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

Submission date
16/10/2020

Recruitment status
No longer recruiting

Registration date
27/10/2020

Overall study status
Completed

Last Edited
05/08/2025

Condition category
Surgery

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

Type(s)
Scientific

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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
Dumfires
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.nhsggc.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?
Protocol article		22/12/2021	30/12/2021	Yes	No
HRA research summary			26/07/2023	No	No
Other publications	reflections on recruitment and process evaluation study	04/08/2025	05/08/2025	Yes	No