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Multislice computed tomography coronary angiography in patients with stable and unstable angina: a multicentre study

Submission date 02/03/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 02/03/2007	**Overall study status** Completed	
Last Edited 17/11/2008	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ZonMw: 945-04-263, NTR490

Study information

Scientific Title

Study objectives
Is diagnostic non-invasive coronary angiography with Multislice Computed Tomography (MS-CT) a cost-effective alternative to diagnostic invasive coronary angiography in the management of patients with stable and unstable angina pectoris, referred for evaluation of the presence of significant coronary obstructions to determine further treatment strategies consisting of medical treatment, or revascularisation (percutaneous coronary intervention or coronary bypass surgery)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Medisch Ethische Toetsings Commissie Erasmus MC on the 19th November 2004 (ref: MEC-2004-274).

Study design
Prospective multicentre non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Angina pectoris

Interventions
Three centres will be involved of which two centres are University Hospitals:
1. Erasmus Medical Centre, and
2. Utrecht Medical Centre
And one affiliated teaching hospital:
3. Antonius Ziekenhuis Nieuwegein

The Erasmus MC will enrol 60 stable and 60 unstable patients while the other two participating centres will enrol 50 - 60 stable and 50 - 60 unstable patients.

All patients will first undergo a non-invasive MS-CT coronary angiogram. The outcome of the MS-CT scan in terms of presence and location of significant coronary obstruction(s) will be separately assessed by two investigators (one cardiologist, one radiologist) unaware of the outcome of the subsequent diagnostic angiogram. In case of disagreement a third reader will achieve consensus. All patients, independent of the outcome of the scan, will be scheduled for diagnostic coronary angiography. Two cardiologists, unaware of the outcome of the MS-CT scan, will separately assess the diagnostic coronary angiogram.

MS-CT coronary angiography:
An MS-CT coronary angiogram is performed using a bolus injection of 100 ml contrast agent into a brachial vein. The scan is made during a breath-hold of 20 seconds. The whole procedure, including patient instruction, preparation and data acquisition requires about 10 - 15 minutes. A technician under supervision of a cardiologist or radiologist performs the scan. Post-processing and reading of the images requires another 10 - 20 minutes, which is done off-line by a cardiologist and radiologist. It is expected that faster post-processing tools will become available which will significantly reduce MS-CT reading time. A Siemens 16 slice MS-CT (EMC, Rotterdam) and a Philips 16-slice MS-CT (UMC, Utrecht; Antonius Hospital Nieuwegein).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Diagnostic accuracy in terms of sensitivity, specificity and predictive value of MS-CT to detect significant obstructive coronary lesions (more than 50% lumenal diameter reduction with Quantitative Angiography [QCA]) using the diagnostic invasive coronary angiogram as the reference standard.

The costs, effectiveness, and the cost-effectiveness of non-invasive MS-CT coronary angiography as an initial test will be compared to diagnostic invasive coronary angiography.

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/11/2004

Completion date
15/08/2007

Eligibility

Key inclusion criteria
Symptomatic patients with stable angina (N = 160) and unstable angina (N = 160) who are scheduled for diagnostic invasive coronary angiography will be enrolled into the study. In addition these patients also need to fulfill the following inclusion criteria:

1. Male and female younger than 70 years
2. Stable angina pectoris that warrants further evaluation by coronary angiography and revascularisation by percutaneous coronary intervention
3. Stable heart rhythm
4. Heart rate less than 70 beats per minute (either spontaneous or drug-induced)
5. No contra-indications such as severe renal or pulmonary dysfunction or X-ray contrast intolerance

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
320

Key exclusion criteria
1. Older than 70 years, and
2. Have an irregular heart rhythm (predominantly atrial fibrillation), or
3. Have severe renal or pulmonary dysfunction or X-ray contrast intolerance

Date of first enrolment
15/11/2004

Date of final enrolment
15/08/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Centre
Rotterdam
Netherlands
3000 CA

Sponsor information

Organisation

Erasmus Medical Centre (The Netherlands)

Sponsor details
Department of Cardiology and Radiology
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Sponsor type
Hospital/treatment centre

Website
http://www.erasmusmc.nl/

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (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