

INFORMED CONSENT FORM

Study title:

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)

Participant ID:

Please initial in the box provided if you agree with all the following statements:

1. I confirm that I have read and understood the Patient Information Sheet dated __ / __ / __ (Version:____) for the above study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily.
2. I understand the risks and benefits, and I freely give my informed consent to participate in the research study described in this form, under the conditions stated in it.
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
4. I understand that if at any point my medical condition changes it may be necessary to withdraw from the trial and have my treatment options reviewed. This will be discussed with me by clinicians and with my agreement.
5. I understand that relevant sections of my medical notes and data collected during the study may be looked at by the medical team from the NHS Trust, Sponsor Office, and regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
6. I understand that my GP will be informed of my participation in the FrailTI study.
7. I understand that study data will be stored securely for 5 years
8. On this basis, I agree to participate in the study.

Print name of patient

Signature

Date

Print name of person taking consent

Signature

Date

Original copy to be stored in site file, one copy for the patient and one copy for medical records

Sponsor ID: 09683

IRAS ID: 294528

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