Cardiac Magnetic Resonance and Computed Tomography First in Suspected Non-ST-Elevation Myocardial Infarction.
An Observational Two-Center Study

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To investigate in patients with suspected non-ST elevation MI meeting the *observe* criteria and who are scheduled for ICA:1. The diagnostic accuracy of CMR to detect obstructive CAD using ICA as gold standard2. The diagnostic accuracy of CT to...

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

Summary

ID

NL-OMON54580

Source
ToetsingOnline

Brief title
CMR-CT-OBSERVE

Condition

- Coronary artery disorders

Synonym
'Non-ST-elevation Myocardial Infarction; 'Myocardial Infarction'

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cardiac CT, Cardiac MRI, High-sensitive cardiac troponin, Non-ST-Elevation Myocardial Infarction

Outcome measures

Primary outcome

The primary endpoint is the sensitivity of CMR to detect obstructive CAD using ICA as gold standard in patients with suspected NSTEMI meeting the *observe* criteria and who are scheduled for ICA.

Secondary outcome

• The diagnostic accuracy of CT to detect obstructive CAD using ICA as gold standard

• The diagnostic accuracy of CMR, CT and ICA to detect a non-ST elevation acute coronary syndrome and differentiate non coronary causes for elevated troponin

• The true incidence of coronary, non-coronary and extracardiac pathology by a comprehensive (non-)invasive pathway

• The association between CMR, CT and ICA findings, and MACE, a composite of MACE, and major non cardiac adverse events after 30 days and one year

• The hypothetical cost-effectiveness of an early discharge strategy based on a CMR or CT first approach versus a routine invasive strategy

• The clinical benefit of CMR and/or CT when added to the diagnostic process in finding the diagnosis and patient management

• The ability of identifying the culprit coronary artery with CMR, CT and ICA

• To correlation of quantitative perfusion methods: CMR perfusion vs CT

perfusion (rest) vs CT-FFR vs intracoronary ICA measurements

• To assess the clinical value of CT and/or CMR (eg. change in clinical

diagnosis, indication for revascularization, patient management [medication])

Study description

Background summary

Evaluating patients with acute chest pain, elevated high-sensitive cardiac troponin (hs-cTn) levels and inconclusive electrocardiogram (ECG), i.e. suspected non-ST elevation myocardial infarction (MI), is a daily challenge. Although contemporary hs-cTn assay-based algorithms have greatly facilitated clinical decision-making, still one-quarter of patients is categorized as *observe* group and in whom a diagnosis initially remains unknown. Although routinely treated as acute MI with referral to invasive coronary angiography (ICA), up to one-third of patients classified as *observe* does not have obstructive coronary artery disease (CAD). Follow-up cardiovascular magnetic resonance imaging (CMR) has been shown to be a very useful diagnostic tool in this setting but is not part of routine clinical care in every patient.
Similarly, cardiac computed tomography (CT) is accurate in detecting CAD, but its role in patients categorized as *observe* remains unknown.

Study objective

To investigate in patients with suspected non-ST elevation MI meeting the *observe* criteria and who are scheduled for ICA:
1. The diagnostic accuracy of CMR to detect obstructive CAD using ICA as gold standard
2. The diagnostic accuracy of CT to detect obstructive CAD using ICA as gold standard
3. The diagnostic accuracy of CMR, CT and ICA to detect a non-ST elevation acute coronary syndrome and differentiate non coronary causes for elevated troponin
4. The true incidence of coronary, non-coronary and extracardiac pathology by a comprehensive (non-)invasive pathway
5. The association between CMR, CT and ICA findings, and MACE, a composite of MACE, and major non cardiac adverse events after 30 days and one year
6. To assess the hypothetical cost-effectiveness of an early discharge strategy based on a CMR or CT first approach versus a routine invasive approach
7. To compare quantitative perfusion methods: CMR perfusion vs CT perfusion

(rest) vs CT-FFR vs intracoronary ICA measurements
8. To identify the culprit coronary artery in patients and compare results between CMR, CT and ICA
9. To assess the clinical value of CT and/or CMR (eg. change in clinical diagnosis, indication for revascularization, patient management [medication])

Study design

In this prospective, observational two-center study in The Netherlands (MUMC+ and Radboudumc), 127 consecutive patients with acute chest pain, an inconclusive ECG and hs-cTnT levels meeting the observe criteria and scheduled for ICA, will be investigated. Patients will undergo a comprehensive CMR and CT examination prior to ICA and will be followed-up for one year. After completion of follow-up, an independent clinical diagnosis committee will adjudicate a final diagnosis based on all available data.

Study burden and risks

CMR and CT are accepted and safe imaging modalities in patients with (suspected) non-ST-elevation myocardial infarction. The treating physician and patient will receive the CMR and CT results immediately after the routine diagnostic work-up, which may be used to improve patient treatment. Additional CT examination with a mean/median estimated additional radiation exposure of <= 10 mSv will be performed during hospital admission.

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

• Acute onset chest pain (or angina pectoris equivalent) suspected of non-ST-elevation myocardial infarction (NSTEMI)
• Hs-cTnT levels meeting the *observe* criteria (defined in the 2020 ESC Guidelines)
• Hospital admission and scheduling for ICA (based on clinical judgement)
• Age between 18 years - 85 years old
• Written informed consent

Exclusion criteria

• Symptoms highly suggestive of non-cardiac origin at presentation (as judged by the cardiac ED physician/cardiologist) or highly suggestive of AAD, PE, or acute peri-myocarditis (unless this has been ruled out using additional diagnostic testing) • Suspected type II MI: e.g. secondary to anemia (<5.6 mmol/L), untreated hyperthyroidism, severe hypertension (>200/110 mmHg), moderate or severe mitral/aortic valve stenosis by latest echocardiography • Atrial fibrillation or ongoing tachycardia (>=100/bpm) • Safety: indication for urgent or immediate ICA: e.g. hemodynamic unstable patients, life threatening arrhythmias, ST-elevation MI, heart failure requiring intravenously medication, refractory angina or on-going severe ischemia • Logistics: Inability to organize CMR and CT early after admission (especially for patients admitted on Friday evenings/nights • History: prior CABG, recent PCI (<6 months), recent myocardial infarction (<6 months), or known CAD not suitable for further interventions (PCI or CABG) • Pregnancy or breast feeding women • Life expectancy <1 year (malignancy, etc.) • Contraindications to CMR or CT: o Metallic implant (vascular clip, neuro-stimulator, cochlear implant) o Pacemaker or implantable cardiac defibrillator (ICD) o Claustrophobia o Body weight >130 kg or BMI > 35 or body habitus that does not fit into the gantry o Renal failure (estimated Glomerular Filtration Rate (eGFR) <30 mL/min/1,73m2) o Known severe allergy to gadolinium or iodine contrast agents (patient with mild allergy is eligible for inclusion when pre-medication according to hospital guidelines can be administered) • Contraindications to adenosine: o High degree atrio-ventricular block (2nd or 3rd degree) o Severe bronchial asthma or recent exacerbation o Chronic obstructive pulmonary disease GOLD * III o Concomitant use of Dipyridamole (Persantin®) o Long QT

syndrome (congenital) o Unable to refrain from caffeine >=12 hours prior to the examination

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2019
Enrollment:	127
Type:	Actual

Ethics review

Approved WMO Date:	06-09-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-02-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-09-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NCT04140019
CCMO	NL65125.068.18