Diagnostic accuracy of coronary CT and contrast enhanced cardiac MRI to detect coronary artery stenoses

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON37796

Source
ToetsingOnline

Brief title
Diagnostic accuracy of coronary CT and contrast enhanced CMR

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
atherosclerosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cardiac Magnetic Resonance Imaging (CMR), Coronary artery disease (CAD), Coronary Computed Tomography Angiography (CCTA), Fractional flow reserve (FFR)

Outcome measures

Primary outcome

1. to compare the diagnostic performance of coronary CTA with MRA to detect significant coronary stenoses (> 50% reduction in lumen diameter), in patients with a range of coronary calcium scores, using conventional angiography as a reference standard

Coronary CTA: Significant stenoses (>50% reduction in diameter)

Coronary MRA: Significant stenoses (>50% reduction in diameter)

CAG: Significant stenoses (>50% reduction in diameter)

2. to assess the diagnostic performance of coronary MRA in combination with perfusion and late enhancement MR imaging to detect hemodynamically significant stenoses, using FFR and CFR as a reference standard

Coronary MRA, perfusion MR and late enhancement MR imaging: visually decreased or absent perfusion.

hemodynamically significant stenoses: (1) diameter stenoses >70%, (2) 30-70% stenoses if the FFR is < 0.8 or CFR < 2

Secondary outcome

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Study description

Background summary

Cardiovascular disease remains the leading cause of morbidity and mortality worldwide. Coronary computed tomography angiography (CCTA) is currently preferable to MR angiography (MRA) for ruling out significant coronary artery disease. Unfortunately, the diagnostic accuracy of CCTA is degraded in the presence of a high calcium score. Cardiac CMR may improving diagnostic accuracy in the detection of coronary artery disease.

Study objective

The primary objectives of our study are:

1. to compare the diagnostic performance of coronary CTA with coronary MRA to detect significant coronary stenoses (> 50% reduction in lumen diameter), in patients with a range of coronary calcium scores, using conventional coronary angiography (CAG) as reference standard

2. to assess the diagnostic performance of coronary MRA in combination with perfusion and late enhancement MR imaging to detect hemodynamically significant stenoses, using FFR and CFR as a reference standard

Study design

Eighty-five patients scheduled for CAG and fractional flow reserve (FFR) will undergo a 256-slice coronary CT and cardiac magnetic resonance (CMR) at 1.5 Tesla. The CMR examination will consist of coronary MRA, perfusion MR and late enhancement MR imaging.
The diagnostic accuracy of CCTA and coronary MRA for the detection of a >50% reduction in lumen diameter will be determined using CAG as the reference method. Furthermore, the CMR examination will be compared against FFR and coronary flow reserve (CFR). FFR and CFR will be measured in all vessels with 40-70% severity stenosis. FFR < 0.80 and CFR < 2.0 will be considered hemodynamically significant.

Study burden and risks

In this study patients will undergo a coronary CT scan and a cardiac MR scan. For any risk associated with the use of contrast all necessary precautions will be taken (see E7/E9). The radiation dose of the coronary CT is very limited. Although the radiation dose is higher than the maximum recommended annual dose for the general population it doesn't exceed the dose limit that applies to those working with X-rays. Furthermore, no adverse effects are known

of 1.5 Tesla MRI. The burden associated with participation is justified given the importance of improved diagnosis in patients with atherosclerosis and in the future the possibility for better treatment.

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

- patients scheduled for coronary angiography (CAG)in combination with fractional flow reserve (FFR)/ coronary flow reserve (CFR) measurements
- 18 years or older
- signed, written informed consent

Exclusion criteria

- acute coronary syndrome
- atrial fibrillation
- previous coronary bypass graft surgery
- previous myocardial infarction
- impaired left ventricular (LV) function (ejection fraction < 40%),
- obstructive pulmonary disease
- pregnancy or possible pregnancy
- lactation
- documented allergic reaction to gadolinium or iopromide
- subjects with impaired renal function (severe renal insufficiency, GFR < 30 ml/min/1.73m2)
- impossibility to undergo a MRI scan (determined by using the standard contraindications for MR imaging as used for clinical purposes)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	90
Type:	Anticipated

Ethics review

Approved WMO

Date:	07-03-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL37846.041.11