

# SONAR: Surveillance Of arterioveNous fistulAe using ultRasound

<b>Submission date</b> 18/07/2018	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 09/08/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/05/2024	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The kidneys remove excess fluid and harmful toxins from the body. If a person develops kidney failure, the build-up of toxins and fluid can be fatal within a few days if untreated. Consequently, patients with kidney failure require either a replacement kidney (kidney transplant) or for the excess fluid and toxins to be removed from the body (dialysis).

The commonest form of dialysis involves blood being filtered by a machine to remove toxins and excessive fluid (haemodialysis). This requires a good flow of blood through the machine to allow the toxins to be removed. The safest way to achieve sufficient flow in the machine is by a small operation that involves joining one of the veins to one of the arteries in the arm (an arteriovenous fistula). With time this fistula increases in size and allows sufficient flow through it to enable dialysis nurses to put two needles into the fistula (one taking blood from patient to machine, and the other returning the "cleansed" blood to the patient).

Fistulas are the best option for most patients, as the risks of a life-threatening blood infection are about ten times less common than for patients who dialyse through a tube in their chest. Unfortunately, the creation of an arteriovenous fistula is not an exact science and up to half of them fail within a year of being created, despite a successful join at the time of surgery. The reasons why this happens and how we can prevent it are largely unknown.

Our study will examine whether we can use 'Doppler ultrasound' (a non-invasive scan that uses high-frequency sound waves to create a picture of the blood flow in the fistula) to identify early problems with a fistula that may lead to it failing. At present we do not know if it is possible to identify problems in this way, or when it is best to perform a scan.

If we were able to identify fistulas that may fail, then we would aim to perform a second study to see whether it is possible to intervene at an early stage in those "at risk" fistulas to prevent them from failing.

### Who can participate?

People aged 16 or older with chronic kidney disease and are going to have an arteriovenous fistula created in their arm, for haemodialysis

### What does the study involve?

Participants who join the study will have a Doppler ultrasound scans at 2, 4, 6 and 10 weeks after their arteriovenous fistula operation. Doppler ultrasound is a non-invasive test that involves

putting cold jelly on the arm and moving the ultrasound probe up and down the arm to assess blood flow. The ultrasound machine then creates pictures of the blood vessels in the arm (including the newly created fistula) using sound waves. These pictures allow us to work out the size of the blood vessels and the flow of blood within them. Each scan takes between 30 and 60 minutes. A member of the dialysis team will also examine the fistula at week 10 to see if they feel it is suitable to be used for dialysis.

What are the possible benefits and risks of participating?

Broadly, there will be no specific benefit for participants in the short-term, though it may benefit them and others in the future. In a small number of participants, we may identify their fistulas have clotted (and so no longer work). We will notify their treating team to allow them to arrange for appropriate care to be planned. This may be sooner than would otherwise have occurred had the patient not been scanned and so may offer a benefit to individual participants. There are no known risks to participants taking part, as Doppler ultrasound is a very safe, well tolerated and non-invasive method of assessing fistulas. We will use sterile probe covers and jelly to minimise any (theoretical) risk of infection while the wound is healing up. The main burden for participants is the inconvenience of attending appointments for Doppler ultrasound scans and clinical assessment. We will try and arrange scans and appointments to correspond with dates of other appointments as far as possible. If a participant visits hospital purely for a study visit, they will be reimbursed their travel expenses.

Where is the study run from?

The lead centre running the study is Addenbrooke's Hospital in Cambridge. 14 other hospitals will also run the study

When is the study starting and how long is it expected to run for?

April 2018 to January 2020

Who is funding the study?

National Institute for Health Research (NIHR) Health Technology Assessment programme (UK)

Who is the main contact?

Anna Sidders

SONAR@nhsbt.nhs.uk

**Study website**

<http://www.sonartrial.org.uk/>

## Contact information

**Type(s)**

Public

**Contact name**

Ms Anna Sidders

**Contact details**

Clinical Trials Unit

NHS Blood and Transplant

Cambridge Blood Centre

Long Road

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United Kingdom  
CB2 0PT  
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sonar@nhsbt.nhs.uk

**Type(s)**  
Scientific

**Contact name**  
Mr Gavin Pettigrew

**ORCID ID**  
<http://orcid.org/0000-0003-3724-9945>

**Contact details**  
Department of Surgery  
Box 202 Level E9  
Addenbrooke's Hospital  
Hills Road  
Cambridge  
United Kingdom  
CB2 0QQ

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
17/99

## Study information

**Scientific Title**  
A prospective observational cohort study to determine whether ultrasound surveillance can reliably predict arteriovenous fistulae failure in patients with chronic kidney disease

**Acronym**  
SONAR

**Study objectives**  
Doppler ultrasound surveillance can reliably predict failing nascent arteriovenous fistulas by identifying potentially-correctable anatomical defects.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Cambridgeshire and Hertfordshire REC, 11/07/2018, 18/EE/0234

**Study design**

Observational prospective multi-center cohort study

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Hospital

**Study type(s)**

Diagnostic

**Participant information sheet**

The participant information sheet will be available on the SONAR website <http://www.sonartrial.org.uk/>

**Health condition(s) or problem(s) studied**

Arteriovenous fistula in patients with established or approaching end stage renal disease (ESRD) requiring dialysis

**Interventions**

Consenting participants who are enrolled will be observed for 10 weeks following creation of their AV fistula and will undergo Doppler ultrasound scans during weeks 2, 4, 6 and 10. Routine clinical examination will be undertaken as per local policy with a final clinical examination at week 10 to evaluate the success of the fistula formation.

**Intervention Type**

Other

**Primary outcome measure**

Primary fistula patency at week 10, according to surrogate ultrasound parameters. This is assessed using venous diameter and blood flow measurements:

1. Wrist fistula, considered to be patent if there is a minimum venous diameter of 4 mm with a blood flow measurement of > 400 ml/min
2. Elbow fistula, considered to be patent if there is a minimum venous fistula diameter of 5 mm, with a blood flow measurement of > 500 ml/min

**Secondary outcome measures**

1. Successful use of the fistula for those patients established on dialysis, determined by its use for dialysis on 3 separate occasions during the 10 weeks after the arteriovenous fistula (AVF) surgical creation
2. Clinical suitability for dialysis based on examination alone according to local practice, assessed 10 weeks after AVF surgical creation
3. Formation of a new fistula (including fashioning of proximal neoanastomosis) or radiological

salvage procedure, measured by collecting the number and type of these interventions during the 10 weeks after AVF surgical creation

4. Fistula thrombosis, measured by collecting the number of fistulae that fully thrombose during the 10 weeks after surgical creation

5. Secondary fistula patency, measured by the time interval (in days) between AVF creation until abandonment of the AVF including all radiological and surgical salvage procedures in between, during the 10 weeks after AVF surgical creation

6. Patient acceptability based on the proportion of patients that complete their study ultrasound scans 10 weeks after AVF surgical creation

**Overall study start date**

01/04/2018

**Completion date**

31/01/2020

## **Eligibility**

**Key inclusion criteria**

1. Aged 16 years or older
2. End stage renal disease
3. Requires haemodialysis or is likely to do so immediately
4. Due creation of an arm arteriovenous fistula (wrist or elbow), including the following types of fistula with a minimal acceptable threshold of 2 mm venous diameter at whatever site chosen:
  - 4.1. Radiocephalic
  - 4.2. Ulna-basilic
  - 4.3. Brachiocephalic
  - 4.4. Brachio-basilic
5. Provides fully informed consent

**Participant type(s)**

Patient

**Age group**

Other

**Lower age limit**

16 Years

**Sex**

Both

**Target number of participants**

347

**Total final enrolment**

348

**Key exclusion criteria**

1. Attempted formation of proximal neo-anastomosis at the forearm cephalic and basilic venous systems following failure of a standard radiocephalic or ulnobasilic fistula
2. Known central venous stenosis (including those who undergo simultaneous central venous angioplasty / stenting and arteriovenous fistula creation)
3. Anticipated that it will not be possible to perform serial ultrasound scanning

**Date of first enrolment**

10/09/2019

**Date of final enrolment**

11/11/2019

## **Locations**

**Countries of recruitment**

England

Scotland

United Kingdom

**Study participating centre****Addenbrooke's Hospital**

Cambridge University Hospitals NHS Foundation Trust

Hills Road

Cambridge

United Kingdom

CB2 0QQ

**Study participating centre****Royal London Hospital**

Whitechapel Road

London

United Kingdom

E1 1BB

**Study participating centre****Guy's Hospital**

Great Maze Pond

London

United Kingdom

SE1 9RT

**Study participating centre**  
**St George's Hospital**  
Blackshaw Road  
London  
United Kingdom  
SW17 0QT

**Study participating centre**  
**St Helier Hospital**  
Wrythe Lane  
Carshalton  
United Kingdom  
SM5 1AA

**Study participating centre**  
**Leicester General Hospital**  
Gwendolen Road  
Leicester  
United Kingdom  
LE5 4PW

**Study participating centre**  
**Oxford University Hospitals NHS Foundation Trust**  
John Radcliffe Hospital  
Headley Way  
Headington  
Oxford  
United Kingdom  
OX3 9DU

**Study participating centre**  
**Edinburgh Royal Infirmary**  
51 Little France Crescent  
Old Dalkeith Road  
Edinburgh  
United Kingdom  
EH16 4SA

**Study participating centre**

**Southmead Hospital**

Southmead Road  
Westbury on Trym  
Bristol  
United Kingdom  
BS10 5NB

**Study participating centre****University Hospital Coventry**

Clifford Bridge Road  
Coventry  
United Kingdom  
CV2 2DX

**Study participating centre****Hammersmith Hospital**

Du Cane Road  
Shepherd's Bush  
London  
United Kingdom  
W12 0HS

**Study participating centre****Nottingham City Hospital**

Hucknall Road  
Nottingham  
United Kingdom  
NG5 1PB

**Study participating centre****Manchester Royal Infirmary**

Oxford Road  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre****Queen Alexandra Hospital**

Southwick Hill Road



Portsmouth  
United Kingdom  
PO6 3LY

**Study participating centre**

**Royal Free Hospital**

Pond Street  
Hampstead  
London  
United Kingdom  
NW3 2QG

## **Sponsor information**

**Organisation**

Cambridge University Hospitals NHS Foundation Trust and University of Cambridge

**Sponsor details**

R&D Office  
Addenbrooke's Hospital  
Hills Road  
Cambridge  
England  
United Kingdom  
CB2 0QQ

**Sponsor type**

Hospital/treatment centre

**Website**

<https://www.cuh.nhs.uk/>

**ROR**

<https://ror.org/04v54gj93>

## **Funder(s)**

**Funder type**

Not defined

**Funder Name**

National Institute for Health Research (United Kingdom)

# Results and Publications

## Publication and dissemination plan

Open access, peer reviewed academic outputs and research reports together with associated summaries and key findings will be produced for funders, policy makers and NHS audiences and held on the study website.

## Intention to publish date

31/12/2022

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Gavin Pettigrew (gjp25@cam.ac.uk). The available dataset will contain details of the scans that have been performed (flow rate / venous diameter), linked to fistula outcome at 10 weeks. The data will be available after publication of the study outcomes and will be available for 25 years. ccess criteria for sharing of data are to be defined. Participants have consented to non-identifiable results to be publicly available. No identifiable data will be shared.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	23/07/2019	07/08/2020	Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Results article</a>		20/03/2021	21/09/2023	Yes	No
<a href="#">Results article</a>		05/01/2024	25/04/2024	Yes	No
<a href="#">Results article</a>		01/05/2024	22/05/2024	Yes	No