PETRI: Prehabilitation in the Elderly with chronic limb Threatening Ischemia

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28123

Source Nationaal Trial Register

Brief title PETRI

Health condition

Chronic Limb Threatening Ischemia (CLTI)

Sponsors and support

Primary sponsor: Prof. dr. L. van der Laan Source(s) of monetary or material Support: None yet. Conceivably: Amphia academy Science fund

Intervention

Outcome measures

Primary outcome

Postoperative delirium

Secondary outcome

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Secondary outcomes will be in-hospital mortality, 30 day, 6 month and 12 month mortality, complications, rates of major amputations, amputation free survival (AFS), length of hospital stay, Quality of Life (QoL, measured by using the WHOQOL-BREF, SF-12 and VascuQoL-6-NL), functional outcome, cognitive function and biochemistry.

Study description

Background summary

The primary aim of our study is to reduce the incidence of delirium among patients >65 years with chronic limb threatening ischemia, requiring revascularization by implementing a multicomponent multidisciplinary prehabilitation program.

Study objective

Our hypothesis is that by implementing the prehabilitation program, the rate of delirium will be decreased from 18% to 9%.

Study design

Preoperative, admission, 6 months, 12 months

Intervention

Prehabilitation program. Participants will be screened by a nurse practitioner, physiotherapist and dietician. In case of criteria for frailty (as described in 'appendix'), a geriatrician will perform a comprehensive geriatric assessment (CGA). Depending on this baseline analysis, patients may receive iron infusion and/or vitamin supplementation, recommendations concerning daily exercise and dietary supplements and guidance in reducing alcohol and/or nicotine use. They are asked to keep track of their activities in a daily diary

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Aged 65 years or older
- All genders
- All ethnicities
- Diagnosis of CLTI (Chronic Limb Threatening Ischemia), based on either:
- o Anamnestic complaints of ischemic rest pain or night pain

o (Minor) tissue loss, non-healing ulcer and/or focal gangrene with diffuse pedal ischemia[11] o Impaired perfusion, quantified by a flat or barely pulsatile ankle or metatarsal PVR (pulse volume recording), a low resting ankle pressure, a low ankle brachial index and/or a low toe pressure.

- Indication and informed consent to undergo either endovascular or surgical treatment

- No need to start treatment earlier then 3 weeks, counting from the moment of diagnosis

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Dementia according to DSM-V
- Inability to complete questionnaires, due to either lingual or cognitive incompetence.
- Need for urgent surgery (<3 weeks)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-04-2021
Enrollment:	170
Туре:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

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Positive opinion	
Date:	29-03-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register NTR-new Other **ID** NL9380 MEC-U : W21.061

Study results

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