Nous fistul Ae using ult Rasound 12 Month Follow Up Study (SONAR-12M)

www.sonartrial.org.uk

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.

Please read through this information sheet to help you decide whether or not you would like to take part. A member of the renal team may also call you to talk it through 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 are inviting you to take part because in 2018 or 2019, you kindly agreed to take part in the SONAR study and may have had some SONAR ultrasound scans of your arteriovenous fistula.

Over 300 UK patients took part in SONAR and we would now like to ask them to take part in this follow up study.

You don't need to have any ultrasound scans or make any extra trips to the hospital to take part this time.

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 follow up study is to see what happened to you and your fistula in the 12 months after it was created by your surgeon and again at 5 years. We will add this information to the information we collected in the SONAR study.

By taking part in the SONAR study, you are one of a group of patients in whom we have unique ultrasound data on how fistulas develop immediately after creation. This will help us better understand how good the Doppler ultrasound measurements were at predicting problems with fistulas. In the future, this may help us to identify and correct problems with fistulas at an early stage.

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What does taking part in the study involve?

Taking part in the SONAR-12M study would involve you agreeing to share some information from your medical records with the researchers. This would be information relating to:

- Your kidney disease
- Details of your medications
- How your fistula developed over time
- Any problems you have had with your fistula
- Any extra operations you have had on your fistula
- If you have managed to use your fistula for dialysis
- If you are using a different type of access for dialysis
- If you have received a kidney transplant

This information would be collected at 12 months, and again at 5 years, after your fistula surgery. We might also ask you whether you can feel the pulse (often called a thrill) of your fistula.

Taking part will not affect your care and you do not need to come into the hospital for any extra visits. There is no risk to your fistula.

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.

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, please sign the study consent form and return it to the research team at your hospital. Or you can speak to the research team on the phone and let them know your decision.

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.

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 [xxx] Research Ethics Committee.

What will happen to the results of the study?

The results of this study will be published 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.

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Will my information 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 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.

We will need to use information from your medical records for this research project. This information will include your initials/ NHS number/ name/ contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. You can find out more about how we use your information at https://www.hra.nhs.uk/information-about-patients/

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

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.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients
- our leaflet available at http://www.hra.nhs.uk/patientdataandresearch
- by sending an email to the Data Protection Officer at Cambridge University Hospitals gdpr.enquiries@addenbrookes.nhs.uk

What if I have a problem?

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): [to be localised for each participating centre.]

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.

Who to contact for further information

You are encouraged to ask any questions you wish. If you have any questions about the study, please speak to the research team at your hospital:

Name:

Telephone:

Thank you for taking the time to consider participating in the SONAR-12M study.