Quantitative Myocardial Blush assessment for Coronary Microvascular Disease

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The objective of the study is to collect data for offline analysis. The analysis will evaluate the correlation of cDSA derived parameters and intracoronary pressure and flow measures.

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

Summary

ID

NL-OMON48332

Source
ToetsingOnline

Brief title
n/a

Condition

- Coronary artery disorders

Synonym
coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Philips/Volcano

Intervention

Keyword: cag, dsa, mvd, myocardial blush

Outcome measures

Primary outcome

Correlation of cDSA-derived parameters and Doppler flow velocity-derived parameters of microvascular resistance during hyperemic flow and coronary flow reserve, pre-and post PCI.

Patiënts will receive a PCI of the LAD following standard of care. However, before the PCI 2 additional angiograms will be acquired, before and after administration of adenosine. Simultaneously, intracoronary flow and pressure will be measured with a Combowire positioned in the LAD. Following the PCI the same will be repeated.

Secondary outcome

Not applicable.

Study description

Background summary

Patients with stable angina complaints and suspected coronary artery disease often have an indication for a coronary angiography (CAG). During CAG the epicardial coronary arteries are visualized with X-ray by injection of iodinated contrast agent, thereby allowing assessment of arterial lumen patency. However, myocardial blood flow is not only regulated by these epicardial vessels but, for a much larger part, by the function of the coronary microvascular circulation. Due to limited visibility of these smaller vessels on CAG the clinical significance of microvascular dysfunction (MVD) has not been given as much attention as epicardial coronary artery disease. More recently, it has been shown that MVD does indicate an adverse prognostic effect in patients with non obstructive epicardial coronary arteries. Furthermore, in 1-14% of patients presenting with an acute coronary syndrome (ACS) the

angiography shows no evidence of obstructive epicardial coronary artery disease and a subset of these patients might actually suffer from MVD.
MVD is characterized by elevated coronary microvascular resistance. Although there is no generally accepted gold standard for the assessment of MVD, there are two invasive coronary physiology measures which represent MVD, respectively the index of microvascular resistance (IMR) and hyperemic microvascular resistance (hMR). The general measure for myocardial blood flow is coronary flow reserve (CFR). All these measures are invasively measured with either flow or thermodilution wires. They furthermore require the administration of adenosine to allow the comparison of the baseline situation to a situation during hyperemia.
Philips has recently developed a non invasive alternative for the assessment of MVD. The tool converts a digital subtraction angiography (DSA) into a perfusion image. Parameters derived from this perfusion image, either comparing pre and post adenosine or comparing potential diseased regions to healthy regions, might show correlation to invasively derived measures of MVR.

Study objective

The objective of the study is to collect data for offline analysis. The analysis will evaluate the correlation of cDSA derived parameters and intracoronary pressure and flow measures.

Study design

The present study encompasses a single-centre observational validation-study to investigate the diagnostic potential of DSA-derived functional parameters to detect CMD as defined by conventional invasive measurements. The study will be funded by an unrestricted research grant supplied by Philips healthcare.

Study burden and risks

The burden of participating in this studies equals the prolongation of the procedure with 20min. moreover, the patient will be exposed to slightly more contrast medium and radiation.

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

* Age >18 years.
* Presence of an epicardial stenosis of *50% diameter stenosis in the left anterior descending (LAD) artery.
* Presence of stable angina (Canadian Cardiovascular Society (CCS) score I-III).
Able to understand and sign the informed consent.

Exclusion criteria

Patients <18 years of age,. +
* Left main involvement requiring revascularization.
* Cardiac arrhythmia.
* Sequential lesions in the LAD
* Extremely tortuous or calcified coronary arteries that impede adequate physiologic measurements.
* Recent (<6 weeks) myocardial infarction (STEMI or NSTEMI).
* Severe valvular abnormalities.
* Impaired left ventricular (LV) function (ejection fraction <55%).
* LV hypertrophy (>13mm septal wall thickness).
* Unable to undergo percutaneous intervention or receive adenosine (severe reactive airway disease, severe hypotension or high-grade Atrio-Ventricular

(AV) block in the absence of a pacemaker.
* Signs or history of cardiomyopathy.
* Signs of (peri)myocarditis
* Collateral formation in target vessel.
* CABG to target vessel.
* Renal failure (MDRD calculated eGFR of <30).
* Pregnancy

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):	07-08-2019
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	07-08-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-03-2020
Application type:	Amendment
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	NL67903.018.18