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

Submission date 11/04/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 11/04/2007	**Overall study status** Completed	
Last Edited 24/11/2011	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.bnpstudy.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
DEDREASE VI

Study objectives
The primary objective of this trial is to validate the screening potential of N-Terminal pro-B-type Natriuretic Peptide (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.

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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Medical Ethics Committee of the Erasmus Medical Centre on the 21st February 2007 (ref: CPB/ss/022897).

Study design
Prospective, non-randomised, non-controlled, parallel group, multicentre trial.

Primary study design
Interventional

Secondary study design
Multi-centre

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Non-cardiac surgery, perioperative cardiac complications

Interventions

Patients scheduled for major vascular surgery (i.e., aorta-iliac/femoral and femoro-popliteal /crural bypass operation) will be screened for the following cardiac risk factors:
1. Aged greater than 70 years
2. A history or symptoms of angina pectoris
3. A history of myocardial infarction (history and/or presence of Q-wave on Electrocardiogram [ECG])
4. A history of congestive heart failure
5. Diabetes mellitus
6. Renal dysfunction (serum creatinine greater than 180 µmol/l), or
7. A history of cerebrovascular accident.

The value of each cardiac risk factor is the same.

In all patients without the above risk factors, 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 of greater than 350 pg/ml will be referred for non-invasive cardiac imaging. Imaging tests will assess Left Ventricular (LV) function at rest, the presence of a pressure gradient over the aortic valve, and the presence and extent of stress-induced ischaemia.

In all high-risk patients, those with three or more risk factors, NT-proBNP concentrations are measured. Routinely, all patients will be referred for additional testing for the evaluation of LV function at rest, the presence of a pressure gradient over the aortic valve, and the presence and extent of stress-induced ischaemia.

Myocardial ischaemia:
Patients without ischaemia as well as those with limited ischaemia are referred for surgery with beta-blocker therapy. In patients with extensive ischaemia, the treating physician will decide further perioperative care. This may be:
1. Cancellation of surgery, a limited procedure, or endovascular repair
2. Surgery with optimal medical cardio-protection, or
3. Prophylactic coronary revascularisation

The type of coronary revascularisation, bypass surgery or percutaneous coronary intervention, is decided by the treating physicians on the basis of coronary anatomy and the possible delay of the index surgical procedure.

Left ventricular failure:
Currently no specific guidelines exist on perioperative management in patients with heart failure. Heart failure has important long-term prognostic value and the decision to continue with surgery can rejected because of this unexpected finding. The attending physicians take this decision.

Aortic valve stenosis:
A mean gradient of 40 mmHg or more is associated with an increased perioperative cardiac event rate. The presence of aortic valve stenosis will influence perioperative anaesthesiological care and haemodynamic management. In selected cases preoperative valve replacement can be considered.

Beta-blocker therapy:
All patients are on perioperative beta-blocker therapy. In patients without beta-blockers,

bisoprolol 2.5 mg once a day is started at the screening visit. Patients on chronic beta-blocker therapy continued their medication. Beta-blocker dose will be adjusted in all patients at admission to the hospital and on the day prior to surgery to achieve a resting heart frequency of 60 - 65 beats per minute. In case of symptoms or markers of myocardial ischaemia accompanied by tachycardia during surgery occurs, additional beta-blocker therapy is administrated. The same dose of beta-blockers will be continued postoperatively except in patients who were unable to take medication orally or by nasogastric tube postoperatively. In these patients, the heart rate is monitored continuously in the intensive care unit or hourly at the ward, and intravenous metoprolol is administered at a dose sufficient to keep the heart rate between 60 - 65 beats per minute. The heart rate and blood pressure are measured immediately before each scheduled dose of beta-blockers. Beta-blockers are withheld if the heart rate was under 50 beats per minute or the systolic blood pressure was under 100 mmHg.

Statin and anticoagulant therapy:
All patients are on perioperative statin therapy. Patients on chronic statin therapy continue their medication. Statin dose is not intensified prior to surgery for reduction of serum cholesterol levels. The same dose of statins will be continued as soon as possible after surgery, either by mouth or nasogastric tube. Statins are withheld if liver dysfunctions occur, defined as an Alanine Aminotransferase (ALT) or Aspartate Aminotransferase (AST) elevations of three-times the upper limit of normal.

Anticoagulant and antiplatelet after percutaneous coronary intervention are continued during surgery.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
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 measures
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.

Overall study start date
01/03/2007

Completion date
01/05/2009

Eligibility

Key inclusion criteria

1. Patients with peripheral vascular atherosclerosis scheduled for vascular surgery involving either of the following are eligible to participate:
a. revascularisation utilising aortic or proximal lower extremity procedures, or
b. distal lower extremity vascular reconstruction

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
1800

Key exclusion criteria
1. Emergency surgical procedures
2. Unability or unwillingness to provide written informed consent
3. Previous participation in this same trial
4. Concurrent participation in another clinical trial
5. Contraindication for cardiac stress testing

Date of first enrolment
01/03/2007

Date of final enrolment
01/05/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Centre
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Sponsor information

Organisation

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ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medical Centre (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration