Data Collection Sheet

FraiLTI Study: (Frailty in chronic Limb Threatening Ischaemia) Study

A multicentre prospective observational study to investigate the prevalence and short-term impact of frailty, multi-morbidity and sarcopenia in chronic limb threatening ischaemia (CLTI)

IRAS number	Project ID **294528**
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Demographics

Patient Consent* No ☐ Yes ☐ **(If no, unable to proceed)**
Date consent recorded ____ /____ /_____ (DD/MM/YYYY)

Initials _____

Local ID* _____

Date of birth* _____

Age _____

Sex* Male ☐ Female ☐

Ethnicity: (Full options)

Patient weight* (kg) _____

Weight change in last 6 months (to nearest kg) (NB: 1 stone = 6kg):

+/-		

Patient height* (m/cm) _____

Postcode* _____

Social history*
Living circumstances ____House/Flat/Bungalow/Residential care/Nursing Home/Other: _____

Care required _____No care/1/2/3/4/5+ care visits a day _____

Walking aid __No / Stick/ Frame / Wheelchair / Other : describe

Admission date* ____ /____ /_____ (DD/MM/YYYY)

Mode of admission* Elective ☐ Non-elective/emergency ☐

Source of referral GP ☐ ED ☐ Other medical specialty ☐ Vascular clinic ☐
Podiatry ☐ Self-referral ☐

Clinical

Laterality of present indication* (*If bilateral select most severe option)*

Right ☐ Left ☐

Recent presentation (last six months) with ipsilateral claudication (not CLTI): Yes☐ No☐

Recent admission for ipsilateral limb (within the last 6months) Yes☐ No☐

If Yes –

Underwent Endovascular intervention / open surgery (including hybrid) / medical management (pain control / iloprost etc.)

Previous contra-lateral major lower limb amputation: Yes☐ No☐

Comorbidities* (Please select as many options as applicable)

Active medical diagnoses recorded in medical notes (tick EITHER yes or no for each diagnosis):

	Yes	No
Any previous diagnosis of ischaemic heart disease		
Previous Stroke		
Chronic Heart Failure		
Diabetes Mellitus		
Atrial Fibrillation		
Hypothyroidism		
Hyperthyroidism		
Dementia		
Anxiety		
Depression		
Parkinsons Disease or Parkinsons plus syndrome		
Chronic obstructive pulmonary disease		
Asthma		
Other lung disease		
Osteoarthritis		

Inflammatory arthropathy	

Current medications (from primary or secondary care records)

Generic Name

Smoking status*

Current smoker ☐ Stopped <2 months ago ☐ Ex-smoker stopped >2months ago ☐

Never smoked ☐

If smoker: how many 0-5/5-10/10-15/15+ a day

Alcohol intake: None / 1-2 drinks per day / 3-4 drinks per day / 5 drinks daily

Baseline bloods on admission*

Haemoglobin(g/L)	
White cell count(x10^9/L)	
Potassium (mmol/l)	
Sodium (mmol/l)	
Creatinine (µmol/l)	
Urea	
eGFR	
Albumin (g/L)	
CRP (mg/L) (where performed)	
Glucose (mmol/l)	
HbA1c (mmol/mol)	
MCV	
Total protein	
Vitamin D (if performed)	

ECG on admission*
Normal / dysrhythmia / other:

Severity of Chronic limb threatening ischaemia
WIFI Scoring used Yes / No

WIfI classification score for the threatened lower limb (if performed) *
Wound (W)
☐0 – No ulcer or gangrene
☐1 – Small or superficial ulcer on leg or foot, without gangrene
☐2 – Deep ulcer with exposed bone, joint, or tendon ± gangrene limited to digits
☐3 – Deep, extensive ulcer involving forefoot and/or midfoot ± calcaneal involvement ± extensive gangrene
Ischaemia (I)
☐1 – ABPI ≥ 0.80; SBP of ankle > 100 mmHg; TP, $TcPO_2$ ≥ 60 mmHg
☐2 – ABPI 0.6-0.79; SBP of ankle 70-100 mmHg; TP, $TcPO_2$ 40-59 mmHg
☐3 – ABPI 0.4-0.59 ≤ 0.39; SBP of ankle 50-70 mmHg < 50 mmHg; TP, $TcPO_2$ 30-39 mmHg < 30 mmHg
Foot Infection (fI)
☐0 – Uninfected
☐1 – Mild local infection, involving only skin and subcutaneous tissue, erythema > 0.5 to ≤ 2 cm
☐2 – Moderate local infection, with erythema > 2 cm or involving deeper structures
☐3 – Severe local infection with signs of SIRS

Rutherford classification for chronic limb ischaemia*
☐0 – Asymptomatic—no hemodynamically significant occlusive disease
☐1 – Mild claudication
☐2 – Moderate claudication
☐3 – Severe claudication
☐4 – Ischaemic rest pain
☐5 – Minor tissue loss—nonhealing ulcer, focal gangrene with diffuse pedal ischemia
☐6 – Major tissue loss—extending above TM level, functional foot no longer salvageable

Frailty assessment 1:

Rockwood clinical frailty scale:

1 – Very Fit - People who are robust active, energetic and motivated. The tend to exercise regularly and are among the fittest for their age.

2 – Well – People who have no active disease symptoms but are less fit that category 1. Often, they exercise or are very active occasionally, eg: seasonally.

3 – Managing well – people whose medical problems are well controlled, but not regularly active beyond routing walking

4 – Venerable – While not dependent on others for daily help, often symptoms limit activities. A common complaint is being 'slowed up' and/or being tired during the day.

5 – Mildly Frail – These people often have more evident slowing, and need help in high order IADLs (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.

6- Moderately Frail – People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.

7 -Severely Frail – Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).

8 Very Severely Frail – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.

9 - Terminally Ill - Approaching the end of life. This category applies to people with a life expectancy <6 months, who are not otherwise evidently frail.

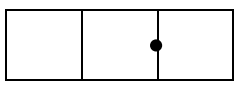
Fried Frailty Assessments:
Physical assessments

Grip strength (kg):

Dominant hand: Right ☐ Left ☐

	Left	Tick if not performed (choose one)	**Right**	Tick if not performed (choose one)
Attempt 1		U D T		U D T
Attempt 2		U D T		U D T
Attempt 3		U D T		U D T

U=Unable D= Declined T=Technical problem



4 metre gait speed: First walk – time (seconds)
Second walk – time (seconds)

	•	

If the patient is unable to do this please record : Fail
Reason:

Chair stand test:

	Tick one
Unable to complete single stand w/o using arms	
Unable to complete 5 stands in <60 secs	
Able to complete 5 stands	

Time (seconds)

	•	

Questions about activity to the patient:

Do you take part in activities that are *vigorous* (e.g. swimming, cycling, digging):

More than once a week	
Once a week	
One to three times a month	
Hardly ever or never	

Tick ONE

Do you take part in activities that are *moderately* energetic (e.g. walking, gardening, dancing):

More than once a week	
Once a week	
One to three times a month	
Hardly ever or never	

Tick ONE

Do you take part in activities that are *mildly* energetic (e.g. vacuuming, laundry, home repairs):

More than once a week	
Once a week	
One to three times a month	
Hardly ever or never	

Tick ONE

Imaging (if CTA performed)
L3 skeletal muscle area: (all at L3) _____cm^2

L3 skeletal muscle index (L3SMI)*
- Muscle area at L3 vertebra level (psoas and total), divided by the patient height (squared)

L3SMI _____

Limb muscle area*
At level of above knee amputation (AKA) level (Mid-femur) _____ cm^2

At level below knee amputation (BKA) level (10cm below tibial tuberosity)_____ cm^2

Planned/undergoing for Revascularisation?
☐Yes – Go to Revascularsation Question

☐No – go to non-revasc questions

Not for revascularisation:
Plan for: Primary amputation / medical (iloprost)/ chemical sympathectomy / pain control and/or palliation
☐Primary amputation
☐Chemical Sympathectomy
☐Pain control and/or palliation

Revascularisation
☐open (inc. hybrid)
☐ endovascular / interventional radiology

Open Revascularisation:
Type of theatre list:
☐Elective
☐Emergency

Date of primary revascularisation: ____ /____ /_____ (DD/MM/YYYY)

Revascularisation strategy:

☐ open surgical

☐ hybrid (open or endovascular in combination)

☐ Endovascular

Debridement surgery: ☐ Yes ☐ No
Site: _____

Reason: _____

Open Surgical Revascularisation:

Anaesthetic start time *

____ /____ /_____ (DD/MM/YYYY); ____ : ____ (HH:MM)

Surgical start time*

____ /____ /_____ (DD/MM/YYYY); ____ : ____ (HH:MM)

Bypass? Yes ☐ No ☐
Inflow: Axillary / Aorta / Common Iliac / External Iliac / Common Femoral / Superficial Femoral / Above knee Popliteal / Below knee popliteal

Outflow: Axillary / Aorta / Common Iliac / External Iliac / Common Femoral / Superficial Femoral / Above knee Popliteal / Below knee popliteal / Tibio-peroneal Trunk / Tibial vessel / Pedal vessel

Conduit: Autologous Vein / Prosthetic (with or with out cuff)

Endarterectomy: Yes ☐ No ☐
Site: Aortic / iliac / Femoral / Popliteal / other:

Was there a 'hybrid component eg: COWER': Yes ☐ No ☐
Iliac angioplasty / other:

Endovascular Strategy:
Percutaneous? Yes ☐ No ☐

☐ Primary balloon Angioplasty
☐ Endovascular Stenting

Site (select all that apply): Aorta / Common Iliac / External Iliac / Common Femoral / Superficial Femoral / Above knee Popliteal / Below knee popliteal Tibio-peroneal Trunk / Tibial vessel / Pedal vessel

Post-revascularisation Critical care admission?
No ☐
Level 3/ITU ☐ Level 2/HDU/PACU ☐
Date of critical care admission ……
Date of Critical care discharge ……
Length of Critical care stay (days) ……

In-hospital events:
Death Yes ☐ No ☐
Date:

In hospital Complications: (tick all that apply)
☐ Cardiac: Myocardial infarction (all-types)
☐ Respiratory: Pneumonia/Chest infection
☐Wound: Clinical wound infection requiring antibiotics or extending admission
☐Urinary: Urinary infection requiring antibiotics or extending admission
☐Ipsilateral limb event: limb-loss
☐Ipsilateral limb-complication: graft occlusion requiring salvage / unsuccessful salvage / failed revascularisation

Discharge:
Was the patient discharged prior to 90-days? Yes ☐ No ☐
Date of discharge:

Discharge environment:
☐Own home with care package
☐Residential care
☐Nursing Home
☐Step-down unit / rehabilitation
☐Other:

Mobility on discharge: (delete / circle)
Independent / walking stick / frame / wheel-chair / unable to ambulate / full-care and hoisting.

90 – day follow up overleaf

90- day follow -up:

Re-admissions
How many 1 ☐ 2 ☐ 3☐ 4☐

Day case Re-intervention?
?Yes / No
How many 1 ☐ 2 ☐ 3☐ 4☐

Re-intervention 1 – branch as needed
Angioplasty Yes ☐ No ☐
Terminalisation/minor surgery Yes ☐ No ☐

Hospital admission (1 – 4 – branch as needed)
Date of admission _____

Date of discharge_____

Discharge environment:
☐Own home with care package
☐Residential care
☐Nursing Home
☐Step-down unit / rehabilitation
☐Other:

Mobility on discharge: (delete / circle)
Independent / walking stick / frame / wheel-chair / unable to ambulate / full-care and hoisting.

Death Yes ☐ No ☐
Date of Death:

Limb loss Yes ☐ No ☐
Date of limb-loss :

Ipsilateral revascularisation Yes ☐ No ☐
If Yes
Redo surgery Yes ☐ No ☐
Re-angioplasty Yes ☐ No ☐

Hospital admission (1 – 4 – branch as needed)
Date of admission _____

Date of discharge_____

Discharge environment:
☐Own home with care package
☐Residential care
☐Nursing Home
☐Step-down unit / rehabilitation
☐Other:

Mobility on discharge: (delete / circle)

Independent / walking stick / frame / wheel-chair / unable to ambulate / full-care and hoisting.

Death Yes ☐ No ☐
Date of Death:

Limb loss Yes ☐ No ☐
Date of limb-loss :

Ipsilateral revascularisation Yes ☐ No ☐
If Yes
Redo surgery Yes ☐ No ☐
Re-angioplasty Yes ☐ No ☐

Hospital admission (1 – 4 – branch as needed)
Date of admission _____

Date of discharge _____

Discharge environment:
☐Own home with care package
☐Residential care
☐Nursing Home
☐Step-down unit / rehabilitation
☐Other:

Mobility on discharge: (delete / circle)
Independent / walking stick / frame / wheel-chair / unable to ambulate / full-care and hoisting.

Death Yes ☐ No ☐
Date of Death:

Limb loss Yes ☐ No ☐
Date of limb-loss :

Ipsilateral revascularisation Yes ☐ No ☐
If Yes
Redo surgery Yes ☐ No ☐
Re-angioplasty Yes ☐ No ☐

At 90 day complications not already recorded whilst an in-patient: (tick all that apply)
☐ Cardiac: Myocardial infarction (all-types) , MACE / major adverse cardiac events
☐ Respiratory: Pneumonia/Chest infection
☐Wound: Clinical wound infection requiring antibiotics or extending admission
☐Urinary: Urinary infection requiring antibiotics or extending admission
☐Ipsilateral limb event: limb-loss (major adverse limb event (MALE)
☐Ipsilateral limb-complication: graft occlusion requiring salvage / unsuccessful salvage / failed revascularisation

Re-interventions:
☐Redo-surgery
☐Redo-endovascular procedure
☐Wound related debridement/drainage
☐Foot debridement/toe amputation

Appendix A - Quality of Life Assessment

Euro-QoL EQ5D-5L health status assessment score*

Baseline Completed: Y / N
90-day Completed: Y/ N

Appendix B – Nottingham Extended Activities of Daily Living (baseline)

Baseline Completed: Y / N
90-day Completed: Y/ N

Appendix C – Food diary (baseline)

Baseline only: Completed: Y/ N