Pressure-Flow Measurements Directly after Primary PCI to Predict Late Occurrence of Microvascular Obstruction

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

Summary

ID

NL-OMON38350

Source
ToetsingOnline

Brief title
PREDICT-MVO trial

Condition

- Coronary artery disorders

Synonym
myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Volcano;St. Jude & VUmc

Intervention

Keyword: acute myocardial infarction, microvascular obstruction, no-reflow, pressure-flow measurement

Outcome measures

Primary outcome

resistance measurements using combowire

thermodilution measurements using the PressureWire Certus

Secondary outcome

MRI scan

PET scan

blood measurements

Study description

Background summary

Over the past decades, the use of advanced revascularization strategies such as primary percutaneous coronary intervention (PCI) in patients with acute myocardial infarction (AMI) has led to a strong decrease in mortality.
Following primary PCI, patency of the occluded coronary artery is achieved in more than 90% of the patients. However, despite successful primary PCI, a large proportion of patients with AMI show inadequate myocardial perfusion, due to microvascular obstruction (MVO). This is also known as the *no reflow* phenomenon and leads to severe impairment of the left ventricle. It is estimated that it occurs in about 40% of patients undergoing primary PCI. Patients with MVO have a largely increased risk for development of heart failure which has a major impact on quality of life and leads to frequent hospital admissions, high use of medication and thus hight costs in hospital care. Futhermore it also leads to an increased mortality. So, the importance of the treatment of MVO seems very important and thus is designated as *the next hurdle in interventional cardiology*.
The process of development of MVO is multifactorial. Myocardial ischemia causes a relative decrease in the bioavailability of nitric oxide, a potent vasodilator, while an excess of vasoconstrictors, such as endothelin-1 and tissue factor are present. Oxygen free radicals further damage endothelial

cells and myocytes. Endothelial cell injury promotes the activation of platelets, the upregulation of adhesion molecules and the release of inflammatory mediators that subsequently initiate inflammatory and coagulation cascades.
Pharmacological intervention potentially could limit the damage caused by MVO. Unfortunately, no such treatment is available yet. Several compounds did show beneficial effects in experimental models and it is conceivable that for example fibrinolytic or anti-inflammatory compounds will be effective. Drugs aiming to prevent MVO are ideally applied directly after performance of the PCI. This will ensure largest possible efficacy of the drug because prior to PCI the artery is occluded. A potential additional advantage to start treatment immediately after PCI is the fact that drugs can be administered directly into the coronary artery, with a catheter still in place.

Study objective

In the present study we aim to determine the value of microvascular resistance measurements in the acute setting to predict the occurrence of MVO in the following days, using the combined pressure-flow wire. Therefore patients with an acute MI will undergo a single resistance measurement directly following successful revascularization and stent-placement. These measurements will then be correlated to MRI measurements of MVO, performed at day 4 after the acute event.

Study design

single center prospective cohort study

Study burden and risks

Minimal risk. Two extra invasive procedures take place, these are the intracoronary resistance measurement using the combowire and the intracoronary thermodilution measurement using the PressureWire Certus. During standard PCI, many different wires are inserten into the coronary arteries and the risks of such procedures is limited (<1%). Intravenous infusion of adenosine, compared to placebo, gives minimal negative side-effects. Hypotension, which in most cases is tolerated well, is the most frequent occuring side-effect. Serious side-effects of intravenous adenosine are not reported.

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 acute STEMI
- Presentation at catheterization laboratory within 6 hours after onset of symptoms

Exclusion criteria

- previous myocardial infarction in the same artery
- significant three-vessel disease (lesions >70%)
- unsuccessful primary PCI
- refusal or inability to give informed consent
- contra indications for abciximab
- cardiogenic shock
- poor kidney function, eGFR < 30 mg/ml/min
-extreme fear and chestpain

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):	06-12-2011
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	05-09-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-01-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-04-2012
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	NL36118.029.11