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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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27132

Bron
Nationaal Trial Register

Verkorte titel
DEDREASE VI

Aandoening

Non-cardiac surgery, NT-proBNP, Perioperative cardiac complications

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Department of Anesthesiology
Overige ondersteuning: Erasmus Medical Center, Department of Anesthesiology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

The primary objective of this trial is to validate the screening potential of NT-proBNP in a population of low to intermediate risk, i.e. patients with zero to two risk factors, scheduled for vascular surgery. Preoperative cardiac testing can identify patients with increased risk. In these patients change of perioperative cardiac management will improve postoperative outcome. However, because of cost-benefit considerations (stress)-testing in this large low to intermediate risk group is not considered. The prevalence of an abnormal test is only 13%. Furthermore, stress testing delays surgery. Presently, no simple cardiac test is available that can be used as an initial screening test to identify either very low risk patients or those with a high likelihood of an abnormal test.
Abnormal NT-proBNP concentrations are associated with abnormal test results such as left ventricular dysfunction, aortic valve stenosis, and stress-induced myocardial ischemia. All these risk factors are associated with adverse postoperative outcome. NT-proBNP may therefore be used as a simple preoperative screening test to direct perioperative management. In patients with a normal NT-proBNP value the risk of perioperative cardiac events should be very low and these patients can be referred for surgery without additional testing. In patients with abnormal NT-proBNP a high incidence of abnormal tests is expected, and these patients might benefit of a testing strategy. This would focus preoperative cardiac screening to a selected high risk population.
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. These patients have a low incidence of postoperative cardiac events and represent approximately half of the population. Commonly, all patients with three or more risk factors are referred for additional testing. If a normal NT-proBNP is associated with a normal test, preoperative assessment can reduce the number of tests.

Doel van het onderzoek

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. 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.

Onderzoeksproduct en/of interventie

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: age>70 years; a history or symptoms of angina pectoris; a history of myocardial infarction (history and/ or presence of Q-wave on ECG); a history of congestive heart failure; diabetes mellitus; renal dysfunction (serum creatinine>180 µmol/l) or a history of cerebrovascular accident. The value of each cardiac risk factor is the same.
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 of >350 pg/ml test will be referred for non-invasive cardiac imaging. Imaging tests will assess LV function at rest, the presence of a pressure gradient over the aortic valve, and the presence and extend of stress-induced ischemia.
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 extend of stress-induced ischemia.
Myocardial ischemia: Patients without ischemia as well as those with limited ischemia are referred for surgery with beta-blocker therapy. In patients with extensive ischemia, 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 cardioprotection or 3) prophylactic coronary revascularization. The type of coronary revascularization, 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 hemodynamic management. In selected cases preoperative valve replacement can be considered.
Beta-blocker therapy: All patients are on perioperative beta-blocker therapy. 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 ischemia 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 ALT or OLT elevations of three-times the upper limit of normal.
Anticoagulant and antiplatelet after percutaneous coronary intervention are continued during surgery.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

1. 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2007
Aantal proefpersonen:	1800
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-02-2007

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL895
NTR-old	NTR919
Ander register	:
ISRCTN	ISRCTN48518771

Resultaten