Towards a non-invasive anatomical and functional diagnostic work-up of patients with suspected coronary artery disease using Cardiovascular Magnetic Resonance Imaging and Multidetector CT

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Primary objectives:1. To determine and compare diagnostic accuracy of CMR, MDCT calcium score and MDCT coronary angiography for the detection of significant CAD, using invasive coronary angiography as reference standard2. To develop a screening...

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

Summary

ID

NL-OMON30468

Source
ToetsingOnline

Brief title
MARCC (MRI an CT in suspected coronary artery disease)

Condition

- Coronary artery disorders

Synonym
coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Funding is aangevraagd.

Intervention

Keyword: coronary disease, diagnosis, imaging

Outcome measures

Primary outcome

Diagnostic accuracy of CMR, MDCT calcium score and MDCT coronary angiography for the detection of significant CAD, using invasive coronary angiography as reference standard.

Development of a diagnostic algorithm (decision tree model) involving the sequential use of both imaging modalities.

Secondary outcome

Costs relative to diagnostic accuracy for CMR and MDCT, and for the proposed algorithm.

One-year clinical outcome.

Study description

Background summary

Establishing the diagnosis of coronary artery disease (CAD) in a patient presenting with chest pain remains a challenging task. Patients with low likelihood of CAD (<10%) according to clinical history may be dismissed without further testing. The management of patients with intermediate to high probability is less clear. Coronary angiography (CAG) is an invasive and expensive procedure, and is considered inappropriate as a first line technique, except in the very high-risk patients, and non-invasive testing is generally used to further refine the clinical suspicion of disease. Current clinical

practice using ECG-exercise testing, stress (nuclear) myocardial perfusion imaging (SPECT), or stress echocardiography leads to a considerable number of unnecessary referrals for CAG.
Based on local availability and expertise, we have therefore recently adopted a different and more structured diagnostic strategy, that uses Cardiovascular Magnetic Resonance imaging (CMR) and multidetector (MD)CT as first line imaging modalities instead of nuclear techniques, echocardiography or exercise testing. CMR effectively assesses myocardial perfusion and function in patients with (suspected) ischemic heart disease. MDCT accurately depicts coronary artery anatomy and atherosclerotic changes including coronary artery related calcium. This project primarily aims at evaluating the diagnostic accuracy of the non-invasive CMR/MDCT work-up by comparison with invasive examinations, and at the development of an optimal diagnostic algorithm by exploring the sequential use of both techniques.

Study objective

Primary objectives:
1. To determine and compare diagnostic accuracy of CMR, MDCT calcium score and MDCT coronary angiography for the detection of significant CAD, using invasive coronary angiography as reference standard
2. To develop a screening algorithm (decision tree model) involving the sequential use of both imaging modalities

Secondary objectives:
1. To calculate and compare the costs relative to diagnostic accuracy for CMR and MDCT, and for the proposed algorithm
2. To record 1-year clinical outcome, from which pilot results can be referred to set up a multicenter study to evaluate the prognostic accuracy of the CMR/MDCT work-up

Study design

220 symptomatic patients (30-70) that undergo the CMR/MDCT work-up for suspected CAD of intermediate likelihood will be invited to participate in the study. All patients will undergo coronary angiography, either clinically indicated because of an abnormal work-up (80%) or for study purposes (20%). Non-invasive and invasive test results will be compared and diagnostic accuracy of CMR, MDCT-calcium score and MDCT coronary angiography for the detection of significant CAD will be calculated. Using these results, a decision tree will be designed for the optimal approach of patients with intermediate likelihood CAD. From 1-year clinical outcome data pilot results will be referred to set up a multicenter study to evaluate the prognostic accuracy of the CMR/MDCT work-up.

Study burden and risks

For the majority of the study group there are no additional risks involved in participation. All patients with a negative work-up will also be invited to undergo coronary angiography (CAG) to assess specificity and negative predtictive value of the work-up.
Compared to MRI and CT, CAG is associated with higher burden and risk (see also item E9). However, the likelihood of complications in this patient group without cardiovascular or renal disease is very low, and acceptable when weighted against the study goals (establishing diagnostic accuracy of the work-up and creating a fast and more effective diagnostic trajectory), which may benefit many future 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

VUMC CMR/MDCT work-up because of suspected coronary artery disease (CAD).
Chest pain of intermediate likelihood for significant CAD as determined from age, gender and history (10-90% according to combined Diamond/Forrester/CASS scale; ref: Gibbons RJ et al. Circ 2003;107:149-158.).
No prior documented CAD.

Exclusion criteria

Any change in clinical condition between the examinations, failure to sign the informed consent.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-09-2007
Enrollment:	220
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL16262.029.07