instantaneous wave-free ratio guided multi-vessel revascularization during percutaneous coronary intervention for acute myocardial infarction

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

Summary

ID

NL-OMON54745

Source
ToetsingOnline

Brief title
iMODERN

Condition

- Coronary artery disorders

Synonym
(ST-elevation) myocardial infarction, heart attack

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Topconsortium voor kennis en innovatie life sciences & health

Intervention

Keyword: iFR, multivessel, PCI, STEMI

Outcome measures

Primary outcome

The primary end point of the study consists of a combined outcome of all-cause mortality, recurrent MI and hospitalization for heart failure at 3 years follow-up.

Secondary outcome

- the primary end point at 6 and 12 months
- Target lesion failure defined as the composite of cardiac death, myocardial infarction or clinically-driven target lesion revascularization by percutaneous or surgical methods at 12 months, 3 years and 5 years follow-up.
- all-cause death, cardiac death, unstable angina, myocardial infarction, clinically-driven revascularization, stroke, major bleeding, coronary angiography, stent thrombosis at 12 months, 3 years and 5 years follow-up.
- Cost-effectiveness and cost-utility analyses with the costs per prevented cardiac event (all-cause mortality, recurrent myocardial infarction and hospitalization for heart failure) and the costs per quality adjusted life year (QALY) as the respective primary health economic outcomes.

Study description

Background summary

In patients with acute ST-elevation myocardial infarction (STEMI), 40-60% have multivessel disease, which is defined as 1 or more non-infarct lesions of >=50%. The presence of multivessel disease is associated with an increased cardiovascular morbidity and mortality. Recent investigations have shown benefits of complete revascularization of residual coronary artery disease during the primary percutaneous coronary intervention (pPCI). The control group in these studies however consisted of patients in whom the residual coronary artery disease was left untreated. This is not in accordance with contemporary practice, in which non-infarct lesions are treated during a second catheterization, preceded by non-invasive imaging (e.g.: cardiac MRI) in the majority of cases.

Revascularization of functionally non-significant coronary lesions carries unnecessary risk and may even worsen outcome. It is known that intervention guided by intracoronary pressure measurements results in better outcome in stable multivessel disease. The fractional flow reserve (FFR) and instantaneous wave-free ratio (iFR) are both pressured derived indices used to assess coronary lesion severity and guide revascularization. The reliability of these indices during the acute phase of myocardial infarction however, has been questioned. In our previous study (registration number: 2016.189) we demonstrated that the iFR of non-infarct lesions measured during primary intervention for STEMI is consistent with iFR measured 1 month afterwards.

Study objective

The iMODERN trial will compare iFR-guided revascularization of noninfarct lesions during acute intervention with a stress perfusion CMR-guided strategy during the outpatient follow-up, to determine the optimal therapeutic approach for STEMI patients with multi-vessel disease.

Study design

The study is a prospective, randomized controlled, open label multicenter European trial.
Patients presenting with an acute STEMI will be screened for study enrollment after succesfull intervention of the infarct lesion. Patients are eligible if they are 18 years or older, have been revascularized within 12 hours of onset of symptoms and have one or more noninfarct lesions of >=50%. Patients with hemodynamic instability, Killips class >=II and patients who refuse or are unable to provide informed consent will be excluded, as well as patients with a history of myocardial infarction, a chronic total occlusion, complex (bifurcation) lesions, a residual noninfarct lesion in the infarct coronary artery or left main stenosis >=50%. Between patient admission and primary intervention, the patient will be asked to participate in the study in case multivessel disease is present. After successful intervention of the infarct lesion the patient is told whether he or she is eligible for the study, and

will be asked again to participate in the trial. Upon verbal agreement, randomization takes place. The subject information sheet (including the informed consent form) will be provided to patients after return to the coronary care unit. Hence on patients have 24 hours to decide whether they still want to participate in the trial.

Intervention

A total of 1146 patients will be randomized in a 1:1 fashion to either active treatment or control. In the active treatment group, complete revascularization of non-infarct coronary lesions >=50% and iFR<0.90 will be performed. Patients randomized to control will undergo an adenosine stress perfusion CMR scan within 6 weeks after STEMI, followed by revascularization of noninfarct coronary lesion if associated perfusion defects are present. In case the patient has contra-indications for CMR (sever claustrophobia, severe renal failure, metal implants) or adenosine (e.g. astma), coronary angiography with iFR measurements of noninfarct lesions will be used as bailout procedure.

Study burden and risks

The risks associated with participation are dependent on the randomized treatment.

After acute intervention of the infarct lesion, patients randomized to the intervention arm will undergo additional iFR measurements of all non-infarct lesions >=50%, followed by stenting of the functionally significant lesions. Intracoronary pressure measurements are routinely performed during interventional procedures and are associated with a very small chance of wire perforation (<0.1%).
Subsequent revascularization of significant non-infarct lesions also bears risks, which are similar to regular PCI. Complications occur in 1% and include coronary perforation, dissection and occlusion of side branches.

Patients randomized to the control group will undergo a stress CMR scan within 6 weeks after STEMI and if indicated additional stenting of significant lesions. A CMR scan has marginal risks and is performed in about 45 minutes.

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 and older
- Clinical presentation of STEMI and successful primary PCI within 12 hours from onset of symptoms
- One or more other, noninfarct coronary artery lesions of >50% stenosis and feasible to
be revascularized (i.e. minimal diameter 2mm)

Exclusion criteria

- History of ST-elevation myocardial infarction or coronary artery bypass graft
- Hemodynamic instability, respiratory failure, Kilips class >=III
- Refusal or inability to provide informed consent
- Life expectancy due to noncardiovascular co-morbidity of less than 12 months
- Chronic total occlusion
- Left main stem stenosis (>50%)
- Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-12-2017
Enrollment:	550
Type:	Actual

Ethics review

Approved WMO Date:	27-01-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-10-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-02-2018
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-09-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-12-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-01-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-09-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-01-2022
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
ClinicalTrials.gov	NCT03298659
CCMO	NL60107.029.16