

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

<b>Submission date</b> 20/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/11/2008	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
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

## **Study type(s)**

Screening

## **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(s)**

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

## **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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)

**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**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes