Trajectories of Frailty before and after Elective Vascular Surgery

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Rationale:A study reporting the frailty trajectories after vascular surgery is currently lacking. The aim of this study is to evaluate the influence of the surgical intervention on the different domains of frailty, by measuring the characteristics...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational non invasive

Summary

ID

NL-OMON48349

Source
ToetsingOnline

Brief title
TRACE study

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
frailty, vascular diseases

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cognitive impairments, Frail elderly, Vascular surgical procedures

Outcome measures

Primary outcome

Primary outcome:

- Changes in frailty (according to the GFI)

Secondary outcome

Secondary outcomes:

Changes in:

- Handgrip strength

- Cognitive functioning (according to the MOCA)

- Body composition (BIA)

- Gait speed (4MWT)

- Body weight

Study description

Background summary

Almost 40% of the people aged between 65 and 74 are suffering from chronic diseases and multi-morbidity is present in 60% of the people aged over 75 years. Multi-morbidity or chronological age does not seem the best method to distinguish a physical frail patient from a fit patient because elderly people have to cope with many conditions during the last stages of their life and can suffer from handicaps and disabilities. All these conditions can lead to poor outcomes after surgery or hospitalization, such as functional decline, complications and nursing home placement. Frailty is a multidimensional geriatric syndrome which is frequently used to describe the most vulnerable or weakest older adults. According to Fried et al., the frailty phenotype model is characterized by accumulation of slowness, weakness, weight loss, low physical activity, and exhaustion. A different but increasingly important approach on

frailty includes cognitive impairment.
Over the past years, various frailty measurements, containing all the domains of frailty, have been developed. However, the different domains of frailty can also be determined separately. Slowness for example is measured by a short-distance gait speed test, weakness by handgrip strength and the other domains (including cognitive impairment) by a questionnaire.
In vascular surgery patients, attention for frailty is particularly important, given that the population consists primarily of older adults with multi-morbidity and prevalent physical disabilities. Studies have already shown that frailty in the vascular surgical ward is common and it predicts poor surgical outcome after various vascular surgery interventions.
In most of the studies, frailty has been assessed at one specific time-point, assuming that frailty is a static state, even though researchers are also looking at a different perspective on frailty and approaching it more as a dynamic process that can be influenced by various factors. Moreover, researchers found that patients who underwent surgery in the year before their death had more hospital admissions, longer duration of stay and a greater number of days spent in intensive care than those who did not have a surgical procedure in the year before death. This finding could suggest that in the last years of frail patients, intervening surgically is not automatically beneficial to the frail state of the patient.

Study objective

Rationale:
A study reporting the frailty trajectories after vascular surgery is currently lacking. The aim of this study is to evaluate the influence of the surgical intervention on the different domains of frailty, by measuring the characteristics of the frailty phenotype (i.e. slowness, weakness, weight loss, low physical activity, and exhaustion) and the cognition of the patients multiple times before and after the intervention.

Main study objective:
How do the cognitive and physical trajectories of frailty change in vascular surgery patients in the first six months after the vascular surgery intervention?

Study design

During the pre-operative screening at the outpatient vascular surgery clinic, eligible patients will be informed by their vascular surgeon and asked to participate in this study. If they are interested, they will be sent to one of our researchers at the outpatient clinic who will provide more information about the study. If they decide immediately to participate in the study, they could sign the informed consent. If they wish to think longer about the decision, they have the time until the preoperative (POPA) screening to sign

the informed consent. If the informed consent is obtained, patients will be included. After inclusion, at the outpatient clinic or POPA, we will determine the frailty state (according to the Groningen Frailty Indicator (GFI)) and cognitive functioning of the patients (using the Montreal Cognitive Assessment (MOCA)). Additionally handgrip strength, gait speed (according to the 4-meter-walk test (4MWT)), body composition (using Bio Impedance Analysis (BIA)) and body weight will be determined. At hospital admission, we will only perform the tests, when the tests during the POPA are >6 weeks ago. All tests will be repeated at discharge, and at the one and six month post-operative outpatient visit.

Study burden and risks

Not applicable since the nature of the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Indication for elective vascular surgery
- Aged >= 65 years
- Physically capable to perform at least half of the tests
- Sufficient command of the Dutch language

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Patients undergoing arteriovenous access surgery, percutaneous transluminal angioplasty interventions (including coil embolization), venous interventions and minor amputations (forefoot amputation, digits and wound revisions).

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2019
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO

Date:	05-08-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	ID
Other	201800817
CCMO	NL69602.042.19