The diagnostic value of late enhancement photon counting CT in myocardial scar with usage of different contrast media
ILLUMINATE

Published: 21-08-2023
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To determine the feasibility of late enhancement imaging in spectral photon counting CT to detect myocardial infarction and viability

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

Summary

ID

NL-OMON56221

Source
ToetsingOnline

Brief title
ILLUMINATE

Condition

- Myocardial disorders

Synonym
myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Academisch fonds en grants aan mede PI;dr. C. Mihl: funding verkregen uit consultancy;speakers buro etc

Intervention

Keyword: Cardiac MRI, Late enhancement, Photon counting CT

Outcome measures

Primary outcome

Detection of MI using spectral photon counting late enhancement

(iodine/gadolinium) CT (extent, mass, percentage of left ventricle,

transmurality)

Secondary outcome

• Correlation of infarct size measurement on CMR versus CT

• Assessment of myocardial viability CMR versus CT

• Assessment of kidney function after dual contrast infusion (eGFR/MDRD)

• Detection of MI and CAD in a single CT scan

Study description

Background summary

Delayed enhancement cardiovascular magnetic resonance imaging (CMR) using Gadolinium contrast media (CM) is the gold standard to detect myocardial infarction and to assess myocardial viability non-invasively. Cardiac computed tomography angiography (CCTA) using iodinated CM is the current non-invasive standard to assess the presence and severity of anatomical coronary artery disease (CAD). It is hypothesized that advances in CCTA technology will allow physicians to assess CAD, myocardial infarction and viability in a single investigation, by using the benefits and differences in dynamics/kinetics of two commonly used CM (Gadolinium and iodine).

Study objective

To determine the feasibility of late enhancement imaging in spectral photon counting CT to detect myocardial infarction and viability

Study design

Prospective single center feasibility study

Study burden and risks

Present study investigates the benefits of using Gadolinium and iodinated CM right after each other to answer different clinical questions in a single investigation. In present daily clinical routine, these questions are answered by using both a CT and MRI scan. Ultimately, our approach intends to reduce patient discomfort, health care costs and improve patient care. The benefit of using Gadolinium and iodinated CM will be assessed in a step-wise approach. Step 1. All participants will undergo a (clinically indicated) CMR scan (with Gadolinium). Immediately after the CMR scan (<15 minutes), all patients will undergo a CCTA examination (on a photon counting system) without additional CM (note that Gadolinium contrast from CMR scan will be still present) Step 2. After 1-4 weeks patients will be randomized in a 1:1 fashion to: - An additional CCTA scan (on a photon counting system) with Iodine contrast infusion only, or; - An additional CCTA scan (on a photon counting system) with both Gadolinium and Iodine contrast infusion. Estimated radiation dose with this high-end CT system is expected to be low (accumulated dose of both scans in total <10 mSv). This study design including randomization of patients for the 2nd CT-scan, minimizes the exposure of patients to additional diagnostic tests, ionizing radiation and CM, while it allows us to compare different imaging techniques. No studies have been performed investigating the influence on kidney function when both CM are injected in close proximity. Gadolinium and iodinated CM have a hypothetical increased risk for respectively nephrogenic systemic fibrosis (NSF) and contrast induced nephropathy (CIN). However, in patients with a normal renal function this risk is negligible.

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

- Myocardial infarction (chronic). The diagnosis myocardial infarction is based on clinical judgement and guideline definitions, such as complaints compatible with myocardial ischemia, ECG changes, cardiac troponin elevation.
- Wall motion abnormalities in >=2 adjacent segments (on echocardiography)
- Clinically referred for CMR (e.g. viability assessment)
- Age 18-80 years of age

Exclusion criteria

- Logistics: Inability to organize CT directly after CMR scan - Safety: pregnancy or breast-feeding - Safety: contraindications to CMR or CT * Metallic implant (vascular clip, neuro-stimulator, cochlear implant) * Pacemaker or implantable cardiac defibrillator (ICD) * Claustrophobia * Body weight >130 kg or BMI > 35 or body habitus that does not fit into the gantry * Contraindications to betablockers of nitrates - Safety: Renal failure (estimated Glomerular Filtration Rate (eGFR) <60 mL/min/1,73m2) - Safety: known moderate-severe allergy to Gadolinium or iodine contrast agents - Irregular heart rhythm (i.e. atrial fibrillation, frequent extrasystole) - Considered not eligible by treating physician

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):	12-06-2024
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	NAEOTOM Alpha CT scan
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-08-2023
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-02-2024
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	03-06-2024
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
CCMO	NL83656.068.23