# SONAR: Surveillance Of arterioveNous fistulAe using ultRasound

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered			
18/07/2018		[X] Protocol			
Registration date	Overall study status	Statistical analysis plan			
09/08/2018	Completed	[X] Results			
Last Edited	Condition category	Individual participant data			
22/05/2024	Urological and Genital Diseases				

#### 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

#### Contact information

Type(s)
Public

Contact name

Ms Anna Sidders

#### Contact details

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#### Type(s)

Scientific

#### Contact name

Mr Gavin Pettigrew

#### **ORCID ID**

https://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

#### Protocol serial number

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

#### Study type(s)

Diagnostic

#### 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(s)

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

#### Key secondary outcome(s))

- 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 abandoment 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

#### 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. Ulno-basilic
- 4.3. Brachiocephalic
- 4.4. Brachiobasilic
- 5. Provides fully informed consent

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Other

#### Lower age limit

16 years

#### Sex

All

#### 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

United Kingdom

England

Scotland

#### 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

#### **ROR**

https://ror.org/04v54gj93

### Funder(s)

#### Funder type

Not defined

#### **Funder Name**

National Institute for Health Research (United Kingdom)

#### **Results and Publications**

#### 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?
Results article		20/03/2021	21/09/2023	Yes	No
Results article		05/01/2024	25/04/2024	Yes	No
Results article		01/05/2024	22/05/2024	Yes	No
Protocol article	protocol	23/07/2019	07/08/2020	Yes	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes