Staff Participant Information Sheet

(1st August, 2020 – Version 2.0)

Title of Study: A Mixed Methods Trial to Explore the Feasibility of Comparing Buttonhole and Rope Ladder Cannulation of Arteriovenous Fistulae for Haemodialysis

AF-CaT Feasibility: AV Fistula Cannulation Trial

IRAS Project ID: 274355

Name of Researchers: Katie (Catherine) Fielding, Sarah Brand, Kelly White, Nicholas Selby, Charlotte Bebb, Heather Buchanan, Fergus Caskey, Maarten Taal

We would like to inform you about a research study happening in you renal unit. We would like you to understand why the research is being done and what it would involves. Please take time to read the following information carefully. Feel free to ask for more information or to clarify parts of the study that you do not understand. Our research team are happy to discuss questions when we are on the haemodialysis unit. There are parts of the study that include patients and other parts that involve nursing staff. At times, we will be asking nursing staff to consent to take part in the study. You have a choice whether to be part of the study and if you decline, this will not affect your employee rights.

This study aims to determine the best way to compare buttonhole and rope ladder needling technique. To do this we will randomly assign 40 haemodialysis patients with new fistulas to one of these techniques, 20 in Nottingham and 20 in Derby. The patient will undergo the technique they are randomised to at each haemodialysis session for 6 months. We will collect data on patients' perspectives of the technique, clinical data and patients and nursing staff's experiences of being part of the study. Study activities for nursing staff are undergoing observation whilst performing cannulation, completing a questionnaire and focus group about the study.

This study is part of an educational qualification (PhD) for Katie Fielding.

More detailed information is in the sections of this leaflet.

Purpose of the Study

What is the purpose of the study?

Previous research studies have compared buttonhole and rope ladder cannulation techniques and disagree as to which is best. Flaws in these studies may have influenced results.

Our study will explore how best to perform a study to compare the two needling techniques. This is known as a feasibility study. This will help ensure future research will produce results that are useful in everyday practice. This study will not let us know which needling technique is best, but let us know how to design a study to compare the two techniques.

Who is organising and funding the research?

This research is being organised by Katie Fielding, with support from Dr. Nicholas Selby from Derby and Dr. Charlotte Bebb from Nottingham. This work is part of a PhD project that is supported by Health Education England and the National Institute of Health Research. The study is supported by 'University Hospitals of Derby and Burton NHS Foundation Trust' (UHDB).

Who has reviewed the study?

Independent group of people called a Research Ethics Committee, looks at all research in the NHS/ This protects your interests. This study has been reviewed and given favourable opinion by the Derby ResearchEthics Committee.

Why am I being included in the study?

We are inviting nursing staff to take part in the study, to obtain your opinions and experiences of the study. This will guide us as to how to design a larger study to compare the two cannulation techniques.

We will also be observing nursing staff who undertake the cannulation of patients included in the study. Whether you are asked to do this will depend on whether you are performing the cannulation on the days we visit your unit. You can decline to be observed.

Do I have to take part?

No. It is completely up to you to decide whether to take part. If you decide to take part, you are still free to withdraw at a later date. This will not affect your employee rights

What does taking part involve?

As a member of the nursing team, you may be asked to take part in one of 3 activities:

- Be observed cannulating a patient who has agreed to be part of the study - this will allow us to assess how easy the cannulation procedures are to follow and whether cannulation is consistent between different cannulators. This is not an assessment of your cannulation skill.
- Complete a questionnaire – this will allow us to assess how and easy and practical the study was to implement from your perspective.
- Take part in a focus group – this will also allow us to assess how easy and practical the study was to implement and identify ways to improve the study.

You may be asked to take part in only one of these activities or more than one of these activities.

What will happen if I agree to be observed as part of the study?

If you are asked to be observed when cannulating a patient participant in the study, one of our research team will initially explain what this will involve and ask if you are willing to be observed. If you are willing to be observed, the researcher or research nurse will ask you to sign a form to say you consent to be observed. You will then be observed cannulation the patient in one of two ways:

1) The researcher will observe you performing the cannulation, using a checklist to assess your compliance with the cannulation procedure. The researcher will also ask you some details about your level of experience and training. During the observation, the researcher may inform you of any actions that are potentially unsafe for patient participants. This will be done to maintain the safety of the patient and to inform you as to the correct way to do this. This will not be a criticism of you or your practice.
2) A research nurse will video the cannulation. We will take measures during the video not to include your face or identify you. We ask that you do not name the patient, any other patients or staff members, including yourself, in the video. The research nurse will also ask you some details about your level of experience and training and may ask you for information about how you cannulated the patient. The renal unit may later receive feedback about any actions that are identified as potentially unsafe for patient participants. However, this will be provided without identifying you.

If the researcher or research nurse is unduly concerned about your practice, she may verbally inform your line manager. This is as her duty of care as a registered nurse. However, beyond this duty of care, any details recorded about the observation or yourself will remain anonymous. The observation checklist will not be shared with your line manager.

What will happen if I agree to complete a questionnaire?

At the end of the study, nursing staff who have cannulated study participants will be asked to complete a questionnaire about the study. If you agree to complete the questionnaire, you will be asked to sign a form stating you consent to this. You will then be given the questionnaire to complete and the researcher will arrange to collect this at a later date.

The questionnaire will be anonymous, but may ask you details about your clinical and demographic background. Quotes from the questionnaire may be used during presentations and publications. However, these will be anonymised, where others will not be able to identify you from these quotes or know they come from you. We will also use answers from questionnaires to guide questions in the focus groups, but again no one will know you have completed the questionnaire.

What will happen if I take part in a focus group?

At the end of the study, nursing staff who have cannulated study participants may be asked to take part in a focus group. This will be advertised through posters in your staff room and at nurses' stations. If you agree to take part in a focus group, this will be arranged at a time that is suitable for all participants. It will be held in a private room in the hospital. This may be outside of your normal working hours. Just before the focus group starts, you will be asked to sign a form to state you consent to take part in the focus group.

The focus group will include other nursing staff from your renal unit and last about 1 hour. During the focus group, we will discuss everyone's opinions on the study and ways to improve implementation of the study. This will help us design a future larger study. A member of the research team will facilitate the discussion. All members of the focus group will be expected to respect others' opinions, even if they do not agree with them.

The focus group will be recorded using a digital recording device. However, the discussions in the focus group will remain anonymous to those outside of the room. The research team may use quotes from the focus group, but these will be anonymised before use. You may be asked to provide details of your clinical experience, which again will be anonymised.

If the coronavirus pandemic is still active when the focus group is performed, this may be completed via a video link with the researcher.

What are the disadvantages if taking part in this research?

The disadvantage of taking part in this research is time inconvenience:

- The observation will be part of your normal working day
- Completing the questionnaires will take some time, approximately 10-20 minutes
- The focus group will take approximately 1 hour and may happen away from the work area

What are the possible benefits of taking part?

The information we get from this study may not help you 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.

Expenses and payments

Unfortunately, no payment can be offered to you for your participation in this study. If you are invited to a focus group, you will be provided with a £20 voucher as a 'thank you' for giving your time to us and a drink and snack will be provided.

How will we use information about you?

As the sponsor for the study, UHDB are responsible for looking after your information and using it. We will need to use information from you medical records for this research project.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our website: https://www.uhdb.nhs.uk/research-how-we-use-your-information
- by asking one of the research team

Other Information about the Study

How does this research fit with other research?

This study is part of a larger study examining cannulation practices for haemodialysis. The questionnaire we are using this part of the study, was developed in an earlier part of the study.

What will happen to the results of the research study?

The results will be published and may lead to further research studies or a change in the way we manage patients with chronic kidney disease. We will send you an information sheet letting you know the results and what they mean.

The results of the study will be submitted to journals for publication and to scientific meetings for presentation. A report of the results will also be published. You will not be identified in any report/publication. Copies of these will be available on request where possible.

What to do if there is a problem

What if there is a problem?

If you have any concerns or queries about any aspect of this study or wish to complain, you should ask to speak to Katie Fielding, who will do her best to answer your questions. If you remain unhappy, we will arrange for you to speak with Dr. Selby (in Derby) or Dr. Bebb (in Nottingham), who will be overseeing Katie's involvement in the study.

At any time, if you have concerns and wish to speak to someone independent of the study, you can contact the Patient Advice and Liaison Service (PALS) using the details below.

What will happen if I do not want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your employee rights being affected.

Contact details

Katie Fielding - The dialysis unit can contact Katie via phone.

katie.fielding@nhs.net

Dr. Nicholas Selby - 01332 724665

nicholas.selby@nottingham.ac.uk

Dr. Charlotte Bebb – 0115 969 1169 ex.56297

Charlotte.Bebb@nuh.nhs.uk

Patients Advice and Liaison Service (PALS) - Derby

0800 783 7691 or 01332 785156 or 07799 337500

dhft.contactpals@nhs.net

Patients Advice and Liaison Service (PALS) – Nottingham

Contact via hospital switchboard - 0115 969 1169

To find out more about the regulation of Research within the NHS visit: www.nres.nhs.uk

Information Given to Patient about the Study

Below is a copy of information given to patients about the study. You are not required to read this, but this may be of interest to you.

Needling for Haemodialysis

What is Needling for Haemodialysis?

'Needling' is when the needles are put into your arm or leg at the start of haemodialysis. Needling is sometimes known as 'cannulation'.

This happens when you use a fistula or graft for haemodialysis. The nurses, you or a carer can put in the needles. This study will only include patients who are using a new fistula for haemodialysis, where the nurses are putting your needles in.

The procedure for needling for haemodialysis normally involves these steps:-

1) The nurse will ask you about previous needling and look at and feel the fistula
2) The nurse decides where to put the needles, with help from yourself
3) The nurse prepares the equipment and cleans the needle sites
4) The nurse inserts the bottom needle, often known as the 'arterial needle'. This is normally the needle closest to your hand / foot, unless your fistula is different.
5) The nurse tapes the arterial needle in place and flushes the needle to check it is working. Flushing is when the nurses pull the syringe back and forth, moving the blood in the needle.
6) The nurse inserts the top needle, often known as the 'venous needle'. This is normally the needle closer to your shoulder / groin, unless your fistula is different.
7) The nurse tapes the venous needle in place and flushes the needle to check it is working.
8) You are connected to haemodialysis.

What are the Risks of Needling for Haemodialysis?

The needling at start of haemodialysis can come with a number of risks and problems. These can include:

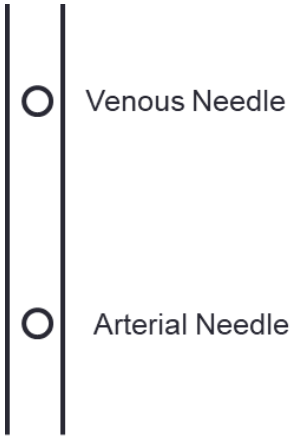
- More than one attempt to put the needle in
- Unable to insert a needle that works well for haemodialysis
- Pain
- Bruising
- Scars and lumps

- Bleeding
- Infection
- Damage that can cause the fistula to stop working

These problems can happen with any needling technique. We know these problems cause a lot of concern and distress for haemodialysis patients. However, we do not know whether these problems will happen more or less with 'buttonhole' or 'rope ladder'. This is why we need research studies looking at these needling practices.

Buttonhole Technique

Buttonhole involves putting the needles in the same place each time you have the needles put in. You normally only have two cannulation sites on your arm or leg, like the images below:

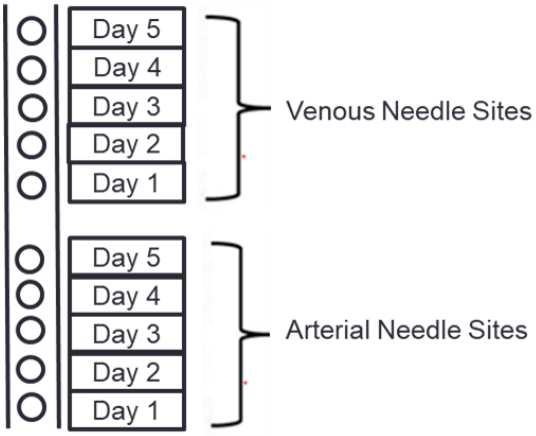


To be able to put the needle into the same hole as last time, the nurse will need to remove the scab from the previous needling. They will also clean your arm twice, before removing the scab and after. Buttonhole develops a 'track' to the fistula. This normally takes about 2-4 weeks. Once the track is formed, they will use different needles, known as 'dull' or 'blunt' needles. When you have the needles removed at the end of your dialysis, anti-biotic cream will be put on the needle sites.

You can use up to 4 different sites with buttonhole, as sometimes sites can become sore. Buttonhole is used for most patients who dialyse in Derby, although this study may change which technique you use.

Rope Ladder Technique

Rope ladder involves putting the needles in a different place each time they are put in. However, where they are placed is still planned and this is not ad hoc. With rope ladder, the needling moves up the fistula each time, as shown in this image:



Once the top of the fistula is reached, needling starts at the bottom again. The image shows 5 sites, however this is just an example. With rope ladder, we will try to use as much of the fistula as we can. Rope ladder is used for most patients in Nottingham, although this study may change which technique you use.

What does taking part involve?

What will happen to me if I take part?

If you are considering taking part, one of our research team will contact you and arrange to meet you to discuss the study. This is likely to be during one of your regular dialysis sessions. You will have an opportunity during this initial meeting to discuss any questions you may have. We will also check with you at this point that it is possible and safe for you to take part. After this, you will be asked to sign a form to say you consent to be part of the study. Once you have agreed to take part in the study, we will arrange for you to start the study.

Once you start the study, we will randomly allocate you to either 'rope ladder' or 'buttonhole'. This will be done using a computer system and we will have no control over how you are allocated. This will not be related to whether you dialyse in Nottingham or Derby or what your clinical team normally recommends. We will then use this technique each time you have haemodialysis, for a period of 6 months. Apart from choosing which needling technique is used, the study will change nothing else about your haemodialysis.

For the 6 months you are in the study, we will collect data on:

- How the needling is performed by the nurses
- Your opinions on the needling technique
- Whether you get an infection
- How much damage the needling causes
- Other clinical outcomes including how well you dialyse, your blood test results and whether there is any problems with the needling
- Your opinions on being part of the study

To collect this data we will:

- Observe the nurses putting your needles in. This will happen a maximum of 6 times whilst you are in the study or may not happen at all. During the coronavirus pandemic, we may need to video this procedure, as the researcher may not be able to visit you. During the video, we will take measures to avoid videoing you face or identifying you, although this may not be possible in all situations. We will ask you to try to avoid using any staff or patients' names whilst the video in being taken. The video will be sent to the researcher, who will view this on a secure computer and then delete it.
- Ask you to complete a questionnaire every month. This will take you 5-10 minutes each time.

- You will also have your temperature taken every month. This will happen during your haemodialysis.
- Patients in Nottingham renal unit will have an extra blood test taken to their normal routine blood samples, known as the 'CRP' blood test. This will be taken at the same time as normal routine samples, so will not require any extra procedures or needles. However, this may mean slightly more blood is taken. This 'CRP' blood test can help monitor you for infection. It is already included in routine blood samples at Derby.
- At the end of the study, we may ask you if you are willing to take part in an interview to find out more information about your opinions on the needling technique. This will take approximately 1 hour.
- We will also ask you to complete a questionnaire about your experiences of being part of the study. This will take you 15-20 minutes.
- We may also ask you if you are willing to take part in an interview to find out more about your experiences of being part of the study. This will take approximately 1 hour.

Interviews will be arranged at your convenience, away from the haemodialysis unit. Interviews can happen face-to-face, via telephone or via video call, as you would prefer. During the coronavirus pandemic, we will only perform interviews via telephone or video calls and we will not perform interviews face-to-face, to reduce the risk of transmitting the virus to you. These are the only study activities that will not happen whilst you are on haemodialysis.

Your answers to interviews and questionnaires will be linked to other research data, so the research team will know your answers to questions. If you complete an interview, we may ask about your answers in questionnaires, to help us get more information. We still encourage you to be honest in your answers to questions. Clinical staff and those outside the research team will not be aware of your personal answers to questions and only be able to view these once anonymised. We may also use quotes from interviews and questionnaires during presentations and publications. However, these quotes will be anonymised, where others will not be able to identify from the quote or know they come from you.

What are the possible disadvantages and risks of taking part?

The disadvantages of taking part are:

- 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 was ask you to do this. The interviews will also happen away from haemodialysis, so if you 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 you feel worried or upset about this procedure. If at any point in time you would like to discuss your needling, please ask to speak with Katie Fielding, one of the dialysis nurses or another member of your healthcare team. Katie is an experienced haemodialysis nurse, so understands the needling process and is happy to discuss this.

What are the possible benefits of taking part?

The information we get from this study may not help you 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.

Expenses and payments

Unfortunately, no payment can be offered to you for your participation in this study. Transport to and from dialysis will be as your usual arrangements. If you are invited to an interview, you will be provided with a £20 voucher as a 'thank you' for giving your time to us.

Why might we stop you being part of the study?

We do not expect anything to go wrong. However, under certain circumstances, we may decide to withdraw you from the study for the following reasons:-

- If you become unable to complete the questionnaire
- If you lose the ability to tell us if you want to remain in the study
- If you decide to start needling yourself
- If you develop a severe complication from the needling, including a wound or infection
- If you have a procedure where your fistula changes and it is not safe to use the needling techniques anymore
- If you stop being able to use your fistula for haemodialysis
- If you stop haemodialysis for any reason.

If this happens, we will do our best to discuss this with you, if this is possible.

If we withdraw you from the study, we will use the data we have collected from you so far, but will use no further data.

What will happen if I get coronavirus whilst I am part of the study?

You can still remain part of the study if you catch coronavirus. During this time, you will still need to have your haemodialysis and it still safe to have your allocated needling technique. Some study activities may be delayed, to reduce how many people you have contact with in this time, but none of this will affect your haemodialysis treatment. If you become very unwell with coronavirus, we may withdraw you from the study. This will happen because you are too unwell to remain part of the study, not because you have coronavirus.