Evaluation of coronary stenosis with instantaneous wave*free ratio (iFR) in patients with acute myocardial infarction

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The aim of this study is to investigate whether iFR-measurement of non-infarct related arteries during the acute phase of STEMI is in agreement with iFR and FFR measurement at the staged procedure.

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

Summary

ID

NL-OMON43289

Source
ToetsingOnline

Brief title
iSTEMI

Condition

- Coronary artery disorders

Synonym
atherosclerosis and coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Aarhus University Hospital
Source(s) of monetary or material Support: klinisch fellow grant ZonMW

Intervention

Keyword: acute myocardial infarction, intracoronary flow measurement, multivessel disease, percutaneous coronary intervention

Outcome measures

Primary outcome

iFR measurement during the acute phase in comparison to iFR measurement during

follow-up.

Secondary outcome

iFR measurement during the acute phase in comparison to FFR measurement during

follow-up.

Comparison of iFR and FFR measurement during follow-up.

Study description

Background summary

In patients with acute ST-elevation myocardial infarction, the recommended treatment is primary percutaneous coronary intervention (PCI) of the infarct related artery. About 40-50% of patients presenting with STEMI have multi-vessel disease. In these patients, treatment of lesions in non-infarct related arteries is not performed during the acute phase. Instead, complete revascularization is achieved during a staged, follow-up procedure. Recent studies however, have shown benefit from supplementary complete revascularization during the acute phase.
Studies have shown that physiologic assessment is superior in estimating the severity of lesions in comparison to angiography. The fractional flow reserve (FFR) is a widely used diagnostic tool for physiologic assessment of coronary lesions. However, reliable measurement of the FFR is probably not possible in STEMI patients during the acute phase due to an decrease in maximal hyperemic flow. The instantaneous wave free ratio (iFR) is another diagnostic tool for physiologic assessment of lesions. In general, iFR and FFR measurements correlate well among stable patients. It is believed that the iFR can be measured more reliable during the acute phase of STEMI.

Study objective

The aim of this study is to investigate whether iFR-measurement of non-infarct related arteries during the acute phase of STEMI is in agreement with iFR and FFR measurement at the staged procedure.

Study design

This study is a multi-center, observational study. Patients can be included if one or more lesions in the non-infarct related arteries are present which, according to the operator, require physiologic assessment during a second angiography. After PCI of the infarct related artery, additional measurement of iFR will be performed during the acute phase. The measurement of iFR will be repeated during the follow-up angiography. Moreover, measurement of FFR will also be performed during the follow-up procedure, which will be used to guide revascularization.

Study burden and risks

Patients participating in this study will be given the standard treatment as per protocol and guidelines. The iFR measurements performed during the acute phase and follow-up are expected to prolong procedural (lying in the intervention suite) times with 5%.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Acute catheterization for myocardial infarction with PCI treatment of acute coronary culprit lesion
- Other coronary non*culprit stenoses that the PCI operator according to the usual clinical standards determines form an indication for follow*up CAG and is amenable for PCI
- Patient age 18 years or more

Exclusion criteria

- The clinical condition of the patient prevents informed consent
- The clinical condition of the patient indicates full revascularisation at the acute CAG (e.g., cardiogenic shock)

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):	18-08-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	13-07-2016
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	NL57292.029.16

Study results

Date completed:	05-01-2017
Actual enrolment:	13

Summary results
Trial is onging in other countries