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Is it feasible to compare two methods of needle insertions for use in kidney dialysis treatment?

Submission date
21/08/2020

Recruitment status
Stopped

Registration date
25/08/2020

Overall study status
Stopped

Last Edited
22/07/2022

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
The kidneys usually filter and remove waste products and excess fluid from the blood. Haemodialysis is a way of replacing some of the functions of your kidney, if your kidneys have failed, by using a machine to filter and clean your blood. Blood is pumped out of your body to the machine where it is passed through a series of tiny tubes, in an ‘artificial kidney’ or ‘dialyser’. The tubes are made of a special membrane that allows waste products and fluid to pass across it. People are normally connected to the dialysis machine through two needles which are inserted into a ‘fistula’ or ‘graft’, usually in your arm. One needle takes your blood to the dialysis machine and the other needle brings back your cleaned blood.
Patients with kidney failure require haemodialysis three times a week, for a period of years. The frequent needle insertions can damage the fistula, eventually causing it to fail. 2 techniques have been developed to reduce this damage - 'buttonhole' and 'rope ladder'.
Previous studies have compared these 2 techniques, but obtained differing results. Systematic reviews recommend a multi-centre randomised controlled trial (RCT) to compare techniques.

This feasibility trial will explore the feasibility of a multi-centre RCT to compare buttonhole to rope ladder when used for haemodialysis. It will focus on whether fidelity of the needle insertion procedures is maintained to allow accurate comparison and whether proposed clinical outcomes are feasible, including patients' perspectives of the needle insertion.

Who can participate?
The study includes both haemodialysis patients and nursing staff.
Patient participants can be a haemodialysis patient who has new arteriovenous fistula that has been used for haemodialysis for less than 6 months.
Nursing staff participants can include any registered or unregistered nursing staff who undertake cannulation for patient-participants.

What does the study involve?
The feasibility trial will be mixed methods, lasting 6 months, recruiting 40 patients at 2 sites. Each patient will be randomised to either buttonhole or rope ladder and undergo this technique for routine haemodialysis treatments, for 6 months. They will
complete a monthly questionnaire to capture their perspective of the needle insertion and may

have the needle insertion procedure observed on selected occasions. Data will also be collected on complications, including the function of the fistula and infection. After 6 months, a selection of patients from both study arms will be asked to undertake an interview to describe their experience of having needles inserted for haemodialysis. Patient participants will also be asked to complete a questionnaire, with some invited for an interview, to explore experiences of being part of the study. Nursing participants will provide data to assess feasibility of the RCT through a questionnaire and focus groups.

What are the possible risks and benefits of participating?
The information we get from this study may not help participants directly. In the future, we hope that it will help us to design a research study that will allow us to determine whether 'rope ladder' or 'buttonhole' is best. This will also help us determine for which individual patients each technique is best. This is the first study to collect information on patients' experiences of each technique. It will help us understand patients' views of their needle insertion for haemodialysis.
Risks and Problems: Whilst we know needling comes with risks of complications, we do not know the risks of each needling technique. One of the reasons this research is needed, is so we can determine whether one technique is less risky than another is. There is a risk that one technique may cause more problems that the other. We will be monitoring possible problems through the study. These problems may happen anyway, regardless of the technique you use, as they are a risk of needling. If you develop one of these problems, you will receive normal treatment from your clinical care team.
Time inconvenience: completing the questionnaires will take some time, approximately 5-10 minutes each time participants are asked to do this. The interviews will also happen away from haemodialysis, so if participants are asked to do this, this will use approximately 1 hour of your time.
Upset and Worry: Thinking about needling for haemodialysis, on rare occasions may make participants feel worried or upset about this procedure.

Where is the study run from?
This study is run by Derby Clinical Trials unit and University Hospitals of Derby and Burton NHS Foundation Trust. This involves healthcare professionals and researchers from University Hospitals of Derby and Burton NHS Foundation Trust, University of Nottingham, Nottingham University Hospitals and University of Bristol (UK).

When is the study starting and how long is it expected to run for?
October 2018 to July 2022

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

Who is the main contact?
Catherine Fielding, katie.fielding@nhs.net

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
274355

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 44529, IRAS 274355

Study information

Scientific Title
A mixed-methods trial to explore the feasibility of comparing buttonhole to rope ladder cannulation of arteriovenous fistulae for haemodialysis

Study objectives
The aim of this feasibility trial is to determine the feasibility of use of the cannulation protocols, patient experience measures and clinical outcomes measures for a multi-centre RCT to compare buttonhole versus rope ladder cannulation of AV fistulae for haemodialysis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/08/2020, Derby Research Ethics Committee (The Old Chapel, Royal Standard Place - Research Ethics Office, Nottingham, NG1 6FS, UK; +44 (0)207 104 8211; derby.rec@hra.nhs.uk), ref: 20/EM/0001

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Participants will be randomised to either use buttonhole or rope ladder cannulation technique, when initiating their haemodialysis treatment, for a period of 6 months. To be able to perform haemodialysis, the AV fistula has to be cannulated with 2 needles, known as the 'arterial' and 'venous' needle. However, both needles enter the same vessel at different points.

For both cannulation techniques, selection of cannulation sites should follow local policy, but should include the following criteria:
• 2 inches away from the anastomosis
• Away from division, dips and 'wiggles' in the vein
• The vessel should have adequate diameter and maturity to support adequate flows for HD. This is normally at least 0.5cm, but is often dictated by clinical judgement rather than measurement of the diameter.

Buttonhole Cannulation
Buttonhole cannulation involves inserting the needle into the cannulation site in the same manner each time that cannulation site is used. Normally there are only 2 cannulation sites, one for the arterial needle and one for the venous needles, which are used at every haemodialysis session. However, some patients may have 3 or 4 sites that are rotated between sessions.
This type of cannulation involves removing the scab prior to inserting the needle. The needle is then inserted at the same angle and depth each time. It involves development of a track scar tissue using sharp needles, where the cannulation is performed in exactly the same manner each time. Once the track is developed, only blunt needles are used to ensure the needle enters the vessel in exactly the same manner each time.
Sites should not be used if there are signs of infection, bruising, the area feels hard or there is evidence of skin breakdown beyond the parameters of the normal cannulation site or in the area around the site.

Rope Ladder Cannulation
Rope ladder cannulation involves progressing up the vessel in a systematic manner, with each cannulation. Once the top of the vessel is reached, cannulation should start again at the bottom. As cannulation sites will change at each haemodialysis session, the vessel develops cannulation segments spanning multiple cannulation sites for each needle (arterial and venous needle). Each cannulation segment for arterial and venous needle should cover at least 5cm. If the 2 segments join (i.e. meet in the middle of the vessel), they should cover at least 8cm together.
NB. the progression of sites is not limited to 5, but dictated by the length of vessel and should meet the minimum criteria set above.

Randomisation will be 1:1 and stratified by site to gain equal numbers of patient participants for each study arm in each site. Randomisation will be performed using a web based system, Sealed Envelope (https://www.sealedenvelope.com/). This will ensure allocation is concealed.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Feasibility outcomes:
1. Time to complete clinical outcome data collection measured by timing how long it takes to complete CRF for 5 patients at baseline, and monthly for 6 months
2. Completion rates of data measured by % of missing date from CRF and patient's perspective of needling questionnaire at 6 months
3. Recruitment rates as defined as the number of patients:
3.1. Available on haemodialysis
3.2. Eligible for the study
3.3. Approached to participate in the study
3.4. Recruited to the study
3.5. Retained within the six month study period
measured using the screening log and enrolment log at the end of trial
4. Reasons for non-participation in study measured using the screening log at the end of trial
5. Reasons for loss-to-follow up measured using loss to follow up semi-structured interviews and loss to follow up
questionnaire on withdrawal from trial
6. Patients experiences of being part of the study measured using patient evaluation questionnaire and patient feasibility semi-structured interviews at 6 months
7. Staff experiences of being part of the study measured using the staff evaluation questionnaire and staff semi-structured focus groups at the end of trial
(added 26/08/2020):
8. Fidelity of the cannulation procedure measured by structured observation using an Observation Checklist in a random selection of 4 participants (1 on each study arm at each site) each month throughout the trial

Key secondary outcome(s))
1. Patient experience of needling measured using the patient's perspective of needling questionnaire (PPN) and patient experience semi-structured interviews monthly for 6 months
2. Patency of AVF fistula measured by:
2.1. Length of time AV fistula used for
2.2. Number of procedures to correct AV fistula function
2.3. Miscannulation
2.4. Fistula problems
all at 6 months
3. Infection measured throughout the study using:
3.1. Rate of bacteraemia (determined by positive blood culture)
3.2. Rate of exit-site infection (determined by positive wound swab with signs of infection (redness, heat. exudate or pus)

Completion date
03/07/2022

Reason abandoned (if study stopped)
This study was originally due to start recruitment in March 2020. However, due to the COVID-19 global pandemic we could not open the study as planned at either site. We suspended the study and aimed to start the end of September 2020. However, we were unable to start at this point due to significant clinical pressures on haemodialysis units across the UK due to COVID-19. This

meant the study had to be suspended until 2021. As this study was funded by a PhD fellowship from the NIHR. This further suspension meant the study could not happen within the deadlines for the PhD or fellowship. Therefore the study was temporarily suspended until September 2022, with an aim to secure funding to complete this study. Funding has not been secured for this study and the current context has changed, particularly through the release of new research knowledge, that means this study requires significant changes. Therefore, we have made the decision to abandon the study without ever opening it or recruiting any participants.

Eligibility

Key inclusion criteria
The study will only include the following type of patients:
1. Adult, in-centre haemodialysis patients
2. Undergoing intermittent haemodialysis or haemodiafiltration, using an AV fistula that has been cannulated for haemodialysis for no longer than 6 months, using any cannulation technique and regularly using two needles for haemodialysis (i.e. more than 75% of the time)
3. Undergoing cannulation performed by registered or unregistered staff in the haemodialysis nursing team
4. Able and willing to complete a questionnaire, either independently or with support from a carer
5. Patients aged 18 years or older with the capacity to provide informed consent
6. Agree to not use topical or sub-dermal local anaesthetic during the cannulation procedure in the study period

Patients undergoing shared care, where they perform part of the cannulation procedure, will not excluded, as long as nursing staff insert the fistula needle.

As this is a feasibility study, it will also include:
Registered or unregistered nursing staff working in dialysis units, who perform cannulation of AV access for haemodialysis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
The study will exclude any haemodialysis patient with a clinical reason not to perform one of cannulation techniques*, which would prevent true randomisation. Criteria that should exclude patients for this reason include:
1. Grafted or stented sections on the AV fistula

2. Metallic heart valve or pacemaker
3. Previous positive MRSA screens of swabs in last 12 months
4. Previous positive MSSA screens of swabs in last 3 months or a history of more than 3 MSSA positive screens
5. Previous positive MRSA or MSSA bacteraemia in last 5 years
6. Previous endocarditis in the last 5 years
7. Previous or known allergy or skin reaction attributed to chlorhexidine or alcohol
8. Current rash or skin wounds over AV fistula vessel
9. Tortuous vessel with no straight segment of at least 7cm
10. Active infection in the AV fistula, being treated with antibiotics
11. Plan to perform a live related kidney transplant in next 6 months
12. Plan to self-cannulate or initiate carer cannulation in the next 6 months
*As per BRS & VASBI recommendations, buttonhole technique should be avoided in patients with high infection risk and rope ladder cannot be performed in vessel with short cannulation segment.

The following nursing staff will be excluded:
1. Nursing staff who have never performed cannulation of trial participants
2. Nursing staff undergoing training to perform cannulation of AV access for haemodialysis, who are yet not deemed competent to perform this without supervision
3. Student nurses or non-English nurses currently undertaking an adaption course to become registered nurses in the UK
4. Bank or agency nursing staff not employed by participating NHS renal units

Date of first enrolment
28/09/2020

Date of final enrolment
03/07/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Derby Hospital
University Hospitals of Derby and Burton NHS Foundation Trust
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre

Queen's Medical Centre
Nottingham University Hospitals NHS Trust
Derby Road
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University Hospitals of Derby and Burton NHS Foundation Trust

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: ICA-CDRF-2018-04-ST2-00

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 datasets generated during and/or analysed during the current study are not expected to be made available due to issues raised by ethics committees in consent forms where this was included. Therefore, this could not be included in consent forms.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version v2.0	01/08/2020	25/08/2020	No	Yes
Participant information sheet	version v2.0	01/08/2020	25/08/2020	No	Yes
Protocol file	version v2.0	27/07/2020	25/08/2020	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes