

# Which strategy is better for patients requiring dialysis, fistula creation or graft insertion first?

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 08/02/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 08/02/2023	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The kidneys perform a vital function in regulating many chemicals and water in the blood. When the kidneys become diseased, these functions may be affected and if severe enough, can lead to a life-threatening buildup of chemicals and water in the body. A kidney transplant is the ideal treatment of this, but most patients with kidney failure need a period of dialysis – where blood is removed from the body, cleaned in a dialysis machine, then returned. The key to this process is the connection to the dialysis machine to allow blood removal and return, and this is called vascular access. Vascular access is vitally important and is often called a patients' lifeline. There are three types of vascular access and each have differing plus and minus points. A tunnelled central venous catheter (TCVC) or 'line' is often used in emergencies, but has the highest rate of infections, lasts the least amount of time, and can lead to long-term problems with the main draining veins. Thus a long-term TCVC is best reserved for patients unable to obtain other types of access. An arteriovenous fistula (AVF) is the best form of vascular access with the longest lifespan and the least number of complications when they are working. However, the downside of an AVF is that they are the hardest to get working with up to half failing – and then a TCVC is needed. Because of this failure rate, patients often get operations a long time before they need dialysis to have a few chances to get the AVF up and running. But this means that many will get an operation that is not needed as their kidneys keep on going. The third type of vascular access is called an early cannulation arterio-venous graft (ecAVG). ecAVG has some big advantages - they can be used immediately and have a high rate of immediate success, which means that this can just be put in when needed and avoid unnecessary operations. However, there is a downside - ecAVGs need higher maintenance and may not last as long.

Thus, there is uncertainty about what is best – an AVF which may be a better long-term option but have high initial failure rates, or ecAVGs which have high initial success but need more long-term maintenance. For some people, the veins and arteries may be a bit small and thus the chances of an AVF operation working are less than 50/50. This study tries to determine which is best for patients like this, who are needing to start dialysis within 6 months – trying to get an AVF to work or waiting and putting in an ecAVG when needed.

### Who can participate?

Patients aged 18 years and over with end-stage kidney failure

What does the study involve?

Patients who enter the study will get either an AVF now or wait and get an ecAVG when needed. This decision will be made randomly – like tossing a coin. The operations are very standard and commonly done in the centres involved in the trial, each of which has very good outcomes. The researchers will keep a very close eye on any complications, treatments or admissions to the hospital that happen over the following 2 years, and every 3 months be asking questions about patients' vascular access and how they are finding it. From all this information they will be able not only to tell which option works best, but which option patients like best. This information will change how we provide this service not only in the UK, but throughout Europe and the world.

What are the possible benefits and risks of participating?

There is no direct benefit to taking part in this study, and patients would be receiving vascular access surgery and follow-up whether they took part or not. It is hope that in the future patients will benefit from the knowledge gained by doing this trial.

There are no additional risks over and above those experienced in standard of care for these procedures. For fistulas, about half of people will need additional surgery and around a third of fistulas will not be used in the next year. For grafts, the most common problem is that they require more maintenance, particularly in the area the graft joins the vein. This often narrows and is usually treated with a balloon stretch (angioplasty).

Where is the study run from?

NHS Greater Glasgow and Clyde (UK)

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

June 2020 to December 2027

Who is funding the study?

Kidney Research UK

Who is the main contact?

Miss Clare Dolan, [clare.dolan3@ggc.scot.nhs.uk](mailto:clare.dolan3@ggc.scot.nhs.uk)

## Contact information

### Type(s)

Public

### Contact name

Miss Clare Dolan

### Contact details

Ward 11 R&I

Dykebar Hospital

Grahamston Road

Paisley

Paisley

United Kingdom

PA2 7DE

+44 (0)141 314 4407

[clare.dolan3@ggc.scot.nhs.uk](mailto:clare.dolan3@ggc.scot.nhs.uk)

# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## Integrated Research Application System (IRAS)

275310

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

GN19RE247, IRAS 275310, CPMS 54766

# Study information

## Scientific Title

A randomized trial of initial strategy of Acuseal versus fistula first in incident patients requiring haemodialysis with sub-optimal options for an arteriovenous fistula

## Acronym

StAFF

## Study objectives

This study aims to change the strategy of initial vascular access in incident patients with a sub-optimal option for an arteriovenous fistula (AVF) by determining if an immediately usable arteriovenous graft (Acuseal) when dialysis is required would be a better option (procedure, costs, and quality of life) than a strategy of pursuing a native AVF pre-emptively.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 27/01/2023, West of Scotland REC 3 (West of Scotland Research Ethics Service, Ground Floor Ward 11, Dykebar Hospital, Grahamston Road, Paisley PA2 7DE, UK; +44 (0)141 314 0212; WoSREC3@ggc.scot.nhs.uk), ref: 22/WS/0177

## Study design

Multi-centre multi-national randomized trial

## Primary study design

Interventional

## Study type(s)

Treatment

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

End-stage renal failure

## Interventions

Participants will be randomized during the screening visit using a central randomization facility accessed online via an interactive web-based randomization system (IWRS) hosted by the Robertson Centre for Biostatistics, University of Glasgow. Patients will be randomized to either creation of an AVF or Acuseal in a 1:1 ratio, using a minimization algorithm with a small random element to ensure balance across recruitment sites and key baseline measures.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Time to vascular access abandonment as measured by the time from procedure to loss of patency of vascular access. This will be measured at 6 weeks post procedure (visit 3) and thereafter 3 monthly at month 3, month 9, month 12, month 15, month 18, month 21 and month 24.

## **Key secondary outcome(s)**

1. Cost of patient care in each arm will be analysed by a health economist. Healthcare resource use data will be collected by electronic case report form (eCRF) from the trial and supplemented from external routine sources, including Hospital Episode Statistics (England) and equivalent databases for other UK nations where feasible. This will be classified into intervention-related resource use (e.g. medical consumables and medicines utilised, the time required to perform the procedure, intervention medical team composition including relevant NHS bands, length of stay etc.) and access-related/follow-up resource use (e.g. access-related complications and hospitalisations, re-interventions, creation of alternative access, GP/nurse/Allied Health Professional/outpatient visits, ambulance attendance, A&E attendance, inpatient admissions, critical care stay). Adverse events related to the intervention that result in resource utilisation will also be recorded and included in the analysis. This will be calculated for the duration the patient is in the trial.
2. Quality of life will be measured by VAS-QoL and EQ-5D. EQ-5D only will be assessed at visit 1 screening and visit 2 procedure. EQ-5D and VAS-QoL will be assessed at Visit 3 Post Operative visit and 3 monthly during visits 4-11.
3. Primary-assisted patency, defined as the interval from the time of access placement until access thrombosis, or the time of measurement of patency, measured by the medical opinion of the staff attempting to use the vascular access for dialysis treatment. This will be measured once access has been established for the duration the patient is in the trial.
4. Functional (secondary) patency, defined as the interval from the time of access placement until access abandonment, thrombosis, or the time of measurement of patency including preceding successful interventional or surgical procedures to maintain or re-establish patency. This will be measured for the duration of the trial.

## **Completion date**

31/12/2027

## **Eligibility**

### **Key inclusion criteria**

1. Age  $\geq 18$  years at the time of informed consent
2. Capable of complying with Protocol requirements, including follow-up
3. Incident patient with end-stage renal failure (ESRF)
4. The time of estimated renal replacement therapy (RRT) or haemodialysis is anticipated within the subsequent 6 months, or have already started within the previous 21 days prior to

recruitment (urgent vascular access to provide life-sustaining haemodialysis will not be an exclusion)

5. Sufficiently fit to withstand initial surgery and maintenance procedures

6. Have contemporary vein and arterial mapping with ultrasound (US)

7. No scheduled immediate transplant within the next 60 days

8. No previous vascular access procedures other than central venous catheter for urgent haemodialysis of duration <3 weeks

9. One or more adverse factors to the successful creation of an AVF in the opinion of the surgeon, such as:

9.1. Anatomical factors:

9.1.1. Wrist: artery <2.5 mm, vein <3 mm

9.1.2. Elbow: artery <4 mm, vein <4 mm

9.1.3. Poor arterial quality due to calcification, occlusion

9.1.4. Aberrant anatomy

9.2. Technical factors:

9.2.1. Distance to skin surface >5 mm

9.2.2. Length of vein for cannulation <6 cm

9.2.3. Need for transposition or superficialisation – either before AVF created or after AVF has been created if unsuitable before

9.3. Patient factors:

9.3.1. Age >65 years

9.3.2. Diabetes mellitus

9.3.3. BMI >29 kg/m<sup>2</sup>

9.3.4. Other patient factors e.g. preservation of a dominant arm and poor vessels in the non-dominant

10. Suitable anatomy for placement of an ecAVG (Gore Acuseal), not necessarily in the same limb

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Been treated in a drug study within 60 days of study enrollment

2. Pregnant at the time of consent

3. Life expectancy <1 year

4. Not likely to require hemodialysis within 6 months

5. Commencing hemodialysis more than 3 weeks prior

6. Having a tunnelled central venous catheter (TCVC) with an anticipated duration >3 weeks

7. Vessels not suitable for an AVG (advised minimum size 4.5 mm inflow brachial artery, 3 mm radial artery, 3 mm vein – complete details in SOP)

8. A good option for an AVF (>50% likelihood of success) in a suitable upper limb that includes all anatomical favorable measurements and characteristics: wrist – radial artery >3 mm AND cephalic vein >3 mm AND cephalic vein length >6 cm AND less than 5 mm from skin surface; elbow – brachial artery >4 mm AND cephalic vein >4 mm AND cephalic vein length greater than 6 cm AND less than 5 mm from skin surface. These are not absolute and should be taken in the context of a clinical decision.

9. A history or evidence of severe systemic disease including:

9.1. Cardiac disease (NYHA Functional Class III or IV, evidenced by the inability to lie flat), myocardial infarction in the 6 weeks prior to randomisation, ventricular tachyarrhythmia requiring continuing treatment, unstable angina

9.2. Systolic blood pressure < 90 mmHg, unless willing to take anti-coagulants

9.3. Uncontrolled diabetes, evidenced by recurrent hypoglycaemic attacks/hyperglycaemic episodes)

9.4. Stroke within 1 month of study entry

9.5. History of cancer (excludes basal cell cancer) with active disease or active anti-tumour (cytotoxic) treatment within the previous year

9.6. Suspected or documented hyper-coagulable state, unless willing to take anti-coagulation

9.7. Bleeding diathesis

9.8. Active clinically significant infection (WBC >15,000 cells/mm<sup>3</sup>) other than treated CVC use

10. Known or suspected central vein stenosis/occlusion on the side of planned access

11. History of heparin-induced thrombocytopenia

12. Biological immunosuppression

13. Any other condition which in the judgment of the investigator would preclude adequate evaluation of the safety and efficacy of the Acuseal / fistula e.g. poor compliance

14. Unwilling or unable to attend standard 3-monthly surveillance

#### **Date of first enrolment**

28/02/2023

#### **Date of final enrolment**

01/02/2025

## **Locations**

#### **Countries of recruitment**

United Kingdom

England

Scotland

Wales

Greece

Italy

Spain

#### **Study participating centre**

**NHS Greater Glasgow and Clyde**

J B Russell House  
Gartnavel Royal Hospital  
1055 Great Western Road Glasgow  
Glasgow  
United Kingdom  
G12 0XH

**Study participating centre**

**Guys and St Thomas' NHS Foundation Trust**

249 Westminster Bridge Road  
London  
United Kingdom  
SE1 7EH

**Study participating centre**

**Barts Health NHS Trust**

The Royal London Hospital  
80 Newark Street  
London  
United Kingdom  
E1 2ES

**Study participating centre**

**Cardiff & Vale University Lhb**

Woodland House  
Maes-y-coed Road  
Cardiff  
United Kingdom  
CF14 4HH

**Study participating centre**

**Insubria University Hospital**

Department of Vascular Surgery and Department of Surgical Sciences  
Via Ravasi, 2  
Varese VA  
Italy  
21100

**Study participating centre**

**Hospital Clinic de Barcelona**  
Vascular Surgery Division  
C. de Villarroel, 170  
Barcelona  
Spain  
08036

**Study participating centre**  
**Nikolaos Karydis**  
University Hospital of Patras  
Department of Surgery  
Pio 265 04  
Patras  
Greece  
26504

## Sponsor information

**Organisation**  
NHS Greater Glasgow and Clyde

**ROR**  
<https://ror.org/05kdz4d87>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
Kidney Research UK

**Alternative Name(s)**

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Trusts, charities, foundations (both public and private)

**Location**  
United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

With relevant permissions anonymised published data will be made available on request on completion of the study.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			26/07/2023	No	No