Microvascular Resistance Reserve Assessment Derived from Absolute flow and Resistance by PET and CT

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The main objective is to compare non-inavsive MRR, obtained using PET and FFRCT (CT-scanning), with invasively measured MRR measurement using continuous thermodilution.

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

Summary

ID

NL-OMON56637

Source
ToetsingOnline

Brief title
The MASTER-PACT study

Condition

- Coronary artery disorders

Synonym
coronary microvascular dysfunction, dysfunction of small arteries of the heart

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Heartflow Inc,Heartflow Inc.

Intervention

Keyword: Computed Tomography, Microvascular Resistance Reserve, Positron Emission Tomography

Outcome measures

Primary outcome

The primary endpoint will be the correlation and agreement between non-invasive

and invasive. To achieve our study objective, MRR calculated by PET and FFRCT

will be compared to invasively measured MMR.

Secondary outcome

The secondary endpoint will be correlation and agreement between non-invasively

and invasively measured resting and hyperemic resistance.

Study description

Background summary

In at least 25% - 50% of patients with chest pain, myocardial ischemia can be present without angiographic evidence of significant epicardial disease. In such patients, it is often assumed that the microvasculature of the myocardium is abnormal, called coronary microvascular dysfunction (CMD). This microvascular dysfunction constitutes a diagnostic and therapeutic problem with considerable morbidity and associated functional limitations, reduces quality of life, impairs outcome, and increases economic burden for healthcare systems. In the last years, a new invasive methodology has been developed for true quantitative investigation of the coronary microcirculation by calculation of the microvascular resistance reserve (MRR). Non-invasively, calculating the MRR is also possible by measuring resting and hyperemic myocardial blood flow (MBF), for example using quantitative Positron Emission Tomography (PET). However, non-invasive MRR can only be calculated by PET alone in the complete absence of any epicardial disease (i.e. a Fractional Flow Reserve [FFR] of 1.0). In order to obtain information on epicardial disease without using invasive interrogation of the coronary arteries, a method has been developed by HeartFlow Inc. to combine PET and FFR calculated from Coronary Computed Tomography Angiography (FFRCT). Using this method, MRR can be calculated non-invasively regardless of the presence of epicardial disease. However,

non-invasive MRR has never been validated against invasively measured MRR.

Study objective

The main objective is to compare non-inavsive MRR, obtained using PET and FFRCT (CT-scanning), with invasively measured MRR measurement using continuous thermodilution.

Study design

This study is a prospective validation study in which all patients will undergo dual energy CCTA and [15O]H2O PET scan before invasive coronary angiography (ICA) in conjunction with invasive flow/pressure and thermodilution measurements.

Study burden and risks

A three day protocol will be completed after referral ensuring the diagnostic work-up of patients is not delayed. On day 1 patients will undergo CCTA. On day 2, patients will receive PET scan. Then, on day 3, irrespective of CCTA and PET results, patients will undergo ICA with invasive pressure/thermodilution measurements. The risks of CT and PET are considered to be low. Patients are referred for a clinically indicated ICA and as such risks of the ICA are not deemed study-related. The risk of invasive measurements during ICA are considered low. No direct benefit is present for the participating patients. Nevertheless, measurement of FFR, microvascular resistance and MRR is often useful to make a better decision on performing or deferring PCI, is helpful to better understand the nature of angina complaints in these patients, and contributes to fine-tuning of medical treatment.

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

1. Referred for ICA because of suspected CAD
2. No documented prior history of CAD
3. Age >=18 and <=80 years old

Exclusion criteria

1. Unstable CAD, Non-ST-Elevation Myocardial Infarction (NSTEMI), ST-Elevation Myocardial Infarction (STEMI), cardiogenic shock or hemodynamically unstable patients 2. Patients with previous coronary artery bypass (CABG) surgery, PCI or myocardial infarction (MI) 3. Tortuous or calcified coronary arteries, if known 4. Coronary arteries with a small caliber (<2,5 mm), if known 5. Atrial fibrillation, second or third degree atrioventricular block or severe conduction disturbances with an indication for temporary or permanent pacing 6. History of severe COPD or chronic asthma 7. Renal failure (i.e. eGFR < 30 mL/min) 8. Use of sildenafil (Viagra) or dipyramidol (Persantin) that cannot be terminated 9. Contra-indications for β-blockers 10. Allergic reaction to iodized contrast 11. Pregnancy 12. Inability to understand and give informed consent

Study design

Design

Study phase: 4

Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2025
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Generic name:	Coronary computed tomography angiography (CCTA)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-03-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL84769.018.24