Peripheral Vascular Disease and Health status

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Primary research question:To evaluate the impact of open versus endovascular invasive treatment in different types of surgery (AAA, CEA, LLR) on health status. Secondary research questions:To examine the prognostic impact of quality of life in PAD…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vascular therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON37994

Source
ToetsingOnline

Brief title
DECREASE VIII

Condition

- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
peripheral arterial disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: non-cardiac vascular surgery, peripheral vascular disease, quality of life

Outcome measures

Primary outcome

The primary study parameter is health status. Health status will be measured by the translated Dutch version of the PAQ, an disease-specific instrument for assessing health status in patients with PAD, and the Dutch version of the EQ-5D, a standardized, generic instrument for describing and valuing health.

Secondary outcome

Delirium (scores on the Delirium Scale > 12); mortality (both cardiac and non-cardiac); morbidity (i.e. a composite of rehospitalisation due to failed grafts). Data for these endpoints will be retrieved from the patients' medical records and assessed 2 years after surgery, including also the date of the event.

Study description

Background summary

Peripheral arterial disease (PAD) is a common chronic condition and is associated with increased cardiovascular morbidity and mortality. The management of patients with PAD has changed in the last decades with the introduction of endovascular techniques and other treatment modalities. Traditionally, the success of interventions is measured with clinical measures, such as the ankle-brachial index, patency rates, and survival rates. Relying solely upon these techniques, however, fails to ascertain whether the intervention has a beneficial impact on the patient*s ability to function in daily life.
The impact of surgical and endovascular interventions on costs, quality of life, and functional status is not systematically evaluated yet. Preliminary evidence in abdominal aortic aneurysm patients indicates that the perioperative

advantages regarding survival and quality of life is not sustained after the first postoperative year. The adoption of sensitive patient-centered outcome measures is increasing in order to quantify the benefits of different treatment strategies and their cost-effectiveness. In addition to using health status measures as outcome measures, health status measurements may provide prognostic information to guide clinical decision-making. Health status measurements can therefore potentially be used in clinical practice to identify patients who are at relatively high risk for adverse health outcomes and may benefit from more intensive follow-up and more aggressive treatment, including pharmacological, invasive and/ or behavioural interventions.

Study objective

Primary research question:
To evaluate the impact of open versus endovascular invasive treatment in different types of surgery (AAA, CEA, LLR) on health status.

Secondary research questions:
To examine the prognostic impact of quality of life in PAD:
a. Short-term prognosis: perioperative complications (e.g. delirium) and graft-patency rates
b. Long-term prognosis: cardiovascular events and mortality

Study design

The current study is a prospective, observational, single-centre study, with a 12-month follow-up. Psychological assessments will take place at 5 time points: T0=pre-operative (i.e., at the anesthesiology department, pre-operative screening), T1=in-hospital delirium assessment, T2=30 days, T3=6 months, T4=12 months. Clinical assessments coincide with the T0 and T1 assessments. It should be noted that none of these parameters are assessed specially for the study, but comprise clinical parameters that are assessed standardly in patients undergoing vascular surgery. During follow-up, survival data for all patients will be obtained from municipal civil registries. A questionnaire is subsequently sent to all living patients together with specific inquiries on repeat hospital admissions and major cardiac events. All questionnaires are standardized and validated. Patients will be approached by the physician for study participation. They will be informed about the study both orally and in writing and be asked to sign an informed consent form.

Study burden and risks

Psychological assessments take place at 5 time moments. The patients will be sent questionnaires, except for T0 and T1, to his or her home address and will be able to complete and return the questionnaires at a suitable time. The

maximal time needing to complete the questionnairesis is 30 minutes.

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

-Patient scheduled for non-cardiac vascular surgery
-Patient older than 18 years
-Patient have signed informed consent

Exclusion criteria

-A life expectancy less than 12 months

-Presence of severe psychopathological comorbidities (e.g., psychosis, suicidal ideation)
-Severe cognitive impairment (Mini Mental Status Examination Score of 23 or lower) --
Insufficient knowledge of the Dutch language.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-11-2008
Enrollment:	900
Type:	Actual

Ethics review

Approved WMO

Date:	19-11-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	30-05-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL24093.078.08