DYNAMIC STRESS PERFUSION CT FOR DETECTION OF INDUCIBLE MYOCARDIAL ISCHEMIA

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To determine the diagnostic accuracy of MPICT for the detection of hemodynamically relevant coronary stenosis (as determined by invasive FFR) in patients with suspected or known CAD clinically referred for invasive angiography. In an optional sub-...

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

Summary

ID

NL-OMON45802

Source
ToetsingOnline

Brief title
SPECIFIC trial

Condition

- Coronary artery disorders

Synonym
due to functional constriction or actual obstruction of a blood vessel., MYOCARDIAL ISCHEMIA; deficiency of blood in a part

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Siemens,Siemens Healthcare

Intervention

Keyword: Ct scan, Dynamic Stress Perfusion, FFR - Fractional flow reserve, Inducble Myocardial Ischemia

Outcome measures

Primary outcome

Myocardial perfusion defect on dynamic CT perfusion imaging, and diagnostic

accuracy as compared invasive FFR.

Secondary outcome

na

Study description

Background summary

Cardiac computed tomography (CT) provides accurate assessment of the coronary arteries and detects significant coronary stenosis with high diagnostic accuracy. However, the hemodynamic relevance of these stenotic lesion remains unclear, although highly relevant for clinical decision-making. Recent technical developments with third-generation dual-source CT allow to determine myocardial perfusion during hyperemia and thus for assessment of the hemodynamic relevance of coronary lesions using a dynamic acquisition mode. To date, there is only very limited evidence of the feasibility of this approach stemming from single-center studies with varying standards of reference.

Study objective

To determine the diagnostic accuracy of MPICT for the detection of hemodynamically relevant coronary stenosis (as determined by invasive FFR) in patients with suspected or known CAD clinically referred for invasive angiography. In an optional sub-study the diagnostic accuracy of MPICT for the detection of myocardial perfusion defects as determined by cardiac magnetic resonance imaging (CMRI) will be investigated.

Study design

Observational cohort study with fractional flow reserve (FFR) during invasive

angiography as the reference standard.

Study burden and risks

The study protocol comprises the CT examination including a standard cardiac CT angiography with the injection of iodinated contrast and a CT perfusion acquisition under pharmacological stress using the latest 3rd generation dual-source CT system. Patients will undergo cardiac catheterization as part of their clinical care (inclusion criterion). FFR will be performed in all potentially hemodynamically relevant lesions (25% to 90% luminal narrowing), which may include lesions otherwise not investigated based on available noninvasive test results. Optionally, subjects may also undergo CMR if available locally and selected by participant forming an MR sub-study. All study exams will be performed in this population according to international guidelines.
The dynamic CT perfusion exam is safe, has been previously applied, and uses a validated pharmacological stress agent (adenosine). Standard risk of CT scanning include radiation exposure (10mSv or less), contrast related allergies or contrast nephropathy. All measures will be taken to keep the radiation dose low, while patients at risk for contrast related injury will be excluded. The optional MRI is free of radiation, although contrast allergies may occur and patients with kidney dysfunction will be excluded in order to avoid the risk of nephrogenic systemic fibrosis. Some FFR measurements will be performed for research purposes only, which in rare cases is complicated by damage to the coronary artery. However, these FFR measurements have been shown to improve patient care (DEFER, FAME, FAME2). All examinations are performed by experiences personnel, qualified and able to handle any adverse events occurring.
Although there are no direct rewards, patients may benefit from the additional information from imaging not related to the study (infarct detection and ventricular function on MRI), incidental imaging findings (i.e. bronchial carcinoma), and the clinically validated information from the additional FFR investigations, which could favorably alter clinical decision making. If confirmed, future patient populations may substantially benefit from a combined CT procedure that includes morphologic and functional information (dynamic CT perfusion) in a single and comfortable exam.

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

* Age > 21 years
* Stable angina symptoms, suspected or known CAD, and referred for invasive angiography on clinical grounds.
* Ability to provide informed consent
* Ability to perform a 20-30 second breath hold

Exclusion criteria

* Hemodynamically and clinically unstable condition (angina at rest, malignant arrhythmias)
* Prior, documented myocardial infarction, other than (procedure related) minor type II myocardial infarction, which includes Q waves on the ECG or evidence of myocardial infarction on prior non-invasive imaging.
* Coronary artery bypass graft surgery or primary PCI for acute myocardial infarction.
* Significant other cardiovascular conditions affecting the interpretation of MPICT, including, but not limited to: clinical heart failure, IECD (pacemaker/ICD), severe valvular heart disease or prosthetic valves, significant intra-cardiac shunting or other relevant congenital heart disease.
* eGFR<60 ml/kg/min
* BMI>35 kg/m2

* Atrial fibrillation or other arrhythmia, >6 ectopic beats / min
* Known or suspected allergy to iodinated contrast medium
* Pregnancy cannot be excluded
* Contra-indications for adenosine: bronchial asthma, second or third degree atrioventricular block, blood pressure <110/70 mmHg, allergies or severe side effects in the past.

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):	08-06-2016
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	11-04-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	02-02-2018
Application type:	Amendment
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
ClinicalTrials.gov	NCT02810795
CCMO	NL55157.078.15