CArdiac magnetic resonance perfusioN imaging for SELection of patients for additional invasive evaluation after CT coronary angiography (CANSEL)

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To validate MR myocardial perfusion by first pass magnetic resonance with adenosine stress in patients with suspected coronary artery stenosis as identified by CT-CA, using FFR as the reverence method.

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

Summary

ID

NL-OMON31103

Source
ToetsingOnline

Brief title
CANSEL

Condition

- Coronary artery disorders

Synonym
coronary atherosclerosis, MRI

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: adenosin, Magnetic resonance imaging, perfusion

Outcome measures

Primary outcome

We expect a high sensitivity and specificity for first pass magnetic resonance imaging to detect a significant coronary artery stenosis as determined by FFR.

Determination optimal cut of value.

There is no benefit for the individual patient. In the future in patients with coronary stenosis identified by CT-CA, myocardial perfusion MRI will predict who may benefit from coronary revascularisation. Furthermore the combination of CT-CA, and myocardial perfusion study using magnetic resonance will also predict who do not have a coronary stenosis and therefore do not need ICA.

Secondary outcome

NA

Study description

Background summary

Invasive coronary angiography (ICA) has been the standard for coronary artery disease detection for many years. More recently CT coronary angiography (CT-CA) has emerged as a safe, non-invasive and accurate diagnostic modality to detect the presence of coronary atherosclerosis. However both techniques provide only anatomical information and the functional significance of the anatomical coronary artery abnormalities may be difficult to determine. At the time of catheterisation, the functional significance of a coronary stenosis can be determined by measuring fractional flow reserve (FFR). FFR is derived from a ratio of the mean distal coronary artery pressure to the aortic pressure during maximal vasodilatation. It is a well established technique with proven clinical

value.
Compared to the invasive FFR measurement, non-invasive stress testing and myocardial perfusion studies may also aid clinical decision making in determining the significance of coronary stenosis. Given the increasing use of CT-CA, such non-invasive functional assessment may avoid the need for ICA in a significant proportion of patients.
One commonly-used non invasive test is myocardial single photon emission computed tomography (SPECT). Myocardial SPECT has high sensitivity and specificity for detection of significant coronary stenosis, but it exposes the patient to radiation, has low spatial resolution, and is time consuming for the patient. Stress echocardiography has similar sensitivity and specificity compared to SPECT, but it is more operator dependent and adequate echo windows may not be available in ~ 5% of patients.
Myocardial perfusion can also be determined non-invasively by first pass contrast magnetic resonance imaging, and this may be a good alternative to myocardial SPECT and stress echocardiography.
Advantages of MRI compared to SPECT include improved spatial resolution and the avoidance of radiation exposure, and MRI may provide a quantitative analysis comparable to FFR measurements. Furthermore, the combination of CT-CA and a MRI perfusion study could provide a comprehensive, non-invasive evaluation of the extent and significance of coronary artery disease. Presently only 1/3 of all patients referred for invasive analysis after abnormal CTCA findings have a positive FFR. A significant improvement in specificity would reduce the number of unnecessary invasive evaluation in the future but still have a high negative predictive value.

Study objective

To validate MR myocardial perfusion by first pass magnetic resonance with adenosine stress in patients with suspected coronary artery stenosis as identified by CT-CA, using FFR as the reverence method.

Study design

We will evaluate the diagnostic accuracy of first pass magnetic resonance in patients with suspected coronary artery disease on CT-CA.
We intend to include seventy-five patients who have suspected obstructive coronary artery disease as determined by CT-CA as part of an evaluation for their chest pain syndrome. These patients undergo ICA as part of their clinical work-up. This includes measurement of FFR by local clinical protocol; FFR will be done when the stenosis calculated with quantitative coronary angiography (QCA) is between 30% and 90% of the lumen of the vessel. Prior to ICA, we will determine myocardial perfusion by first pass magnetic resonance.

Study burden and risks

Participating in the study will involve data collection and MR imaging with low-dose adenosine stimulation. MR imaging itself has no known risks. Contrast agent gadolinium diethyltriaminepentaacetic acid has minimal adverse effects in the population to be studied (note especially the exclusion of patients with insufficient renal function). The risk inherent in administration of low doses of adenosine is minimal. During the MRI imaging there will always be a physician present to answer any questions and/or provide medical attention if necessary. The physician is trained in CPR. ECG monitoring leads will be applied for continuous rhythm control and a brachial blood pressure curve for regular blood pressure measurements. Nitroglycerine will be present in case the patient has angina pectoris. There is a crash car at the Department of Radiology to stabilize the patient to his/her way to the CCU, if necessary.

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. Suspected obstructive CAD on CT-CA
2. Planned invasive coronary angiography

Exclusion criteria

1. Previous myocardial infarction
2. Previous percutaneous coronary intervention or coronary artery bypass grafting
3. Contraindications for MRI
4. Possible pregnancy and/or breast feeding
5. Inability to breath hold for up to 15 seconds
6. Inability to give reliable informed consent
7. Known claustrophobia
8. Unstable coronary artery disease
9. Known allergy to contrast material
10. Renal insufficiency
11. COPD.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-08-2007
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	06-08-2007
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	NL17545.078.07