

# Investigating local or regional anaesthesia during surgery to create a connection between an artery and a vein

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<b>Registration date</b> 27/10/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/08/2025	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Many patients with kidney failure need dialysis to remove toxins from the bloodstream. During dialysis, blood from the patient is taken into the dialysis machine, cleaned and then returned back to the patient. This requires entry and exit 'access' points into patients' blood vessels. The best form of access is called a fistula (an artificial connection between the artery and vein made with a small operation in the arm).

Unfortunately, fistula creation is not an exact science. Up to half fail within a year of being created. The reason why fistulas fail and how this can be prevented are largely unknown. The fistula operation can be performed under local anaesthetic (i.e. injection of anaesthetic into the wrist or elbow to numb the area where the surgeon will operate) or anaesthetic 'block' (i.e. injection of anaesthetic around the nerves in the neck or armpit to numb the entire arm for many hours). It is known that the 'block' also improves blood flow to the arm. Theoretically, this could improve the success of a fistula operation but this is not yet clear. Currently, in the UK there is no agreement on what to do and each unit chooses based on local preference and resources.

This study aims to compare the success of fistulas created under local anaesthetic versus an anaesthetic 'block'.

### Who can participate?

Adult patients with either end-stage renal disease (ESRD) and receiving renal replacement therapy (RRT), or chronic kidney disease (CKD) stage IV or V and referred for arteriovenous fistula creation.

### What does the study involve?

Patients requiring fistula creation will be randomised (like tossing a coin) to have their fistula made under local anaesthetic or 'block'. After the surgery most patients will be able to go home on the same day. They will be reviewed twice afterwards (3 and 12 months following surgery) to assess how they, and their fistula, are getting on.

Recent research has shown that patients consider fistula function rather than simply blood flow is most important when determining the success of a procedure. Therefore success will be judged if a fistula can deliver dialysis without the need for any additional procedures or surgery. This will be easy to assess in patients receiving dialysis. However, it is anticipated that about half of study participants will not have started dialysis yet. In these patients the fistula will be assessed by ultrasound (jelly scan) instead. The trial team will compare the number of patients with a successful fistula at 12 months in each group to determine which anaesthetic technique (if either) is better.

Information will be collected about complications (infections, blockages, needling problems), additional procedures, hospital visits or 'lines' (plastic tubes inserted to allow dialysis if the fistula isn't working properly). Finally, patients will be asked to complete some short questionnaires to evaluate general wellbeing. One of the questionnaires has been recently designed by doctors specifically to look at the effect of the 'access' on patient lifestyle. This information will allow us to determine if the treatments are good value for money.

What are the possible benefits and risks of participating?

Wherever possible, patients will be followed-up in their dialysis units to avoid additional hospital visits and only hospitals that already offer both local anaesthetic and 'block' within their current practice will be eligible to participate. In this way, it is hoped that the costs of running the trial will be kept down and the trial team will draw on existing relationships to make everything run efficiently.

It is anticipated that the results of this trial will be used to influence the decision-making of NHS funders and ensure that, in the future, the best treatment option is available for every patient with kidney failure in the UK.

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?

From October 2020 to July 2024

Who is funding the study?

National Institute for Health Research (UK) - NIHR130567

Who is the main contact?

Dr Emma Aitken

emmaaitken@nhs.net

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Emma Aitken

**ORCID ID**

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## Contact details

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

290482

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

IRAS 290482, NIHR130567

## Study information

### Scientific Title

Anaesthesia Choice for Creation of arteriovenous fistulae (ACCess)

### Acronym

ACCess

### Study objectives

Does regional (RA) compared to local anaesthesia (LA) improve unassisted functional patency at 1 year and/or cost-effectiveness in patients undergoing primary radiocephalic (RCF) or brachiocephalic (BCF) fistula creation?

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 07/01/2021, West of Scotland REC 3 (Research Ethics, Clinical Research and Development, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 314 0212; WoSREC3@ggc.scot.nhs.uk), ref: 20/WS/0178

### Study design

Multicentre observer-blinded randomized controlled trial (RCT) with an internal pilot and embedded process evaluation study

### Primary study design

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Quality of life

## **Participant information sheet**

Participant information sheets are currently in draft and being prepared for ethics submission, will be added once approved

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

Patients undergoing primary (Radiocephalic fistula) RCF or (Brachiocephalic fistula) creation

## **Interventions**

Each participant will be randomised, at a ratio of 1:1, to either receive Regional Anaesthesia (RA) or Local Anaesthesia (LA) during their planned surgery to create a connection between an artery and a vein. (Primary radio- (RCF) or brachio-cephalic (BCF) fistula surgery).

Those randomised to the RA Intervention Arm will receive a 1:1 mixture of 0.5% L-bupivacaine, 1% lidocaine and epinephrine (mixed to 1 in 400,000 final concentration). Maximum dose limits are dependent on weight of participants - 2 mg/kg for bupivacaine and 7 mg/kg for lidocaine with epinephrine. This is administered by single Perineural injection.

Those randomised to the LA Comparator Arm will receive a 1:1 mixture of 0.5% L-bupivacaine and 1% lidocaine. Maximum dose limits are dependent on weight of participants - 2 mg/kg for bupivacaine and 3mg/kg for lidocaine will be observed. This is administered by single subcutaneous injection.

## **Intervention Type**

Drug

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

1. Regional anaesthesia (RA): an ultrasound-guided supraclavicular or axillary block 1:1 mixture of 0.5% L-bupivacaine and 1% lidocaine with epinephrine (final concentration 1 in 400,000) 2. Local anaesthesia (LA): a 1:1 mixture of 0.5% L-bupivacaine and 1% lidocaine

## **Primary outcome measure**

1. Unassisted functional arteriovenous fistula (AVF) patency at 1 year measured as the ability of access to uninterruptedly deliver the prescribed dialysis without intervention at 12 months

## **Secondary outcome measures**

1. Vascular access complications (e.g. infection, stenosis, steal, thrombosis, bleeding) measured at 3 and 12 months  
2. Re-operation/re-intervention measured using the number of re-operations/re-interventions at

3 and 12 months

3. Alternative accesses measured using alternative access requirements at 3 and 12 months

4. Cannulation difficulties measured using access complications (inc infection, stenosis, thrombosis, steal, bleeding) at 3 and 12 months

5. Mortality measured using the number of deaths at 3 and 12 months

6. Dialysis and access modality measured using change of renal replacement therapy at 3 and 12 months

7. Access-related hospitalisation measured using a number of re-operation/re-intervention required to maintain or re-establish patency (revisional surgery, angioplasty, stenting or thrombectomy) at 3 and 12 months

8. Health-related quality of life (HR-QoL) measured using patient-reported questionnaires at 3 and 12 months

9. Cost-effectiveness measured at 3 and 12 months

10. Efficacy and safety of anaesthesia measured using perioperative pain score on a numeric rating scale (NRS 0-10) and collection of relevant adverse events at 3 and 12 months

**Overall study start date**

01/10/2020

**Completion date**

31/07/2024

## **Eligibility**

**Key inclusion criteria**

1. Aged >18 years

2. End-stage renal disease (ESRD) and receiving renal replacement therapy (RRT), or chronic kidney disease (CKD) stage IV or V and referred for primary radiocephalic (RCF) or brachiocephalic (BCF) fistula creation

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

566

**Total final enrolment**

571

**Key exclusion criteria**

1. Unable or unwilling to provide informed consent
2. Preference for general or alternative anaesthesia
3. Active infection at surgical or anaesthetic site
4. Previous ipsilateral arteriovenous fistula (AVF) creation (a previous attempt at distal AVF creation which fails immediately is not considered a contraindication, however any distal access which has previously run sufficiently to mature the outflow vein or proximal revision of an existing AVF is considered a contraindication)
5. Known ipsilateral cephalic arch or central venous stenosis (even if previously treated)
6. USS evidence of stenosis in inflow artery
7. Radial or brachial artery <1.8 mm diameter and/or cephalic vein <2 mm at wrist or <3 mm at elbow (with tourniquet) on pre-operative USS
8. Allergy to Local anaesthesia (LA) or any excipient agents
9. Acquired or inherited coagulopathy (including warfarin/ heparin/ novel oral anticoagulant use where it has not been possible to stop the anticoagulation in anticipation of surgery) and/or platelets <75 or INR >1.4
10. Significant pre-existing neurological disorder affecting the upper limb
11. Weight <45 kg

**Date of first enrolment**

01/05/2021

**Date of final enrolment**

17/05/2024

## **Locations**

**Countries of recruitment**

England

Northern Ireland

Scotland

United Kingdom

**Study participating centre**

**Queen Elizabeth University Hospital**

1345 Govan Road

Govan

Glasgow

United Kingdom

G51 4TF

**Study participating centre**

**Stobhill Ambulatory Care Hospital**

133 Balornock Rd

Glasgow  
United Kingdom  
G21 3UW

**Study participating centre**  
**Addenbrookes Hospital**  
Hills Road  
Cambridge  
United Kingdom  
CB2 0QQ

**Study participating centre**  
**Belfast City Hospital**  
Lisburn Road  
Belfast  
United Kingdom  
BT9 7AB

**Study participating centre**  
**Bradford Royal Infirmary**  
Duckworth Lane  
Bradford  
United Kingdom  
BD9 6RJ

**Study participating centre**  
**Dumfries and Galloway Royal Infirmary**  
A75 Cargenbridge  
Dumfries  
United Kingdom  
DG2 8RX

**Study participating centre**  
**The Freeman Hospital**  
High Heaton  
Newcastle upon Tyne  
United Kingdom  
NE7 7DN

**Study participating centre**  
**Guy's and St Thomas' NHS Foundation Trust**  
Westminster Bridge Road  
London  
United Kingdom  
SE1 7EH

**Study participating centre**  
**The James Cook University Hospital**  
Marton Road  
Middlesbrough  
United Kingdom  
TS4 3BW

**Study participating centre**  
**University Hospital Monklands**  
Monkscourt Ave  
Airdrie  
United Kingdom  
ML6 0JS

**Study participating centre**  
**University Hospital Hairmyres**  
218 Eaglesham Road  
East Kilbride  
Glasgow  
United Kingdom  
G75 8RG

**Study participating centre**  
**Leeds General Infirmary**  
Great George Street  
Leeds  
United Kingdom  
LS1 3EX

**Study participating centre**  
**Ninewells Hospital**  
James Arnott Dr



Dundee  
United Kingdom  
DD2 1SG

**Study participating centre**  
**Norfolk and Norwich University Hospital**  
Colney Lane  
Norwich  
United Kingdom  
NR4 7UY

**Study participating centre**  
**The Royal Free Hospital**  
Pond St  
Hampstead  
London  
United Kingdom  
NW3 2QG

**Study participating centre**  
**Royal Sussex Hospital**  
Barry Building  
Eastern Rd  
Brighton  
United Kingdom  
BN2 5BE

## **Sponsor information**

**Organisation**  
NHS Greater Glasgow and Clyde

**Sponsor details**  
Grahamston Road  
Paisley  
Scotland  
United Kingdom  
PA2 7DE  
+44 (0)141 314 4012  
Maureen.Travers@ggc.scot.nhs.uk

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.nhs.uk/ggc.org.uk/>

**ROR**

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

## **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**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal within 1 year after the end of trial.

**Intention to publish date**

31/05/2025

**Individual participant data (IPD) sharing plan**

The trial statisticians, health economist, and TSC will have access to the full dataset. Site investigators will be able to access the full dataset if a formal request describing their plans is made to the steering group.

The trial protocol, full trial report, anonymised participant-level dataset, and statistical code for generating the results will be made publically available within 12 months of the End of Trial via an online data repository and by direct request from the CI

Data is being collected via eCRF hosted by the Robertson Centre for Biostatistics at Glasgow University. Anonymised data entered into the eCRF will be managed and stored by the RCB in line with the detailed Data Management Plan, which will be developed for the study in line with approved templates, reviewed regularly, and all members of the project team will adhere to the plan, and well established local SOPs. All anonymised trial data will be retained for 10 years following End of Trial Glasgow CTU (of which RCB is part) will serve as custodian of the data generated from this trial.

**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>		22/12/2021	30/12/2021	Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Other publications</a>	reflections on recruitment and process evaluation study	04/08/2025	05/08/2025	Yes	No