Electron Beam Computed Tomography in the selection of (the) patients with chest pain in the practice of the general practitioner.

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We expect that Myocardial Perfusion Imaging will show significantly more frequent ischemia in the case of a positive EBCT than in the case of a positive ETT.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON30012

Source
ToetsingOnline

Brief title
EBT-GP

Condition

- Coronary artery disorders

Synonym
atherosclerose, coronary artery calcification

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chest pain, Electron Beam Computed Tomography (EBCT), exercise tolerance test, ischemia

Outcome measures

Primary outcome

Ischemia on the MIBI scan is the primary endpoint of this study. The predictive

value for the occurence of ischemia on the MIBI scan will be compared between

positive EBCT and positive ETT test results.

Secondary outcome

n.a.

Study description

Background summary

Coronary heart disease is the most frequent cause of death in the Netherlands. It frequently presents with chest pain, which is the common complaint in practice of the general practitioner (GP). The Exercise Tolerance Test (ETT) is used by GP to objectivate the risk of the patient with chest pain for the ischemic heart disease. But ETT has several important disadvantages. The patient has to be able to bike well for this test, which does not always occur. The another disadvantage is that the negative ETT result can not exclude the presence of atherosclerosis.
Therefore a better investigation procedure is required for the patients with chest pain. Electron Beam Computed Tomography (EBCT) is a new CT scan, which performs the calcification in coronary arteries. The risk for the cardiovascular events can be determined using the calcification scores of EBCT.

Study objective

We expect that Myocardial Perfusion Imaging will show significantly more frequent ischemia in the case of a positive EBCT than in the case of a positive ETT.

Study design

This study is a cooperation of the departments of Cardiology, Radiology and General Practitioner Medicine of University Medical Centre Groningen (UMCG). The GP will refer the patients with typical angina pectoris complaints for the ETT to the LabNoord. The patients will be given an explanation about the study design by the GP. The patients who agree with the participation in this research will undergo EBCT in the UMCG.
The outcomes of EBCT and ETT will be compared by the cardiologist and the radiologist of the UMCG. The results of both investigational methods will be sent to the GP with the commentary of the cardiologist. We will evaluate the patients by keeping telephone contact with them (during) after one year of follow-up. The patients will be asked about the developing of the cardiac events, the reference to the specialist and the determination of the diagnosis.

Intervention

The patients will undergo the ETT and EBCT. The patient with negative results of both investigations will be reassured by GP. If one of the investigations will show any abnormalities, the GP is advised to refer the patient to a cardiologist for additional diagnostic procedures (Myocardial Imaging Perfusion scan; MIBI).

Study burden and risks

EBCT has a radiation of 2 mSV. We do not expect that this will have any disadvantages for the patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) patients above the age of 40 years and below 75 years
2) patients with typical angina pectoris complaints
3) patients without a history of cardiac event

Exclusion criteria

1) patients with myocardial infarct, coronary artery bypass graft and/or percutaneous transluminal coronary angioplasty in the medical history
2) pregnant patients

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	04-04-2007
Enrollment:	128
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	27-06-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL11801.042.06