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12-month follow-up of the surveillance of arteriovenous fistulae in haemodialysis (SONAR) study

Submission date
04/03/2021

Recruitment status
No longer recruiting

Registration date
04/03/2021

Overall study status
Completed

Last Edited
22/05/2024

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The kidneys are required for the excretion of excess fluid and harmful toxins. If a person develops kidney failure, then the build-up of toxins and fluid can be fatal within a few days. 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 by a process known as dialysis. Most patients who develop chronic kidney failure will need dialysis at some point. Two-thirds of patients with kidney failure (around 20,000 patients a year in the UK) receive regular dialysis through a machine (haemodialysis).

Haemodialysis involves attachment to the machine requires either the placement of semi-permanent 'lines' (plastic tubing) into one of the big veins in the patient's chest, or the surgical creation of an 'arterio-venous fistula', in which one of the small arteries in the arm is joined directly to one of the veins. The vein becomes gradually bigger allowing for a greater flow of blood. The fistula vein can then have two needles inserted into it to enable connection with the dialysis machine. The increased rate of blood flow within the fistula vein, coupled with the increased size and wall thickness of the vein, allow for successful, and repeated needling. 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 via their 'line'.

Unfortunately, the creation of an arterio-venous 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.

To test whether ultrasound helps predict which fistulas will fail, this study will recruit patients who need to have a fistula created. The study team will perform a series of scans in the weeks after the operation but the results will not be shared with the patients or their clinicians. This should allow the study team to find out whether the scan helps to predict fistula failure or not,

and when the best time is to perform the scan after the operation. If this study is able to show that ultrasound can be used to successfully identify fistulas that are not likely to mature, then the study team will proceed to undertake a second study. This second study will evaluate whether it is possible to intervene at an early stage in those fistulas that are identified by ultrasound as unlikely to mature, and by doing so improve the longevity of the fistula (patency). There is still a great deal of debate about the role of ultrasound in predicting the chances that a fistula will mature successfully. This is important because the use of ultrasound is expensive, but also means that patients have additional scans that may not be needed.

This study, which will involve a number of large UK dialysis centres, will show clearly how effective or otherwise ultrasound is at predicting whether fistulas develop successfully and whether this represents a good use of NHS funds. By doing so, it is anticipated that the study will influence current dialysis practices in the UK and abroad.

Who can participate?
Patients who took part in the Surveillance of arteriovenous fistulae using ultrasound (SONAR) study (isrctn.com/ISRCTN36033877) can participate in SONAR-12M

What does the study involve?
The study involves giving consent for the researchers to collect additional information from the medical records of participants. Data collected will be about the arteriovenous fistulae studied in the SONAR study, haemodialysis, kidney transplantation, and venous access surgeries or procedures. This data will be collected at 12 months after the fistula was created, and again at 5 years after the fistula was created. There are no additional hospital visits or tests involved.

What are the possible benefits and risks of participating?
There are no immediate benefits of participating, and no clinical risks as there are no tests, procedures, or study visits. All routine clinical care will continue. The researchers hope that the study may benefit kidney disease patients in the future.

Where is the study run from?
Cambridge University Hospitals NHS Foundation Trust (UK) and the University of Cambridge (UK). Clinical Trial Management, Data Management, and Statistics are provided by the NHS Blood and Transplant Clinical Trials Unit (UK).

When is the study starting and how long is it expected to run for?
From October 2020 to December 2025

Who is funding the study?
The National Institute for Health Research (UK)

Who is the main contact?
Gavin Pettigrew, gjp25@cam.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
290717

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 290717, CPMS 47958, HTA grant reference 17/27/11

Study information

Scientific Title

Surveillance of arteriovenous fistulae in haemodialysis- 12 Month (SONAR-12M) follow-up study: a prospective observational cohort study to determine whether ultrasound surveillance can reliably predict arteriovenous fistulae failure in patients with chronic kidney disease

Acronym
SONAR-12M

Study objectives
Early doppler ultrasound of arteriovenous fistula creation predicts 6- and 12-month fistula patency.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/01/2021, West Midlands - Edgbaston Research Ethics Committee (3rd Floor Barlow House, Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8089; edgbaston.rec@hra.nhs.uk), ref: 20/WM/0331

Study design
Prospective observational cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Clinically indicated need for the creation of an arteriovenous fistula (AVF), established (dialysis dependant) renal disease, approaching End-Stage Renal Disease (ESRD)

Interventions
For this prospective observational cohort study, there will be no formal interventional comparison. Participating patient’s medical records will be reviewed to collect data on their fistula. Data will be collected at 12 months after the fistula was created, and again at 5 years after the fistula was created

Intervention Type
Other

Primary outcome(s)
Primary fistula patency at 6-months post-creation measured as the interval (in days) between access creation to the earliest of fistula thrombosis, abandonment (except abandonment because of steal or pseudoaneurysm), intervention on the fistula (to re-establish patency), or the time of measurement of patency measured from medical records at 12 months after fistula creation

Key secondary outcome(s))

1. Formation of a new fistula (including fashioning of proximal neoanastomosis) or radiological salvage procedure measured from medical records at 12 months after fistula creation
2. Fistula thrombosis measured from medical records at 12 months and 5 years after fistula creation
3. Secondary fistula patency at 6- and 12-months post-creation measured from medical records at 12 months after fistula creation
4. Assisted primary fistula patency at 6- and 12-months post-creation measured from medical records at 12 months after fistula creation
5. Primary fistula patency at 12-months post-creation
6. Functional patency and, if functionally patent, time to the event, measured from medical records at 12 months and 5 years after fistula creation
7. Haemodialysis discontinued (due to improvement in renal function, withdrawn from dialysis, switched to peritoneal dialysis, or kidney transplant received) measured from medical records at 12 months after fistula creation
8. Continued dialysis, transplantation, or death measured from medical records at 5 years after fistula creation
9. Primary and secondary fistula patency measured from medical records at 5 years after fistula creation

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1. Previously participated in the SONAR study
2. Provides full informed consent to participate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
192

Key exclusion criteria
1. Death since SONAR participation
2. Withdrew from the SONAR trial

Date of first enrolment
01/04/2021

Date of final enrolment
30/11/2021

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
The Royal London Hospital
Whitechapel Road
London
United Kingdom
E1 1FR

Study participating centre
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

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

Study participating centre

Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

Study participating centre
Churchill Hospital
Old Road, Headington
Oxford
United Kingdom
OX3 7LE

Study participating centre
Edinburgh Royal Infirmary
51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Southmead Hospital
Southmead Road
Bristol
United Kingdom
BS10 5NB

Study participating centre
University Hospital Coventry and Warwick
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Nottingham University Hospitals
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Frimley Park Hospital
Portsmouth Road
Camberley
United Kingdom
GU16 7UJ

Study participating centre
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
Hull Royal Infirmary
Anlaby Road
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Study participating centre
The James Cook University Hospital
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Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

ROR
https://ror.org/04v54gj93

Organisation
University of Cambridge

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2024	22/05/2024	Yes	No
HRA research summary			28/06/2023	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