LVI LEEDS VASCULAR INSTITUTE

NHS The Leeds Teaching Hospitals NHS Trust

Can a dedicated CLTI clinic improve patient self-reported quality of life?

(Participant information leaflet)

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with relatives, friends or carers if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Consumers for Ethics in Research (CERES) publish a leaflet entitled 'Medical Research and You'. This leaflet gives more information about medical research and looks at some questions you may want to ask. A copy may be obtained from CERES, PO Box 1365, London N16 0BW. Thank you for reading this.

What is the purpose of the study?

Chronic limb-threatening ischaemia (CLTI) is a serious condition of the arteries that results in inadequate blood flow to one or both of your legs, resulting in pain, ulcers and/or gangrene. Patients with this condition require various tests and, often, an operation to improve blood flow to the affected leg(s) to save it. More than half of CLTI patients are older and often have other health problems that can make operations very risky.

Previously, patients with this condition could only be admitted to hospital to have their tests and operations; the hospital stay was often long and inefficient. There is a national and international drive to improve outcomes for patients with this condition.

Recently, we have started running a specialist clinic for patients who have the condition, instead of admitting them to hospital. The aim is to minimise the length of time you might need to spend in hospital, minimising possible complications and to improve your experience. The clinic is run by our specialist nurses and consultants to arrange the relevant tests, and any operations or other procedures you may require.

In addition, we have clinics run by a specialist team who can try and improve other health problems before an operation, talk to you about whether an operation is in your best interests, or if it might be too risky. We call this service the **P**eri-operative medicine for the **O**lder **P**erson undergoing **S**urgery (**POPS**) service, and if we feel that it would be beneficial for them to see you, we arrange this as part of your routine care.

We have designed these services with patients in mind, in order to try and improve the experience and outcomes for patients. We would like to ask participants what they think of the service, if it has made their lives better, and if anything else can be done to improve.

Why have I been chosen?
You have been chosen because you are suspected to have a diagnosis of CLTI and are being seen in the clinic. Participants in this study have not been chosen at random, rather they are selected because they have the medical condition of interest and have used the service we want to assess.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You are still free to stop at any time without giving a reason. This will not affect the standard of care you receive. If you do not wish to take part, you will still see our nurses and consultants, and have all the relevant tests and procedures.

What will happen to me if I take part?
If you agree to participate, we would ask you to complete a standardised Quality of Life questionnaire:

- before the first clinic appointment
- 6-12 weeks after all the scans and treatment is complete
- at 12 months after your treatment has finished.

These interviews can be done in person at your regular clinic appointments, or over the telephone. You do not need to come to clinic especially to answer the questionnaire. We would hold you personal data for up to 12 months after your involvement in the study has finished, and your research data for 5 years total.

After your first appointment in the CLTI clinic, we would also like to know your opinions in a feedback survey. We only need to ask this once. If you have other health problems and are over 65, and are referred to the POPS service, we would ask if you would be prepared to fill out a feedback survey on the opinions of the service you received. Again, we only need to ask this on one occasion.

The main purpose of this study is to observe how the CLTI clinic helps people with the condition, and to what extent it improves people's lives by asking you and other participants to tell us how your Quality of Life has changed as a result of being seen in the clinic. We also want to know what you think of the CLTI clinic and / or POPS clinic.

If we discover that you do not have CLTI, we will not ask you to complete any further questionnaires after the initial one.

What do I have to do?
All you are required to do is to complete the questionnaires detailed above during different points within your treatment journey.
The questionnaires are electronic and if you feel unable to answer the questions yourself, you can tell a researcher your response and they can answer on your behalf. Similarly, if you struggle with memory impairment, you can ask a relative or carer to help you answer. The questionnaire can also be done over the telephone.

What are the possible disadvantages and risks of taking part?
The only disadvantage of taking part is it may lengthen your hospital visit. We plan to give you the surveys whilst you are attending for your appointment, however, and the survey takes less than 5 minutes to complete. **If you run into any problems, please tell one of the researchers, or the doctors and nurses in clinic** as we are here to help you. You can call one of our Nurse Specialists on 0113 392 0943.

If you don't feel that your concerns have been dealt with, please contact the Patient Advice and Liaison Service (PALS) on 0113 206 6261, 07468753025 (textphone if you have hearing and/or speech impairments) or email patientexperience.leedsth@nhs.net.

What are the possible benefits of taking part?
The benefit is that you can help shape services to better suit your needs. We are conducting this study to see if the changes we have made actually help the patients who it is designed for; your feedback can tell us whether we are helping you and how we might change it. This could improve your care and also for other patients in the future.

What happens when the research study stops?
When the research study stops, we will analyse your responses and those of other participants. We will use these responses to help us determine if the CLTI clinic has made any meaningful improvements to your life. If it hasn't, we can look at your feedback and try and take this onboard to change the service for the better. We will keep your answers anonymous and stored safely for a maximum of 5 years before it is deleted.

Will my taking part in this study be kept confidential? Mostly yes. If you agree to take part, you are required to sign a consent form, which you may keep a copy of, and the hospital another. It is also good practice for us to tell your GP that you are participating in the study. No one aside from you, the researchers, or your GP will know. The responses from the survey are anonymous and we will ensure you are not identifiable individually. **Everything you say/report is confidential unless you tell us something that indicates you or someone else is at risk of harm**. We would discuss this with you before telling anyone else.

How will we use information about you?
We will need to use information from you for this research project. This information will include your:

- Name
- NHS number
- Contact details like phone number

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 or contact details. 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 won't 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/
- By asking one of the research team
- By sending an email to leedsth-tr.researchgovernance@nhs.net, or assad.khan3@nhs.net

What will happen to the results of the research study?
We plan on showing the results of this study to senior hospital staff so they can see what participants feel about the service, both good and bad.
We will present this data to other colleagues in our discipline at scientific conferences or journals, either as a presentation or journal article.
Your personal details will be kept strictly anonymous and never be mentioned.
If you would like a copy of the finished articles, please let us know, or contact the principal investigator on assad.khan3@nhs.net

Who has reviewed the study?
The study has been approved by the Leeds Teaching Hospitals Research and Innovation team, and also given favourable opinion by a National Institute for Health Research independent Research Ethics Committee who are unrelated to the researchers. They ensure that the study is fair and appropriate.

Contacts for Further Information
Principal investigator:
Mr. Assad Khan
Vascular Research Fellow
Leeds General Infirmary
Email: assad.khan3@nhs.net
Research & Governance

Thank you for taking the time to read and participate