ABSOLUTE-PET study: Validation of Invasive Absolute Quantification of Coronary Microcirculatory Resistance against [15O]H2O Myocardial Perfusion Positron Emission Tomography

Published: 20-03-2017
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The aim of this study is to validate the new invasive method of quantifying MR with the gold standard: [15O]H2O PET perfusion imaging

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

Summary

ID

NL-OMON47124

Source
ToetsingOnline

Brief title
ABSOLUTE-PET

Condition

- Coronary artery disorders

Synonym
Coronary microvascular dysfunction, dysfunction of the small vessels in the heart

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Coronary, Heart, Microcirculation, Resistance

Outcome measures

Primary outcome

Correlation between [15O]H2O PET perfusion imaging MR and invasive MR.

Secondary outcome

To investigate whether saline infusion and adenosine infusion produce coronary

microvascular vasodilation equally. We expect this to be true, and if this is

the case, adenosine administration is no longer needed for this measurement.

Study description

Background summary

In patients with coronary artery disease, there is a mismatch between visual interpretation of the coronary angiogram and the presence of myocardial ischemia. Absolute quantification of coronary blood flow (CBF) in millilitres per minute and microcirculatory resistance (MR) is heralded as the holy grail of physiological assessment of the coronary circulation. At present, only myocardial perfusion [15O]H2O PET is able to quantify volumetric CBF and MR, and is the gold standard for assessment of CBF. Widespread application is prohibited however, due to poor availability of [15O]H2O PET. New insights and developments have led to a simple invasive measurement to quantify CBF and MR.

Study objective

The aim of this study is to validate the new invasive method of quantifying MR with the gold standard: [15O]H2O PET perfusion imaging

Study design

Prospective cohort study

Study burden and risks

The study is deemed to have mild risks for the patient. The risk of this study consists of the occurence of AV-nodal block during infusion of cold saline. Previous studies however, have shown that conduction disturbances do not occur unless infusion temperature exceeds the minimum 33 degrees Celsius. Thus, it is of critical importance that the saline infusion is not adjusted to rapidly. As long as interventional cardiologist are aware of this, AV-conduction disturbances will not pose a threat. If somehow, AV-block does occur, this condition can be easily treated by ceasing saline infusion with or without administration of atropine. Finally, study participation increases patient radiation exposure by 3,772 mSv. The PET-scan and absolute flow measurements results in an additional 3,1 mSv and 0,672 mSv, respectively. The results of this study however, are tremendously important in order to understand and diagnose microvascular angina in the future.

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

* Stable 1 or 2 vessel ischemic heart disease with at least 1 unobstructed reference coronary artery, where at least 1 coronary artery with a stenosis and 1 reference coronary artery both subtend 10% or more of the left ventricle as estimated by coronary computed tomography angiography (CCTA)
* Age at least 18 years
* Presence of a segment of at least 3 cm without major side branches proximal to the stenosis and in the reference coronary artery a segment with a length of at least 3 cm without major side branches has to be present

Exclusion criteria

* Pregnancy
* Uncorrected severe valvular heart disease
* Non-ischemic cardiomyopathy with left ventricular ejection fraction <35%
* Previous or active myocardial infarction in either the territory with stenosis or reference territory
* Previous coronary artery bypass grafting
* Presence of chronic total occlusion in any coronary artery
* Absolute contra-indications to intravenous adenosine administration (Chronic Obstructive Pulmonary Disease Gold class IV, systemic hypotension (Mean blood pressure <70 mmHg), third degree AV nodal conduction disturbances).
* Estimated Glomular Filtration Rate < 30 ml/min/1,73m²

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):	31-03-2017
Enrollment:	26
Type:	Actual

Ethics review

Approved WMO Date:	20-03-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-07-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-02-2018
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	NL59594.029.16

Study results

Date completed: 24-04-2018

Actual enrolment: 26