Assessment of Coronary Artery Disease with Multi-Slice Computed Tomography combined with Stress Cardiac Magnetic Resonance Imaging compared to Coronary Angiography combined with Fractional Flow Reserve Trial

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

Summary

ID

NL-OMON39232

Source
ToetsingOnline

Brief title
COMFORT

Condition

- Coronary artery disorders

Synonym
angina pectoris, stable angina pectoris

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Cardiac Magnetic Resonance, Computed Tomography, Coronary Artery Disease, Fractional Flow Reserve

Outcome measures

Primary outcome

The diagnostic accuracy of MSCT coronary angiography in combination with stress CMR imaging as compared to invasive CAG and FFR measurement, as a standard of reference to detect obstructive and hemodynamically significant stenoses in patients with low to intermediate pre-test likelihood of CAD will be investigated.

Secondary outcome

The ability of combined use of MSCT coronary angiography and stress CMR imaging to predict treatment strategy (medical therapy versus revascularization therapy) as compared to CAG and FFR will be determined.

Study description

Background summary

It has been demonstrated in previous studies that there is a discrepancy between the coronary artery stenosis severity and its hemodynamic significance.

Moreover, data are available that only lesions with hemodynamic significance may be appropriate to treat with revascularization. Accordingly, the ability to detect hemodynamically significant lesions is clinically relevant. Multi-slice computed tomography (MSCT) allows non-invasive detection of coronary artery stenoses, whereas stress cardiac magnetic resonance (CMR) imaging allows non-invasive visualisation of myocardial ischemia.

Study objective

The purpose of the study is to assess the diagnostic accuracy of a combined use of non-invasive coronary angiography with multi-slice computed tomography (MSCT) and stress cardiac magnetic resonance (CMR) imaging in patients with obstructive lesions on MSCT and with low to intermediate pre-test likelihood of coronary artery disease (CAD) as compared to invasive coronary angiography (CAG) and Fractional Flow Reserve (FFR) measurements.

Study design

Multi-center prospective study.

Study burden and risks

Based on currently available clinical evidence, risks related to the devices used in this study are comparable to standard equipment used. Dual source MSCT is performed in routine clinical practice and is considered as a safe, non-invasive investigation, although it involves administration of contrast medium, and the use of radiation. Accordingly, only patients with good kidney function and with no prior history of allergy to contrast agents will be included in the study. The MSCT protocols with the least possible radiation exposure will be applied, so that exposure favourably compares to other non-invasive imaging modalities (such as myocardial perfusion scintigraphy).
For stress CMR imaging, gadolinium contrast agent and adenosine administration will be required. Accordingly patients with known contraindications to one of these agents will not be eligible for participation.
Similarly, administration of adenosine is necessary for the FFR measurements. Accordingly, patients with contraindications for adenosine will not be included in the study.

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.Patients with stable angina pectoris with low to intermediate pre-test likelihood of CAD;
2.no previous history of CAD;
3.obstructive stenosis (*50% luminal narrowing) on MSCT coronary angiography;
4.informed consent.

Exclusion criteria

1.patients with a previous history of CAD;
2.patients with contraindications for MSCT:
a.cardiac rhythms other than sinus rhythm,
b.pregnancy,
c.allergy for contrast medium,
d.renal failure (estimated glomerular filtration rate (eGFR) < 50ml/min),
e.resting heart rate >75 bpm plus contra-indications for beta-blockade,
f. weight >100 kilograms;
3. contraindications for cardiac magnetic resonance (CMR) imaging:
a.MR-incompatible implants,
b. Claustrophobia,

c. contraindications for adenosine:
i. known or suspected hypersensitivity to adenosine,
ii. known or suspected bronchoconstrictive or bronchospastic disease,
iii. 2nd or 3rd degree atrioventricular (AV) block,
iv. Sinus bradycardia (heart rate < 45 bpm),
v. Systemic arterial hypotension (<90 mmHg).
d. contraindications for gadolinium:
i. renal failure (estimated eGFR <30 ml/min);
4. no informed consent.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2011
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	15-07-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-08-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL36359.042.11