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

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
14/11/2008

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://jc.med.uu.nl/ground/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR340

Study information

Scientific Title

Acronym
GROUND

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Multicentre, randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Peripheral arterial disease (PAD), coronary artery stenosis

Interventions
1. Patients randomised to the control group will undergo a computed tomography (CT) scan to determine the coronary calcium score
2. Patients in the intervention group will undergo a CT scan for calcium score, and a contrast enhanced CT scan for the evaluation of coronary stenosis.

If no stenosis is found a dobutamine stress MRI of the heart will be performed to identify myocardial ischaemia. 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.

Intervention Type
Other

Phase
Not Specified

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

Secondary outcome measures
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. Extracranial haemorrhage
8. Complications of coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA)
9. All cause mortality

Overall study start date
01/01/2005

Completion date
31/12/2012

Eligibility

Key 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

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1200

Key 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 magnetic resonance imaging (MRI) examination
6. Contra-indications to iodine contrast
7. Severe arterial hypertension (greater than 220/120 mmHg)
8. Significant aortic stenosis
9. Unable to remain in supine position for at least 60 minutes
10. Morbidly obese (body mass index [BMI] greater than 40)
11. Renal insufficiency (creatinine greater than 140mmol/l)
12. Severe physical deterioration due to concomitant illness
13. Language barrier
14. Acute coronary syndrome
15. Contra-indications to dobutamine

Date of first enrolment
01/01/2005

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Utrecht (UMCU)
Utrecht
Netherlands
3508 GA

Sponsor information

Organisation
Julius Centre for Health Sciences and Primary Care (The Netherlands)

Sponsor details
University Medical Centre Utrecht (UMCU)
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Sponsor type
Hospital/treatment centre

Website
http://www.juliuscentrum.nl/julius/

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Groningen (UMCG) (The Netherlands) - Department of Radiology

Funder Name
Julius Centre for Health Sciences and Primary Care (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