Non-invasive cardiac screening in patients with peripheral arterial disease: the GROUND study.

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Screening of asymptomatic coronary artery disease using non-invasive modalities in patients with manifestations of atherosclerosis, ie peripheral arterial disease, and subsequent treatment will result in a reduction of cardiac morbidity and...

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

Samenvatting

ID

NL-OMON26430

Bron
Nationaal Trial Register

Verkorte titel
GROUND

Aandoening

peripheral arterial disease; Fontaine II and up; coronary artery stenosis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Fatal and non-fatal myocardial infarction and stroke, and vascular death (death due to vascular disease).

Toelichting onderzoek

Achtergrond van het onderzoek

Background:
Patients with peripheral arterial disease (PAD) have a considerably increased risk of coronary events. The majority of PAD patients die from coronary artery disease. Non-invasive cardiac imaging offers the possibility to assess presence of severe coronary atherosclerosis and /or cardiac ischemia and may further help to identify those PAD patients at very high risk of coronary artery disease.
Furthermore, providing tailored medical care to PAD patients with cardiac abnormalities may actually reduce risk and prevent events.

Objective:
To evaluate whether minimal invasive cardiac imaging, followed by subsequent medical treatment reduces the 5-year risk of cardiovascular events in cardiac asymptomatic patients with PAD.
Design: Multicenter randomized controlled clinical trial.

Methods:
Patients with PAD and no history of coronary artery disease will all be subjected to cardiac imaging using non-invasive cardiac computed tomography (CT). Next, patients will be randomized to either undergo usual medical care or to be actively referred to a cardiologist based on the findings of cardiac imaging. In the latter group, patients will undergo computed tomography angiography (CTA) additionally.
Those patients with a coronary stenosis of the left main coronary artery (or its equivalent) of 50% or more will be referred to a cardiologist for appropriate treatment.
Those with a left coronary artery stenosis of less than 50% will be scheduled for a dobutamine stress magnetic resonance imaging (DSMR) test to assess cardiac ischemia. Patients with cardiac ischemia will be referred for appropriate medical care to a cardiologist, whereas those without cardiac ischemia will be followed for the occurrence of future cardiovascular events. The occurrence of these events, i.e. the combination of fatal and non-fatal coronary heart disease and stroke, will be monitored in both groups. Sequential interim analyses on events will be performed by an independent Data Safety and Monitoring Board. The main efficacy analyses will be performed using a Kaplan Meier model based on the intention-to-treat population. A sample size calculation estimated that 1200 patients have to be enrolled in the GROUND study in order to detect a relative risk reduction of 24% between the two groups.

Conclusion:
The present study will provide insight into the question whether non-invasive cardiac imaging reduces the risk of cardiovascular events in patients with PAD but yet without symptoms of coronary artery disease.

Doel van het onderzoek

Screening of asymptomatic coronary artery disease using non-invasive modalities in patients with manifestations of atherosclerosis, ie peripheral arterial disease, and subsequent treatment will result in a reduction of cardiac morbidity and mortality.

Onderzoeksproduct en/of interventie

Patients randomized to the control group will ondergo a CT scan to determine the coronary calcium score;
Patients in the intervention group will undergo a CTscan for calcium score, and a contrast enhanced CT scan for the evalluation of coronary stenosis.
If no stenosis is found a dobutamine stress MRI of the heart will be performed to identify myocardial ischemia.
If a stenosis is found on either diagnostic test, the patient will be referred to the cardiologist, who will decide if and which treatment he will give the patient for the encountered coronary stenosis.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. PAD patients, stage Fontaine II (intermittent claudication) diagnosed by the vascular surgeon;

2. Patients must provide consent in writing after proper education and discussion with the treating physician and/or research physician;

3. Patients must be aged 50 years or over.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. History of symptomatic cardiac disease;

2. Cardiac rhythm other than sinus;

3. Unable to sustain a breath-hold for 25 seconds;

4. Asthma (contraindication beta-blockers);

5. Contra-indications to MRI examination;

6. Contra-indications to iodine contrast;

7. Severe arterial hypertension (>220/120 mmHg);

8. Significant aortic stenosis;

9. Unable to remain in supine position for at least 60 minutes;

10. Morbidly obese (BMI > 40);

11. Renal insufficiency (creatinine >140mmol/l);

12. Severe physical deterioration due to concomitant illness;

13. Language barrier;

14. Acute coronary syndrome.

15. Contra-indications to dobutamine.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2005
Aantal proefpersonen:	1200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-09-2005
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	NL302
NTR-old	NTR340
Ander register	: N/A
ISRCTN	ISRCTN08433694

Resultaten

Samenvatting resultaten
N/A