Clinical Validation of Computed Tomography derived Myocardial Perfusion Imaging : a Hybrid PET/CT Study (ContRaSt)

Published: 22-02-2021
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Primary objective:1. Is the MBF based on rest MPI-CT as accurate as gold standard rest 15O-water PET-CT?

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

Summary

ID

NL-OMON51073

Source
ToetsingOnline

Brief title
ContRaSt

Condition

- Coronary artery disorders

Synonym
coronary artery disease, myocardial perfusion

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: University Medical Center Groningen;Medical Imaging Center

Intervention

Keyword: 15O-water PET-CT, MPI-CT

Outcome measures

Primary outcome

The main study endpoint is the validation of rest phase MPI-CT against the gold standard of rest phase 15O-water PET-CT.

The main parameter we are going to measure is myocardial blood flow (MBF). Myocardial perfusion will be calculated quantitatively by a software as MBF in ml/g/min based on CT acquisitions. MBF is calculated on a per voxel basis by dividing the maximal slope of time-attenuation curve (TAC) by the area under the maximum arterial input function (AIF). The arterial input function is sampled from two regions of interest (ROI) placed separately in the descending aorta with every table position (cranial and caudal) and combined into one arterial input function.

MBF=(Max Slope TAC)/(Maximum AIF)

Secondary outcome

Not applicable

Study description

Background summary

The prevalence of Chronic Coronary Syndromes (CCS) ranges from 5-7% in women aged 45-64 years to 10-12% in women aged 65-84 and from 4-7% in men aged 45-64 years to 12-14% in men aged 65-843. Although acute coronary symptoms are a clear indication for intervention, stable CCS requires thorough diagnosis. In fact, the COURAGE trial demonstrated that in CCS coronary revascularization as an initial management strategy, without functional assessment of coronary stenosis, offers no benefits over optimal pharmacologic therapy alone in reducing mortality4. According to the current guidelines, the presence of significant myocardial ischemia, during stress, is the most important indication to perform revascularization. There is a variety of non-invasive and invasive methods to assess myocardial ischemia.
Novel hybrid imaging modalities using SPECT/CT, PET/CT, MRI and CT (including coronary computed tomography angiography-CCTA and MPI-CT) facilitate non-invasive assessment of ischemia. Hybrid imaging is a technique combining both functional and anatomical assessment of coronary arteries and thus holds much promise for future clinical applications. So far, PET, MRI and SPECT have become established tools to detect myocardial perfusion defects5,6. Recently anatomical assessment with CT also has shown its diagnostic value in CCS. In patients with suspected CCS, studies using 64-slice CT have shown sensitivities of 98-99% and specificities of 82-89% as well as negative predictive values of 99-100% for the identification of patients with at least one coronary artery stenosis found on ICA7,8. MPI-CT can also be used as a quicker, cheaper tool compared to PET and SPECT, however MPI-CT is still in research phase and needs clinical validation. The benefit of MPI-CT is combining both morphology (coronary stenosis) and functionality (myocardial perfusion) in a single CT setting, because of relatively low cost of CT and wider availability as compared with SPECT/CT and PET/CT.
The first adenosine stress MPI-CT was performed in 2005 by Kurata9. Since then, several trials have established the significance of myocardial MPI-CT compared to reference standards as SPECT, ICA (with or without FFR) and stress perfusion MRI10-16.
15O-water PET-CT is a well-established reference modality to assess myocardial perfusion. The following study will employ the latest state-of-the-art digital PET-CT scanner to validate MPI-CT. The Biograph Vision PET-CT at the institute will be used to perform rest 15O-water PET-CT and Siemens SOMATOM Force will be used to perform rest MPI-CT. As a next step we plan to validate rest MPI-CT against gold standard 15O-water PET-CT.
As a first step we propose to compare rest MPI-CT results with rest 15O-water PET-CT. The hypothesis is that MBF based on rest MPI-CT calculated from dynamic CCTA is as accurate as gold standard rest 15O-water PET-CT.
If rest MPI-CT will be as accurate as rest 15O-water PET-CT to detect ischemia, the aim is to use this data in a next research proposal where we will compare the stress phase of MPI CT and 15O-water PET-CT. Finally, the application of complete MPI-CT consisting of stress and rest phase, may improve patient*s

safety during the CCS diagnosis and significantly decrease the costs of diagnosis.

Study objective

Primary objective:

1. Is the MBF based on rest MPI-CT as accurate as gold standard rest 15O-water PET-CT?

Study design

Proof-of-conccept

Study burden and risks

The main risk of the study is the exposition to a higher radiation dose (1mSv of 15O-water-PET vs. 6.3 mSv of MPI-CT). The benefit of MPI-CT is combining both morphology (coronary stenosis) and functionality (myocardial perfusion) in a single CT setting, because of relatively low cost, wider availability and faster acquisition time as compared with SPECT/CT and PET /CT for the detection of functional ischemia.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Patients admitted for CCS diagnosis and ischemia detection with intermediate pre-test probability (PTP) between 15% and 85%3.
2. Patients able to give informed consent.
3. 40-80 years old.

Exclusion criteria

• Renal insufficiency with the glomerular filtration rate less the 30ml/min/kg.
• Known or suspected iodinated contrast allergy.
• Prior stenting or Coronary Artery Bypass Grafting (CABG).
• Atrial fibrillation or other arrhythmia.
• Tachycardia.
• Pacemaker.
• BMI larger than 30 kg/m2 or weight larger than 120 kg
• Not able to hold breath for 20-30 seconds
• Possible pregnancy
•Individuals with high radiation exposure

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-06-2021
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	22-02-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-03-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	04-11-2021
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	NL75435.042.20