PATIENT INFORMATION SHEET

Frailty in Chronic Limb Threatening Ischaemia (FraiLTI): A multicentre prospective observational study to investigate the prevalence and short-term impact of frailty in chronic limb threatening ischaemia (CLTI)

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 information carefully and ask us if there is anything that is not clear or if you would like more information. The Sponsor of this study is the Newcastle-upon-Tyne Teaching Hospitals.

In this research study we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study, we will save some of the data in case we need to check it or for future research.
We will make sure no-one can work out who you are from the reports we write.

The information pack tells you more about this.

Chief investigator:
Mr Sandip Nandhra; National Institute of Health Research Clinical Lecturer/Vascular Registrar, Northern Vascular Centre, Freeman Hospital, Newcastle upon Tyne, NE7 7DN, email: sandip.nandhra@nhs.net

Independent contact in the department: Samantha Jones, cardiovascular research, Freeman hospital. Telephone: 0191 244 8457

Patient liaison service contact details: If you prefer to raise your concerns with someone not involved in your care, you can contact the Patient Advice and Liaison Service (PALS). This service is confidential and can be contacted on Freephone: 0800 032 0202

Alternatively, if you wish to make a formal complaint you can contact the Patient Relations Department through any of the details below:

Telephone: 0191 223 1382 or 0191 223 1454
Email: nuth.patient.relations@nhs.net
Address: Patient Relations Department
The Newcastle upon Tyne Hospitals NHS Foundation Trust
The Freeman Hospital
Newcastle upon Tyne
NE7 7DN

Sponsor contact details: The Newcastle upon Tyne Hospitals NHS Foundation Trust Newcastle Joint Research Office, Regent Point Newcastle
NE3 3HD

PART 1

1.0 What is the purpose of the study?

We want to find out if there is any routine bedside tests or test used in everyday care for your condition that might suggest that you are at an increased risk of poorer outcomes. One of the conditions known to influence outcome is frailty. Frailty is a mix of a reduction in function of multiple areas such as muscles strength, movement and other medical problems. These all contribute to less effective recovery and outcome in other areas of medicine and surgery. We wonder if there is a similar problem that is not yet fully understood for patients with blood supply issues affecting the lower legs (termed CLTI or Chronic limb threatening ischaemia). We hope to find out how many patients are affected by frailty and if there are any links with the outcome of their care for the lower limb blood supply.

1.1 Why have I been invited?

You have been invited to take part because you have been diagnosed with chronic limb threatening ischaemia (CLTI), you may have an ulcer, continuous pain or gangrene ('black toes or patches).

With your involvement, we hope to find out more about the role frailty plays in patients like you. We are interested to find out if frailty affects the recovery, success of the procedure, ability to go home with or without support and other adverse events or complications, things we currently know very little about.

1.2 Do I have to take part?

Your participation in the FraiLTI study is entirely voluntary. It is up to you to decide whether or not to take part. You can discuss your participation in the trial with your family, friends or GP. If you do decide to take part you will be asked to sign a consent form, a copy of which will also be given to you to keep. If you decide to take part, you are still free to withdraw at any time without giving a reason. If you decide not to take part in the study, the standard of care you receive will not be affected.

1.3 What will happen to me if I take part?

We (the Sponsor) will collect data regarding your health, procedure you undergo and the aftermath. We are most interested in your frailty score around the time of your diagnosis and over the course of your admission. If you agree to take part, we will assess your level of frailty prior to proceeding to your surgical intervention. The study will not alter any aspect of the care you will receive, we will simply be collecting additional information regarding your current health. All data will be anonymised.

If you agree to take part the following will take place:

i. We will collect details about you (age, sex, weight, height) and the surgery you will receive, as well as carry out routine blood tests

ii. Your current level frailty will be assessed through a physical test and through routine (CT) medical imaging (if performed).
   a) The physical test will entail a grip strength assessment, and a 5 times sit-to-stand test, where we will ask you to stand up from a chair and sit back down a total of five times (if you can)
   b) The medical imaging will involve a CT scan to assess for the muscle mass in your back and the affected limb. We would also use the ultrasound scan images that will routinely be carried out to look at the blood supply in your limbs.

iii. We will then observe your recovery following your procedure, taking note of your recovery time and overall progress.

iv. We will invite you to fill out a questionnaire 90 days after your procedure, which you can either carry out through telephone or through the post. The questionnaire will be a widely utilised health survey looking at your current wellbeing.

v. We will also see you back in the clinic as per your routine care.

1.4 What will I have to do?

If you take part in this study, you will be asked to come into hospital to carry out a grip strength assessment and a 5 times sit-to-stand test. As part of your care, you are likely to undergo or have undergone a recent CT (scan) to look at the blood supply. If you have, we would like to use this to measure the amount of muscle. The results of these tests will be used to assess your current level of frailty.

After your surgery you will be asked complete a questionnaire related to your health at day 90, which you will be able to do either via telephone or post.

This is a study that involves observation only, we will not be trailing different treatments or care.

1.5 What are the possible disadvantages and risks of taking part?

There would be no significant disadvantages or risks in taking part in the study. You will be receiving the same care as before, and all the data collected will be anonymised.

1.6 What are the possible benefits of taking part?

The information from this trial will be useful to improve the overall quality of care that we will provide for future patients diagnosed with chronic limb threatening ischaemia. The results are likely to improve care not only in the local area, but also nationally.
Being part of a trial also means that there is extra healthcare input compared to standard care.

1.7 What happens when the study stops?

When this study is stopped, you will no longer need to undergo any study-related follow-up. You will continue with any routine follow-ups just as you would have before you enrolled in this study.

1.8 What if there is a problem?

Any complaint about the way you have been dealt with during the trial or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

1.9 Will my taking part in the trial be kept confidential?

Yes. We (the Sponsor) will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

1.10 Will my GP be informed?

If you decide to take part in this study and consent to have your GP informed, then we will inform your GP. Your participation in the study will also be noted in your medical records

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

2.0 What will happen if I don't want to carry on with the trial?

You can withdraw at any point without the need to give us a reason as to why you chose to withdraw. If you lose your capacity to provide consent for inclusion in this study, we (the Sponsor) will withdraw your participation. If you withdraw from the study, you will still undergo standard NHS care.

2.1 What if there is a problem?

Complaints

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. However, if you wish to complain or have any concerns about the way you have been approached or treated in connection with the study, you should ask to speak to the chief investigator who will do their best to answer your questions. If you remain unhappy and wish to address your concerns or complaints on a formal basis, you should contact Patient Information & Liaison Service.

Harm

It is very unlikely that you will be harmed by taking part in this research study, we are observing your clinical course. The Newcastle upon Tyne Hospitals NHS Trust has liability for clinical negligence that harms individuals toward whom they have a duty of care. NHS Indemnity covers NHS staff conducting the trial for potential liability in respect of harm arising from the conduct of the study.

2.2 How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your initials, NHS number, name and contact details. 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 (for 5 years) 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.

2.3 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.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from [central NHS records/ your hospital/ your GP]. If you do not want this to happen, tell us and we will stop.

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.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

2.5 Will any genetic tests be done?

No genetic testing will be performed at any point.

2.6 What will happen to the results of the research study?

The results of this research will be published and presented at scientific meetings when the study has ended. Published reports will not include your name or any other information that would identify you. You have the right to be informed of the overall results of this study. Updates will be published on the trial webpage throughout the course of the study, including when results are available.

2.7 Who is organising and funding the research?

The Sponsor is Newcastle-Upon-Tyne Hospitals with overall responsibility for the study. The Newcastle upon Tyne Hospitals NHS Trust has liability for clinical negligence that harms individuals toward whom they have a duty of care. NHS Indemnity covers NHS staff conducting the trial for potential liability in respect of harm arising from the conduct of the study.

The study is organised and run by the Chief Investigator, Mr Sandip Nandhra, and the co-investigators listed above. The National Institute of Heal Research Biomedical Research Centre North East has funded this research as well as a funding from the Newcastle Hospitals Charities and Northern Vascular Centre.

2.8 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 at your local site.
- Calling us on at the vascular research office in Newcastle Telephone: 0191 244 8533.

Further, a Data Protection Officer ensures that individual rights are respected and that we (the Sponsor and research team) comply with the law. If you have any concerns or questions about how we look after your personal information, please contact the Data Protection Officer.

Thank you for taking time to consider participating in the study. If you agree to take part, you will be given a copy of this information sheet and a copy of the signed consent form.

You can find all relevant contact details on the 1st page of this information sheet.