(Non-)ST-elevation myocardial infarction and Multivessel coronary Artery disease: coronary Resistance guided multivessel Treatment.

Published: 18-03-2011
Last updated: 30-04-2024

1) Assessment of the prognostic value of epicardial (FFR, CFR, REF-CFR and HSR) and microvascular (microvascular resistance; MR) parameters in patients with ACS and MVD. 2) Determination, quantification and development of epicardial and...

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

Summary

ID

NL-OMON34491

Source
ToetsingOnline

Brief title
SMART

Condition

- Coronary artery disorders

Synonym
coronary artery disease; coronary sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,Nederlandse Hartstichting

Intervention

Keyword: acute myocardial infarction, intracoronary parameters, microvascular dysfunction, multi vessel disease

Outcome measures

Primary outcome

A composite of cardiac death, acute myocardial infarction, recurrent

revascularization guided by objective evidence of myocardial ischemia at 12

months.

Secondary outcome

A composite of all-cause death, myocardial infarction, stroke, severe vascular

events, recurrent revascularization guided by objective evidence of myocardial

ischemia at 12 months.

Study description

Background summary

Multivessel coronary artery disease (MVD) occurs in around half of patients presenting with acute myocardial infarction. At present, management is based on treatment of the culprit coronary lesion only by primary percutaneous coronary intervention (PCI) in the acute setting. The remaining lesion(s) will be treated in a following procedure weeks or months later based on the first angiogram, based on residual ischemia or based on residual complaints. Early post AMI stress testing, such as myocardial perfusion scintigraphy, may be inconclusive due to a reduced perfusion caused by an altered microvascular resistance in infarct related and remote regions. Moreover, there is limited data on the microcirculatory function in acute myocardial infarction (AMI) and there are no data regarding the role of the microcirculation on the effects of functional coronary lesion severity in these acutely ill patients. The development of guidewires equipped with miniaturized pressure- or flow velocity-sensors has led to the introduction of hemodynamic measurements in the

diseased coronary vessel and allow examination of the coronary (micro-) circulation in significantly ill patients. In the line of research outlined in this proposal we shall explore the diagnostic and prognostic value of invasive parameters of myocardial ischemia; i.e. fractional flow reserve (FFR), coronary flow reserve (CFR) and hyperemic stenosis resistance (HSR) in patients with AMI and multivessel coronary artery disease. Moreover, the role of the microcirculation (microvascular resistance; MR) on FFR, CFR, reference CFR (REF-CFR) and HSR values will be studied.

Study objective

1) Assessment of the prognostic value of epicardial (FFR, CFR, REF-CFR and HSR) and microvascular (microvascular resistance; MR) parameters in patients with ACS and MVD.
2) Determination, quantification and development of epicardial and microvascular disease parameters for ischemia in patients in with AMI and MVD.
3) Evaluation of the relation of biochemical markers and intracoronary physiological and anatomical changes.
4) Evaluation of a cost effectiveness strategy in patients with AMI and MVD.

Study design

PCI will be performed during the first admission with a first AMI. After PCI of the infarct related artery intracoronary pressure and flow will be assessed in the treated vessel, the vessel with the residual coronary lesion(s) of interest and the angiographic normal reference vessel (if present). Before hospital discharge echocardiography will be performed and patients will undergo a bycicle stress test. Patients who have a positive result of the stress test will undergo a second cardiac catheterisation during which intracoronary pressure and flow will be assessed as during primary PCI. In the case of both FFR and CFR resembling myocardial ischemia, PCI of the lesion of interest will be performed; in all other cases PCI will be deferred. Clinical follow up will be performed on an outpatient basis at 2, 4, 12, 24 weeks and 1 year after primary PCI. At these timepoints a venous bloodsample will be taken to determine standard cardiac markers as troponin, CK-MB, NT-pro BNP and hsCRP levels and a quality of life questionnaire will filled out. PCI of the ischemia related coronary lesion will be performed when clinically indicated (according to the Guidelines). Echocardiography will be performed before discharge and after 24 weeks to assess cardiac function and abnormalities.

Intervention

In case of a postive exercise test, PCI of the laesion of interest will only be performed when both CFR and FFR are indicative for ischemia.

Study burden and risks

In this study patients wil only undergo another cardiac catheterization when this is clinically indicated regarding international guidelines.The risk associated with intracoronary hemodynamic measurements is small in the hands of an experienced operator. Sensor-equipped guide wires are approved for this purpose (FDA and CE) and have been used as an adjunctive diagnostic tool at our and other institutions for many years. The burden in this study is mainly due to the more frequent clinical follow-up and the venous bloodsamples taken at these timepoints.

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

Patients with a second and/or third coronary lesion in the presence of a successfully treated acute coronary occlusion of another coronary vessel are amendable for inclusion.

Exclusion criteria

- Age under 18 and above 80 yrs.
- Cardiogenic shock
- Anatomical or anticipated problems for complete percutaneous coronary revascularization i.e. diffuse disease, chronic total occlusion.
- Prior or indication for coronary artery bypass grafting (CABG)
- Presence of a significant left main coronary artery stenosis (> 50% diameter stenosis)
- Renal impairment (e.g. serum creatinine level of more than 130 *mol/L)
-Unable to exercise
-Ventricular arrhythmias, i.e. sustained ventricular tachycardia (VT) or ventricular fibrillation (VF), more than 48 hours after primary PCI
-Severe valvular heart disease requiring cardiac surgery within twelve months
-Serious known concomitant disease with a life expectancy of less than one year
-Factors making follow-up difficult (e.g. not fixed home or address, psychological instability, drugs or alcohol addiction, etc.).
-Current participation in another trial.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2010
Enrollment:	300
Type:	Anticipated

Ethics review

Approved WMO

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	NL32391.018.10