Anesthesia Geriatric Evaluation on predicting health related quality of life after peripheral vascular surgery in elderly patients.

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1. To determine the influence of frailty on predicting an increase in HRQL in elderly peripheral vascular surgery patients. 2. To develop an 'AGE-VASC score' for predicting an increase in HRQL after cardiac surgery based on surgical risk...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Age related factors
Study type	Observational invasive

Summary

ID

NL-OMON55685

Source
ToetsingOnline

Brief title
AGE-VASC

Condition

- Age related factors
- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
fragility, Frailty, vulnerability, weakness

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Maatschap Anesthesiologie St Antonius Ziekenhuis en vakgroep Vitale Functies UMC Utrecht

Intervention

Keyword: Elderly, Frailty, Preoperative risk stratification, Quality of Life

Outcome measures

Primary outcome

Primary endpunt is an increase >10 points of the physical or mental component

score of the SF-12 health status 12 months after cardiac surgery.

Secondary outcome

Secundary endpoints are the incidence of postoperative complications, length of

ICU and hospital stay, HRQL at 3 months, psychosocially and physical

functioning (WHODAS) and impairment in walking (Walking Impairment

Questionnaire WIQ (WIQ)) at 3 and 12 months.

Study description

Background summary

In elderly patients peripheral arterial surgery is associated with risk of postoperative morbidity, mortality, loss of self-reliance and decreased health related quality of life (HRQL). Such risk is further increased in frail patients. Frailty results in loss of functional capacity and is characterised by weight loss, sarcopenia and decreases physical activity. The influence of frailty on postoperative outcome after peripheral vascular surgery is not implemented in current international risk prediction models.

Study objective

1. To determine the influence of frailty on predicting an increase in HRQL in elderly peripheral vascular surgery patients.

2. To develop an 'AGE-VASC score' for predicting an increase in HRQL after cardiac surgery based on surgical risk factors, comorbidities and frailty.

Study design

Prospective, observational, cohort study. Patients are followed up for 1 year. Primary endpoint is an increase in HRQL.

Study burden and risks

Since this is an observational study, there is no associated risk for the patient. It takes 30 minutes to perform the additional questionnaire, 3 physical tests and 1 AGE reader test. Blood sampling will take place at 1 time point. One sample will be taken at start of surgery. It takes 10 minutes to complete the SF-12 health status questionnaire, WHODAS 2.0 questionnaire and WIQ at 3 and 12 months after surgery. Study patients undergo regular anesthesia screening prior to surgery at the outpatient anesthesia clinic, similar to patients not included in the study. The results of the additional questionnaire and tests hold no consequences for whether or not the patient proceeds to surgery. After visiting the outpatient clinic a study patient receives regular preoperative cardiac care, similar to patients not included in 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

• >=70 jaar
• mentally competent
• Elective surgical intervention for peripheral arterial disease
• Signed informed consent

Exclusion criteria

Not applicable

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-06-2016
Enrollment:	88
Type:	Actual

Ethics review

Approved WMO Date:	08-03-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-02-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-06-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-03-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL55038.100.15

Study results

Date completed:	02-02-2022
Actual enrolment:	74

Summary results
Trial ended prematurely