Comparing dynamic contrast enhanced CT with Rb-82 PET for myocardial perfusion assessment in patients with suspicion for chronic coronary syndrome: The DYNAMORE study

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The aim of this study is to compare the myocardial flow reserve measured with DCE-CT to the myocardial flow reserve measured with Rb-82 PET.

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

Summary

ID

NL-OMON56989

Source
ToetsingOnline

Brief title
DYNAMORE study

Condition

- Coronary artery disorders

Synonym
chronic coronary syndrome, ischemic heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: GE Healthcare

Intervention

Keyword: Coronary blood flow quantification, Dynamic CT perfusion, Myocardial perfusion, Rubidium-82 PET

Outcome measures

Primary outcome

The myocardial flow reserve measured with DCE-CT in comparison to myocardial

flow reserve measured with Rb-82 PET. The myocardial flow reserve (MFR) is

calculated as the ratio of stress to rest myocardial blood flow.

Secondary outcome

Secondary Objective(s):

1. To compare DCE-CT and Rb-82 PET myocardial blood flow on rest and stress

acquisitions separately, as well as on a segment and vessel territory level

2. To assess the clinical utility of DCE-CT for myocardial perfusion assessment

in comparison to Rb-82 PET.

Study description

Background summary

Ischemic heart disease is the world*s leading cause of mortality1. For patients with suspected stable coronary artery disease (CAD) it is recommended to test for ischemia instead of directly performing invasive coronary angiography2-4. Coronary computed tomography (CT) angiography can be used to visualize stenosis in the coronary anatomy and has an excellent negative predictive value for ruling out CAD5, but is unable to assess the functional significance of stenosis. Using Rb-82 myocardial perfusion imaging (MPI) with positron emitting tomography (PET), the functional significance of a stenosis can be assessed

with high sensitivity and specificity. For a full analysis of CAD, anatomical and functional imaging can be combined. However, the drawbacks of Rb-82 PET are the availability of PET scanners as well as Rb-82 generators and the associated high costs.6
Dynamic contrast enhanced CT (DCE-CT) has become possible in recent years due to CT scanners with a larger field of view covering the whole myocardium in a single rotation and the significant reduction in associated radiation dose.
This DCE-CT technique offers the potential to detect the functional significance of stenosis similarly to PET, theoretically making it a good alternative for Rb-82 PET. Yet studies comparing DCE-CT versus PET are scarce. One study has quantitatively compared DCE-CT with O-15 PET7,8and another compared DCE-CT with Rb-82 PET9. Although both showed correlation between the quantitative MBF values, the variation in MBF using DCE-CT was relatively large, possible due to the use of self-made, non-commercial available software.
The aim of this study is to explore how DCE-CT quantitative myocardial perfusion assessment using commercially available software compares to Rb-82 PET and if it can be used as an alternative.

Study objective

The aim of this study is to compare the myocardial flow reserve measured with DCE-CT to the myocardial flow reserve measured with Rb-82 PET.

Study design

A single centre prospective interventional study, preceded by a learning curve cohort.

Study burden and risks

• Patients will be asked to adhere to dietary restrictions in the 24 hours before scanning (no caffeine), and if they have a heart rate above 65, asked to follow an oral metoprolol preparation regimen to reduce resting heartrate.
• Patients will be asked for an additional visit (of approximately one hour) to the Nuclear Medicine department at Isala hospital in Meppel
• Patients will undergo 2 dynamic contrast enhanced dynamic acquisitions (rest + coronary CTA and stress), resulting in 2 additional contrast administrations and radiation dose of approximately 5 to 8 mSv per acquisition set, for stress and rest acquisitions respectively, totalling approximately 13 mSv additional radiation dose. The clinically indicated Rb-82 PET/CT scan (regular care) results in a radiation absorbed dose of ~2.1 mSv (Isala data). The total radiation absorbed dose of both clinically indicated Rb-82 PET/CT and the DCE-CT is approximately 15 mSv.
• In addition, patients will have to undergo pharmacologically induced stress for the stress CTA scan using regadenoson.

Patients receive a coronary CTA scan which they would otherwise not, allowing their diagnosing physician to have a better anatomical understanding of the coronary arteries and the location of potential obstruction.
The data acquired can contribute to improve the diagnostic work-up of patient suspected of having obstructive coronary artery disease preventing the need for special equipment such as a PET scanner and expensive Rb-82-generator and will contribute to knowledge extension on the clinical applicability of DCE-CT.
Moreover, it may also reduce the number of negative invasive coronary angiography procedures in centers not having PET Rb-82 equipment.

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 who underwent clinically indicated MPI Rb-82 PET

- Age >= 55
- Written informed consent

Exclusion criteria

- Patients who underwent a coronary CTA < 3 months prior to inclusion
- Previous coronary artery bypass grafting (CABG)
- Atrial fibrillation
- Contraindication to iodinated contrast (known allergy)
- eGFR older than 12 months or < 60 mL/min
- Contraindication to regadenoson
- Any difficulty in undergoing a Rb-82 PET scan, such as difficulty holding arms above head during the scan, receiving IV access or claustrophobia.
- A technically poorly executed Rb-82 PET scan
- Patients with difficulty understanding Dutch

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-06-2024
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	23-08-2024
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-10-2024
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	NL86225.042.24