Dual Energy Computer tomography in acute and chronic myocardic infarction.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON34601

Source
ToetsingOnline

Brief title
Demi study

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
Myocardial infarction; heart attack

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: acute myocardial infarction, chronic myocardial infarction, Dual energy computed tomography, Magnetic resonance imaging

Outcome measures

Primary outcome

Assessment of the presence of myocardial infarction per coronary distribution

on Dual Energy CT images, using MR as the reference standard.

Secondary outcome

assessment of the presence of no-reflow areas per coronary distribution on Dual

Energy CT images, using MR as the reference standard

visual-semiquantitative analysis of scar tissue

manual planimetry for the quantification of the scar tissue

Study description

Background summary

In patients with coronary artery disease (CAD), myocardial dysfunction due to acute or chronic myocardial infarction may remain viable and may be restored with revascularization. The identification of the viable myocardium has important clinical and prognostic implications on the outcome of patients with CAD. Magnetic Resonance Imaging (MRI) is considered the standard of reference in the detection of myocardial scarring in both acute and chronic infarctions. Thanks to several technical developments, cardiac Computed Tomography (CT) with Dual Energy technique can be used not only for the detection of coronary artery stenoses but also for the study of the myocardium.
We hypothesize that Dual Energy CT can accurately detect and quantify areas of myocardial scarring in patients with acute and chronic infarctions. Patients who are not suitable for MRI imaging due to contraindications (e.g. patients with defibrillators and pacemakers) could be investigated with cardiac Dual energy CT for the evaluation of myocardial viability.

Study objective

The main goal of this study is to assess the diagnostic performance of Dual Energy CT in the detection of acute and chronic myocardial infarctions using MRI as a reference standard. The diagnostic performance of Dual Energy CT will be also assessed for the detection of no-reflow areas using MRI as reference of standard.

Study design

Prospective diagnostic accuracy trial. Patients with either acute or chronic myocardial infarction will undergo both cardiac Dual Energy CT and MRI. In addition to the standard CT coronary angiography for the evaluation of the lumen of the coronary arteries, an extra delayed scan with Dual Energy mode will be performed for the evaluation of the myocardium. After the CT examination, the patients will be examined with MRI.

Study burden and risks

Nature and extend of the burden and risk associated with participation, benefit and group relatedness:
Cardiac CT is associated with radiation exposure to the patient. The patient will be scanned twice in this research protocol: to evaluate first pass perfusion and no-reflow (arterial phase, scan 1), and delayed enhancement (late phase, scan 2). However, several radiation reduction techniques will be applied to minimize radiation exposure.
The results of this study are one step in improving the diagnosis and monitoring of persons with cardiac infarction.

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 with acute myocardial infarction
- Age>40 years
- Onset of symptoms no more than 14 days before CT and MRI;If Acute no ST-elevation myocardial infarction (NSTEMI)
- Clinical presentation: rest angina/ new-onset severe angina/ increasing angina
- ST segment depression >=0.05mV or inverted T waves >=0.2mV
- Detection of troponine T or CK elevation over a period of 24-48 hours
- Imaging evidence of new loss of viable myocardium or new regional wall motion abnormalities;Patients with chronic myocardial infarction
- Age>40 years
- Impaired left ventricle ejection fraction
- Regional myocardial dysfunction

Exclusion criteria

Clinical contraindications:
- Ongoing ischemia
- Relevant arrhythmias
- Coronary artery by-pass graft (CABG)
- Impaired renal function (serum creatinine>120 *mol/l or GFR<60 ml/min)
- Hemodynamic instability
- Possible pregnancy and breast feeding
- Body weight exceeding 120 kg
- Inability to breath hold for up 15 seconds
Contraindications for CT coronary angiography, including:
- Known allergy to iodated contrast material
Contraindications for MRI, including:

- MR incompatible metal in the body (pacemaker, metal implants, cerebral aneurysm clips, *)
- Severe claustrophobia
- Known allergy to gadolinium-based 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):	25-01-2011
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO

Date:	13-01-2011
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	NL33466.078.10