MR Adenosine Perfusion in the functional evaluation of patients undergoing PCI for single or two vessel disease

Published: 12-10-2006
Last updated: 20-05-2024

To assess the diagnostic value of adenosine myocardial stress perfusion MR in the functional evaluation of patients undergoing a standard PCI with FFR-measurements for single or two vessel disease.

Ethical review	Approved WMO
Status	Pending
Health condition type	Myocardial disorders
Study type	Observational non invasive

Summary

ID

NL-OMON29951

Source
ToetsingOnline

Brief title
MAPPCI

Condition

- Myocardial disorders

Synonym
coronary atherosclerosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: adenosine, MR, Myocardium, Perfusion

Outcome measures

Primary outcome

The presence of visual or measurable reversible perfusiondefects

Secondary outcome

Agreement between adenosine perfusion MR with CAG and FFR-measurements.

qualitative versus quantitative assessment of myocardial perfusion. Quantifying

the effect of PCI on left ventricular function. Feasibility of TSENSE sequence

in an adenosine perfusion MR protocol

Study description

Background summary

The increase in flow through the coronary arteries relies mostly on vasodilatation. Compensatory vasodilatation distal to a stenosis is able to maintain flow during rest, but during stress (or pharmacologically induced stress) conditions this capacity is exceeded. Adenosine induces vasodilatation of the coronary arteries. Stenotic coronary arteries bear the capacity to further dilate, which creates a relative area of hypoperfusion in the supplied myocardium compared to segments supplied by normal coronary arteries. A persisting perfusion abnormality after coronary intervention is associated with a higher risk of significant restenosis. Therefore a non-invasive imaging technique that can accurately assess the functional effect of percutaneous coronary intervention would be ideal.

Study objective

To assess the diagnostic value of adenosine myocardial stress perfusion MR in the functional evaluation of patients undergoing a standard PCI with FFR-measurements for single or two vessel disease.

Study design

Prospective, exploratory study in patients with single or two vessel disease, who are planned for PCI on the basis of a CAG. an adenosine perfusion MR will be performed on the day of admittance and one day after the PCI.

Study burden and risks

Untill present day no hazardous effect of MRI are documented. MRI is contra-indicated in patients with non-MR compatible implants and claustrofobia. The contrast agent used with MR examinations, Gadoterate meglumine is considered very safe, and has been used in clinical practice for many years. In some cases nausea (1-2%) or hives(<1%) can occur. In very rare cases an anaphylactoid reaction can occur.
Adenosine is well tolerated and is widely used in a clinical setting for visualisation of myocardial perfusion in nuclear imaging, as well as in MRI. Contra-indications for adenosine are documented and described in the exclusion criteria. Severe side-effect are rare,and consist of AV-block, ventricular fibrillation, bradycardia, hypotension, bronchospasm and ST-depression. Side-effects expressed in order of incidence are: flushing (37-44%), chest discomfort (35-40%), dyspnoe (28-35%), headache (14-18%), anginal discomfort of neck, throat or jaw (12-15%), gastro-intestinal discomfort (13-15%), lightheadedness (9-12%), ST-segment-depression (3%), first-degree AV-block (3%), second-degree AV-block (3%), third-degree AV-block (0.8%), hypotension (2%), arrhythmia (1%). Adenosine is contra-indicated in second or third degree AV block, sick-sinus syndrome, asthma and other obstructive pulmonary disease, severe hypotension, unstable angina, heart failure, prolonged QT-interval and pregnancy.

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

single or two-vessel coronary artery disease

Exclusion criteria

COPD
asthma
persantin usage
Non-MR compatible implants
claustrophobia
second and third degree heart block
Sick-sinus syndrome
severe hypotension
heart failure
prolonged QT-time
Pregnancy

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2006
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	NL12386.042.06