The role of MRI viability testing to decide on percutaneous coronary interventions strategies of complex coronary artery disease.

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To evaluate the predictive value of different MRI techniques to establish viability to guide percutaneous interventions decisions in patients with complex coronary artery disease.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON30200

Source
ToetsingOnline

Brief title
VICAD

Condition

- Heart failures

Synonym
myocardial infarction, viability

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: Dobutamine, Magnetic resonance imaging, Revascularisation, Viability

Outcome measures

Primary outcome

regional wall motion abnormalities

Secondary outcome

end-diastolic volume

end-systolic volume

ejection fraction

Study description

Background summary

Revascularisation has proven to be of benefit for survival of patients with left main or 3-vessel disease and depressed systolic left ventricular function when compared to medical therapy. The evidence is largely based on two non-randomised surgical studies performed almost 20 years ago. Randomized studies evaluating the effect of percutaneous coronary interventions (PCI) on survival in such patients are not performed. Improvement of left ventricular function can be used as a surrogate and ejection fraction is presently used as selection criteria for ICD implantation. Studies on the effect of PCI on left ventricular function are limited and not focussed on patients with 3-vessel disease and depressed systolic LV function.
The effect of revascularisation in patients with depressed systolic left ventricular function can be predicted by establishing the viability of hypo- or akinetic segments. MRI has been recently introduced as non-invasive imaging tool that can identify reversible dysfunctional myocardium since it offers transmural differentiation of necrotic and viable myocardium in the setting of chronic myocardial infarction. The transmural extent of infarction predicts regional functional recovery after revascularization and the extent of dysfunctional but viable myocardium predicts recovery of global left ventricular function. However, in myocardial segments with >25% to <75% transmural extent of infarction, prediction of improvement is less reliable. In a first study on recovery of wall motion after percutaneous recanalisation of chronic total occluded coronary arteries we observed the same limitation.

Alternatively low-dose dobutamine MRI can be used to establish viability and may especially be useful for segments with an intermediate extent of viability. Quantitative assessment of wall motion by tagging combined with rapid post processing algorithms may be another less cumbersome and more quantitative option to improve sensitivity and specificity.

Delayed enhanced MRI and low-dose dobutamine MRI are relative new techniques which offer an increased resolution to investigate prior myocardial infarction and functional myocardial reserve. This project will increase the knowledge in MRI as diagnostic tool and lead to prediction rules before complex coronary interventions. In the near future the techniques developed may guide treatment of the individual patient. This may lead to reduction in cost by avoiding unnecessary interventions or reduction of vessels treated.

Study objective

To evaluate the predictive value of different MRI techniques to establish viability to guide percutaneous interventions decisions in patients with complex coronary artery disease.

Study design

The project will be a prospective follow-up study where one hundred patients will be studied before, 6 and 12 months after percutaneous intervention with contrast enhanced cardiac MRI. Two patient groups will be included.
First group will be patients (N =50) referred for PCI of complex coronary artery disease defined as a chronic total occlusion (CTO) with regional wall motion abnormalities.
The second group will be patients (N =50) referred for PCI in multivessel disease with severe depressed LV function (EF< 35%).

Study burden and risks

The patient has to visit the hospital one time before the PCI and 6 and 12 months after the PCI-procedure.
The patient will be informed concerning the procedure; the breath hold, contrast injection and dobutamine injection will be explained. An intravenous catheter will be placed in the antecubital vein. ECG monitoring leads and a brachial blood pressure curve will be applied.
During the scan the patient will be continuously monitored with ECG leads. Systolic and diastolic blood pressures will be recorded with an automatic device at baseline and every 3 minutes. After baseline acquisitions dobutamine (5-10 mcg/kg/min) will be infused intravenously using a pump injector. During the infusion of dobutamine the researcher and the cardiologist will be present to monitor the conditions of the patient and to evaluate the images. Patient and researcher will be able to communicate at every moment, ensuring good

clinical conditions of the patient. MRI is not dangerous for the patient physically.

Dobutamine;
Dobutamine can rise the blood pressure with 10-20 mmHg. When the patient is known with hypertension, blood pressure can rise with 40 mmHg.
In 1-3%; headache, nausea, angina.
Pregnant patients will be excluded in this study because there is less known about the effects of dobutamine in pregnant women.

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

chronic coronairy arterie disease

ejection fraction <50%
approximately 3 adjacent segments with wall motion abnormalities at rest

Exclusion criteria

(1) contraindications for MRI, pacemaker, cochlea implant (2) pregnancy (3) Inability to breath hold for up to 15 seconds (4) Inability to give reliable informed consent (5) known claustrophobia, (6) unstable coronary artery disease, (7) known allergy to contrast material.

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):	22-08-2006
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	22-08-2006
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	NL11721.078.06