

# How do frailty, muscle strength and multiple health conditions affect outcomes (survival, limb loss and return to normal function) for patients with longstanding circulatory problems in the lower limbs?

<b>Submission date</b> 06/09/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/10/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/10/2021	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

In this study the researchers want to find out if there are any routine bedside tests or tests used in everyday care that might suggest that patients 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 muscle strength, movement and other medical problems. These all contribute to less effective recovery and outcome in other areas of medicine and surgery. There may be a similar problem that is not yet fully understood for patients with blood supply issues affecting the lower legs (termed chronic limb-threatening ischaemia [CLTI]). The researchers 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.

### Who can participate?

Patients aged over 18 years with a leg wound (ulcer), constant pain at rest or gangrene, due to vascular (circulatory) disease

### What does the study involve?

The researchers will collect details about the participants (age, sex, weight, height) and the surgery they will receive, as well as carry out routine blood tests. Their current level of frailty will be assessed through a physical test and through routine (CT) medical imaging (if performed). The physical test will involve a grip strength assessment and a five times sit-to-stand test, where participants will be asked to stand up from a chair and sit back down a total of five times (if they can). The medical imaging will involve a CT scan to assess for the muscle mass in the back and the affected limb. The researchers will also use the ultrasound scan images that will routinely be carried out to look at the blood supply in the limbs. The researchers will then observe the participant's recovery following their procedure, taking note of their recovery time and overall progress. Participants will be invited to fill out a questionnaire 90 days after their procedure,

which they can either complete through the telephone or through the post. The questionnaire will be a widely utilised health survey looking at their current wellbeing. The researchers will also see participants back in the clinic as per routine care.

What are the possible benefits and risks of participating?

The information from this study will be useful to improve the overall quality of care 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 study also means that there is extra healthcare input compared to standard care. There would be no significant disadvantages or risks in taking part in the study. Participants will be receiving the same care as before, and all the data collected will be anonymised.

Where is the study run from?

Freeman Hospital (UK)

When is the study starting and how long is it expected to run for?

April 2019 to September 2022

Who is funding the study?

NIHR Biomedical Research Centre Newcastle (UK)

Who is the main contact?

Sandip Nandhra

sandip.nandhra@nhs.net

## Contact information

### Type(s)

Scientific

### Contact name

Mr Sandip Nandhra

### ORCID ID

<http://orcid.org/0000-0002-6036-5760>

### Contact details

Northern Vascular Centre

Newcastle University

Level 4, Freeman Hospital

Newcastle

United Kingdom

NE7 7DN

+44 (0)191 233 6161 - switchboard

sandip.nandhra@nhs.net

## Additional identifiers

### EudraCT/CTIS number

Nil known

**IRAS number**

294528

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

CPMS 49622, IRAS 294528

## Study information

**Scientific Title**

A multicentre prospective observational study to investigate the prevalence and short-term impact of frailty in chronic limb-threatening ischaemia

**Acronym**

FraiLTI

**Study objectives**

Patients with chronic-limb threatening ischaemia (CLTI) are vulnerable to limb loss and premature death. Due to the nature of vascular disease CLTI patients often have multiple long-term conditions. The interaction of these conditions leaves patients at risk of frailty and deconditioning. It is expected that patients with multiple conditions and/or frailty might have worse clinical outcomes. They may well be more susceptible to limb loss, perhaps death and other complications. Potentially they may too be unable to return to their home environment. The FraiLTI study hopes to understand this interaction and highlight key areas for potential optimisation research.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 13/07/2021, Health Research Authority (HRA) and Health and Care Research Wales (HCRW, Ground Floor, Temple Quay House, Health Research Authority, BS1 6PN, UK; +44 (0)207 104 8328; [approvals@hra.nhs.uk](mailto:approvals@hra.nhs.uk)), REC ref: 21/PR/0750

**Study design**

Observational; Design type: Cross-sectional

**Primary study design**

Observational

**Secondary study design**

Cross sectional study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

## **Participant information sheet**

See additional files

## **Health condition(s) or problem(s) studied**

Chronic limb-threatening ischaemia

## **Interventions**

All patients admitted with chronic limb-threatening ischaemia (CLTI) to a dedicated vascular centre will be invited to participate. Confirmation of CLTI diagnosis will be made by the admitting vascular specialist. These will then be screened according to the inclusion and exclusion criteria. Patients meeting the below inclusion criteria will be invited to participate in the FraiLTI study. Patients will undergo routine care in the hospital. On admission, patients will be first notified about the study by a member of the clinical team. If potential participants are interested and would like more information verbal consent for their details to be shared with the FraiLTI (local site academic or clinical academic team). At this point a member of the FraiLTI study team (on the delegation log and meeting GCP etc) will approach the patient to provide the details of the study, PIS etc. After a period of typically 24 hours a study team member will consent the patient formally for participation. Routine data will be collected that is already part of the admission process (no new blood tests or scans). In addition, the EQ5D Quality of Life assessment will be made at baseline. Two functional assessments will be made: Grip strength and sit/stand test. This will provide data on frailty. Thereafter if the patients undergo a CT (as per their routine care - no additional imaging) these will be used to measure muscle area. After this patients will then continue on their routine care journey. On discharge, their admission length, surgical procedure and outcomes will be recorded. At 90 days patients will be reviewed electronically to record and adverse outcomes in line with the follow-up data. Patients will be invited to complete an EQ5D Quality of life assessment over the telephone.

## **Intervention Type**

Other

## **Primary outcome measure**

The prevalence of frailty measured using the Fried Frailty Score at baseline

## **Secondary outcome measures**

Measured using patient records:

1. Major cardiovascular events (MACE) recorded according to standard international definitions and occurring within 90 days follow-up
2. Major adverse limb events (major amputation, trans-femoral, through knee or trans-tibial) occurring within 90 days
3. Survival measured by record of date of death up to 90 days follow-up
4. Re-interventions defined as the number of times within 90 days that repeat surgery or procedure (open or endovascular) is required
5. Length of stay in days up to 90 days
6. Discharge home or to another care environment within 90 days

## **Overall study start date**

01/04/2019

## **Completion date**

01/09/2022

# Eligibility

## Key inclusion criteria

1. All adults aged over 18 years, able to consent and participate with ongoing assessments
2. All chronic limb-threatening ischaemia patients with specifically:
  - 2.1. Tissue loss
  - 2.2. Rest-pain

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

Planned Sample Size: 300; UK Sample Size: 300

## Key exclusion criteria

1. Admissions for non CLTI
2. Unable to agree to assessments or participate in study assessments
3. Pregnant women
4. Under 18 years of age

## Date of first enrolment

01/10/2021

## Date of final enrolment

01/06/2022

# Locations

## Countries of recruitment

Northern Ireland

Scotland

United Kingdom

Wales

## Study participating centre

**St Cadoc's Hospital**

Lodge Road  
Caerleon  
Newport  
United Kingdom  
NP18 3XQ

**Study participating centre****Hull Royal Infirmary**

Anlaby Road  
Hull  
United Kingdom  
HU3 2JZ

**Study participating centre****Sunderland Royal Hospital**

Kayll Road  
Sunderland  
United Kingdom  
SR4 7TP

**Study participating centre****St. James's University Hospital**

Beckett Street  
Leeds  
United Kingdom  
LS9 7TF

**Study participating centre****University Hospitals Bristol**

Marlborough Street  
Bristol  
United Kingdom  
BS1 3NU

**Study participating centre****St Mary's Hospital**

South Wharf Road  
London  
United Kingdom  
W2 1BL

**Study participating centre**  
**Leicester Royal Infirmary**  
Infirmary Square  
Leicester  
United Kingdom  
LE1 5WW

**Study participating centre**  
**Queen Elizabeth Hospital**  
Mindelsohn Way  
Edgbaston  
Birmingham  
United Kingdom  
B15 2GW

**Study participating centre**  
**Freeman Hospital**  
Freeman Road  
High Heaton  
Newcastle upon Tyne  
United Kingdom  
NE7 7DN

**Study participating centre**  
**Royal Liverpool University Hospital**  
Prescot Street  
Liverpool  
United Kingdom  
L7 8XP

**Study participating centre**  
**NHS Lothian**  
Waverley Gate  
2-4 Waterloo Place  
Edinburgh  
United Kingdom  
EH1 3EG

**Study participating centre**  
**Belfast Health & Social Care Trust**  
Knockbracken Healthcare Park  
Saintfield Road  
Belfast  
United Kingdom  
BT8 8BH

## Sponsor information

### Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust

### Sponsor details

Newcastle Joint Research Office  
Level1, Regent Point, Regent Farm Road  
Newcastle-Upon-Tyne  
England  
United Kingdom  
NE3 3HD  
+44 (0)191 2825959  
nuth.nuthsponsorship@nhs.net

### Sponsor type

Hospital/treatment centre

### Website

<http://www.newcastle-hospitals.org.uk/>

### ROR

<https://ror.org/05p40t847>

## Funder(s)

### Funder type

Government

### Funder Name

NIHR Newcastle Biomedical Research Centre

### Alternative Name(s)

Newcastle Biomedical Research Centre, Newcastle NIHR Biomedical Research Centre

### Funding Body Type



Private sector organisation

### Funding Body Subtype

Research institutes and centers

### Location

United Kingdom

## Results and Publications

### Publication and dissemination plan

1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. The study collaborative includes the Chair NHS England National Clinical Reference Group (CRG) for Vascular Services and this will act as a vector for communication of the results to NHS England and relevant commissioning

### Intention to publish date

01/09/2023

### Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version 1.2	01/07/2021	10/09/2021	No	Yes
<a href="#">Protocol file</a>	version 2.0	01/07/2021	10/09/2021	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No