Computed tomography versus exercise testing in suspected coronary artery disease

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

Summary

ID

NL-OMON34065

Source
ToetsingOnline

Brief title
CRESCENT trial

Condition

- Coronary artery disorders

Synonym
Coronary artery disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Angina pectoris, Computed tomography, Coronary artery disease, Stress testing

Outcome measures

Primary outcome

a) Absence of chest pain at 1 year

b) Diagnostic yield of high-risk coronary artery disease

Secondary outcome

Absence of chest pain at 3 and 5 years

Quality of life at 1, 3, 5 years

Time and cost until diagnosis

Proportion of invasive catheterizations followed by a revascularization

procedure

Overall costs: diagnostics, therapy at 1, 3, 5 years.

Cost-effectiveness (including non-medical costs, including those related to

lost productivity)

Event-free survival, composite endpoint: death, myocardial infarction, CVA,

UAP, ED visits, late revascularizations.

Radiation exposure

Study description

Background summary

Invasive coronary angiography is still regarded as the diagnostic standard for obstructive coronary artery disease (CAD).
However in clinical practice, non-invasive testing is recommended in patients with suspected chest pain largely because of

safety concerns and costs considerations, partly related to the ability of functional tests to assess the hemodynamic relevance of CAD. Due to wide-spread availability and low cost, exercise ECG is recommended as the initial test, followed by stress imaging in selected cases.
CT coronary angiography, which lacks many of the drawbacks of invasive catheter angiography, has emerged as an alternative (anatomical) test for patients with suspected CAD. While CT has been explored scientifically and clinically for this purpose over the past few years, and registry (outcome) data support its value, there is growing demand for randomized-controlled data to establish its incremental diagnostic value and economic consequences.
The cardiology community is currently experiencing renewed appreciation for medical therapy in stable angina, with invasive diagnostics and therapy reserved for selected patients. On the other hand, there is an increasing demand for means to identify individuals at increased risk for adverse cardiovascular events.

Study objective

We designed a trial to evaluate a new diagnostic approach to suspected CAD with consideration for the contemporary insights towards the management of CAD, which incorporates plaque imaging for prevention of adverse events, and maintains a role for functional testing when anatomical imaging is insufficient for medical decision making.
The purpose of this trial is to establish the effectiveness, efficiency and safety of this new diagnostic workup using cardiac CT in comparison to the current standard approach to suspected coronary artery disease.

Study design

Study design:
Multi-center, randomized-controlled, clinical efficiency trial, by intention to diagnose.
After the initial clinical assessment, eligible consenting patients will be randomized:
1) Standard clinical care based on functional testing according to guidelines
2) Clinical management based on CT imaging.

Recruitment and randomization:
Patients will be screened at the time of referral to the respective out-patient cardiology clinic, and potentially eligibility patients will receive documentation before their visit (including baseline questionnaires). All patients will undergo a comprehensive

history and physical examination, blood analysis and ECG. During their visit questions regarding the study will be answered
and in case of confirmed eligibility and willingness to participate an electronic 2:1 randomization will take place.

Investigational CT group:
First a low-dose (<1 mSv) CT scan (64/128-slice dual source CT) without contrast injection is performed to quantify coronary
calcifications (CCS):
- Negative CCS (and <80% CAD probability): obstructive CAD excluded (est. 37%).
- High CCS (>400): proceed to stress testing because of the high probability of angiographic CAD and limited discriminative
value of CTA (14%).
- Remaining patients will undergo CTA (+/-50%).

Contrast-enhanced CT (average 5 mSv, heart rate modulation, sublingual nitroglycerin), will be performed to identify coronary
stenoses and atherosclerotic plaque (CTA):
- Stenosis <50%: obstructive CAD excluded (63%).
- Low-risk obstructive CAD (1-/2-vessel CAD, not being the left main or proximal LAD) treated with medication, catheter
angiography when symptoms persist (+/-25%).
- High-risk CAD: left main >50%, proximal LAD >70% or 3-vessel CAD referred to invasive angiography (<10%).
- Non-conclusive CTA (technical failure, borderline disease) for stress testing (+/-5%).

Patients referred to stress testing (<30%) undergo XECG and/or SPECT perfusion scintigraphy (MPS) with the same criteria as
the standard care group.
In addition to conventional indications (risk profile, SCORE criteria), patients with a CCS>400, extensive plaque or >50%
stenosis on CTA will qualify for intensified prevention (lifestyle advise, medication).
Standard care group
Patients referred to stress testing (<30%) undergo XECG and/or SPECT perfusion scintigraphy (MPS) with the same criteria as
the standard care group.
In addition to conventional indications (risk profile, SCORE criteria), patients with a CCS>400, extensive plaque or >50%
stenosis on CTA will qualify for intensified prevention (lifestyle advise, medication).

Standard care group
XECG and/or myocardial perfusion SPECT (MPS), and invasive angiography if required, is performed and interpreted in a
protocolized manner, in accordance with international guidelines [7]. Similarly

to the investigational arm, low-risk obstructive
CAD will be treated medically before referral to invasive angiography and/or revascularization.

Follow-up
Baseline/3/6/12 months:
* Seattle Angina Questionnaire
* Quality of Life rating scale
12 months:
* CBS mortality record
* Telephone interview
* SF-36, EuroQol (quality of life)
* Medical cost, patient costs and productivity
Clinical events will be confirmed by hospital records

Intervention

Diagnostic intervention with replacement of the stress test by a cardiac CT scan (in the absence of contra-indications)

Study burden and risks

Risks:
1) A larger proportion of patients will receive iodine contrast medium. Known allergies or kidny dysfunction are contraindications to iodine contrast. The risk of kindeydysfunction is small in patients with a normal kidneyfunction (which will be checked). Allergic reactions are rare. Medciation and personnel is available to deal with unexpected reactions. Patients with minimal, or uncertain reactions in the past will be pre-medicated with H2-antagonists and corticosteroids. Contrast extravasation can cause skin damage but bis rare and can be limited by special extravasation detectors.
2) Exposure to radiation is not increased by participation to the study.
3) Although an expected improvement in patient experience and outcome is expected in the overall population, individual cases of the oposite may occur. Given the low mortality of chronic coronary disease we expect that the clinical consequences will be of a minor scale, and (again) will be outbalanced by individuals in whom better and faster decisicon scould be made based on the CT result.

Time burden:
There are no significant physical burdens. As a matter of fact many patients tolerate the CT examninations better than the stress tests.
In terms of time particiaption will take a few hours over 5 years, mostly related to filling out quyestionnaires.

Benefits & group relatedness:

If the hypothesis is correct, then patients that underwent CT will benefit. In general, participation to the study benefits similar patients in the future.

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

Stable symptoms of hest pain/dyscomfort or dyspnea that is possibly the result of coronary artery disease.
Age >18 yrs, ability and willingness to provide infromed consent

Exclusion criteria

A history of surgical or percutaneous coronary revascularization, or non-revascularized angiographic obstructive coronary artery disease (>50% diameter reduction).
Normal invasive coronary angiography or stress imaging less than 1 years ago.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-04-2011
Enrollment:	1250
Type:	Actual

Ethics review

Approved WMO

Date:	03-01-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL34060.078.10