ISRCTN36033877 https://doi.org/10.1186/ISRCTN36033877

SONAR: Surveillance Of arterioveNous fistulAe using ultRasound

Submission date
18/07/2018

Recruitment status
No longer recruiting

Registration date
09/08/2018

Overall study status
Completed

Last Edited
22/05/2024

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Cambridge
United Kingdom
CB2 0PT
01223 588915
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 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

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. Ulno-basilic
4.3. Brachiocephalic
4.4. Brachiobasilic
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?
Protocol article	protocol	23/07/2019	07/08/2020	Yes	No
HRA research summary			26/07/2023	No	No
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