A prospective study to assess the screening value of N-terminal pro-B-type natriuretic peptide (NT-proBNP) for the identification of patients that benefit from additional cardiac testing prior to vascular surgery.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON30697

Source
ToetsingOnline

Brief title
DECREASE VI

Condition

- Coronary artery disorders
- Vascular therapeutic procedures

Synonym
Perioperative cardiac risk stratification

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Roche Diagnostics, Mannheim, Duitsland,Roche Diagnostics;Mannheim;Duitsland; Stichting Lijf & Leven;Bergschenhoek;Nederland

Intervention

Keyword: Cardiac Outcome, NT-proBNP, Perioperative Care, Risk Stratification

Outcome measures

Primary outcome

The primary objective of this trial is to validate the screening potential of

NT-proBNP in a population of low to intermediate risk patients, i.e. patients

with zero to two cardiac risk factors, scheduled for vascular surgery.

Secondary outcome

The secondary objective is to identify prior to vascular surgery high risk

patients, with three or more cardiac risk factors, with a normal stress test.

Study description

Background summary

Patients undergoing major vascular surgery are at significant risk for perioperative cardiac complications. Although the overall perioperative event rate has declined over the past 30 years; 30 day cardiovascular mortality remains as high as 3% to 5%. Myocardial infarction (MI) is the most frequent fatal complication in this respect, accounting for 10-40% of postoperative fatalities.
For preoperative cardiac risk stratification scoring of clinical cardiac risk factors, eg. previous MI, diabetes mellitus, etc., is important. The cardiac risk can be predicted more accurately by applying cardiac stress tests. However in patients at low or intermediate risk (0, 1, or 2 clinical cardiac risk

factors) only 14% of these tests are positive. This implies that 86% of the additional tests does not have any clinical consequences.
In cardiac patients the concentration of a certain bloodmarker (NT-proBNP) is predictive for future adverse cardiac events. Recent retrospective studies indicated that NT-proBNP might also predict perioperative cardiac events in patients undergoing major vascular surgery.

Study objective

This is a multi-centre prospective study to assess the screening value of N-terminal pro-B-type natriuretic peptide (NT-proBNP) for the identification of patients that benefit from additional cardiac testing prior to vascular surgery.

Study design

This is a prospective observational cohort study including 1800 vascular surgical patients. These patients will be screened for clinical cardiac risk factors and NT-proBNP levels will be assessed.
In all patients without and those with one or two risk factors NT-proBNP concentrations are measured. Those with a normal test are referred for surgery without additional testing. Patients with an abnormal NT-proBNP concentration will be referred for non-invasive cardiac stress imaging. In all high risk patients, those with three or more risk factors, NT-proBNP concentrations are measured and irrespective of the NT-proBNP concentration, routinely all patients will be referred for additional cardiac stress testing.

Study burden and risks

In patients with 3 or more clinical cardiac risk factors an extra blood sample for measurement of NT-proBNP is needed. This extra blood sample is also needed in patients with 0, 1, or 2 clinical cardiac risk factors. Furthermore, in these patients (0, 1, or 2 risk factors) an additional cardiac stress test will be performed in case of an elevated NT-proBNP level. Based on the results of this test the treating physician might do additional testing and/or therapy.

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

Patients with peripheral vascular atherosclerosis scheduled for vascular surgery involving either; a) revascularization utilizing aortic or proximal lower extremity procedures, or b) distal lower extremity vascular reconstruction, are eligible to participate.

Exclusion criteria

No written informed consent.
Unstable coronary disease.
Undergoing emergency surgery.
Previous participation in the DECREASE VI trial.
Reoperation within 30 days of an initial surgical procedure.
Participation in another clinical trial within the last 30 days.
Age <18 years

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-08-2007
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	21-02-2007
Application type:	First submission
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	NL15713.078.06