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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26430

Source
Nationaal Trial Register

Brief title
GROUND

Health condition

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

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Fatal and non-fatal myocardial infarction;

2. Fatal and non-fatal stroke;

3. Vascular interventions;

4. Amputation;

5. Aortic rupture;

6. End stage renal failure;

7. Extra cranial hemorrhage;

8. Complications of CABG or PTCA;

9. All cause mortality.

Study description

Background summary

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.

Study objective

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.

Intervention

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.

Contacts

Public
University Medical Center Utrecht (UMCU),
Housepost nr E.01.132,
P.O. Box 85500
A.M. Vos, de
Utrecht 3508 GA
The Netherlands
+31 (0)30 2509111
Scientific
University Medical Center Utrecht (UMCU),

Housepost nr E.01.132,
P.O. Box 85500
A.M. Vos, de
Utrecht 3508 GA
The Netherlands
+31 (0)30 2509111

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2005
Enrollment:	1200
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-09-2005
Application type:	First submission

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
NTR-new	NL302
NTR-old	NTR340
Other	: N/A
ISRCTN	ISRCTN08433694

Study results

Summary results
N/A