Patient 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

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We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve. 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 see you on haemodialysis or you can ask to see us. You have a choice whether to be part of the study and if you decline, this will not affect your rights or medical care. If you wish you can talk to other doctors, nurses, friends and family about the study, please feel free to do so.

This study aims to determine the best way to compare buttonhole and rope ladder needling technique. To do this we will randomly assign you to one of these techniques. For 6 months, the nurses will use your allotted technique each time you have haemodialysis. We will collect data on your experience of the technique and being part of the study as well as some clinical data. Study activities will mainly coincide with your haemodialysis treatment, so these will require no extra visits. You may be asked to attend a maximum of two interviews away from haemodialysis, each taking about 1 hour. We will keep any personal information we collect secure and only share with researchers and authorised personnel as required. 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?

There are two different needling techniques used for haemodialysis. One is called 'rope ladder' and one is called 'buttonhole'. Previous research studies have compared these two 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 sponsored 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 is to protect your interests. This study has been reviewed and given favourable opinion by the Derby Research Ethics Committee.

Why have I been invited?

You are being invited to take part because you receive (or are going to be starting) regular haemodialysis for chronic kidney disease using a new fistula. We are inviting 40 people like you, in two renal units (Derby and Nottingham), to take part.

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 any time and without giving a reason. This would not affect your legal rights. If you withdraw or decide not to take part, it will not affect the standard of care you receive in any way.

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:

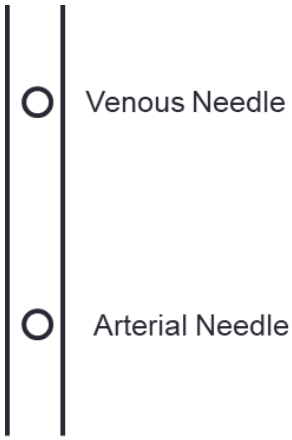
- More than one attempt to put the needle in
- Unable to insert a needle that works well for haemodialysis
- Pain
- Bruising
- Scars and lumps
- Bleeding
- Infection
- Damage that can cause the fistula to stop working

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:

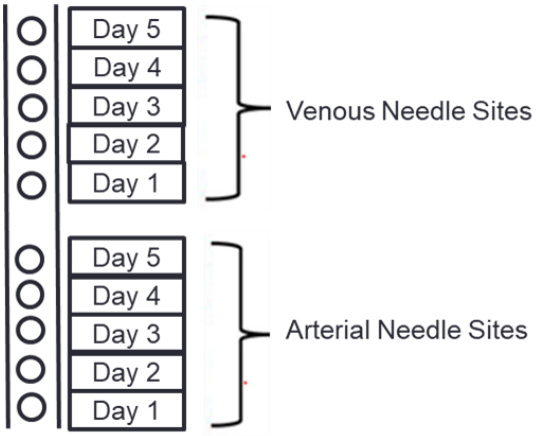


To be able to put the needle into the same hole as last time, the nurse will need to remove the scab from the previous needling. They will also clean your arm twice, before removing the scab and after. Buttonhole develops a ‘track’ to the fistula. This normally takes about 2-4 weeks. Once the track is 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. The video will focus on the needle insertion only. 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.

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 and your medical records for this research project.

This information will include your, name and date of birth. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name. Your data will have a code number instead.

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

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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?

When the research study ends, no changes will be made to your treatment and we will analyse the data. 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 legal rights being affected. If you choose to withdraw from the study, we will ask if you are willing to take part in an interview. This will last approximately 1 hour and arranged at your convenience. You can decline to take part in this interview.

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