

# Fractional Flow Reserve in non- culprit Coronary Arteries during Acute Coronary Syndromes.

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The aim of the present study is to investigate if FFR measurement of a stenosis in a remote coronary artery are influenced by the presence of acute myocardial infarction.

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

## Summary

### ID

NL-OMON32345

### Source

ToetsingOnline

### Brief title

Fractional flow reserve in acute coronary syndromes

### Condition

- Coronary artery disorders

### Synonym

Acute coronary syndrome, acute myocardial infarction.

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Catharina-ziekenhuis

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Acute myocardial infarction, Fractional Flow Reserve (FFR)

## Outcome measures

### Primary outcome

Variability of Fractional Flow Reserve in the non-infarct related artery between the 2 measurements (immediately after PPCI of the infarct-related artery vs 5 days- 4 weeks later.

### Secondary outcome

Not applicable.

## Study description

### Background summary

It has been questioned if during acute myocardial infarction, flow disturbances occur in remote coronary arteries. This means that functional investigations of the severity of a stenosis in a remote coronary artery, needs to be postponed for several weeks when microcirculatory function has normalized. For patients with an indication for such invasive functional investigations of that remote artery, it is mandatory then to undergo a second cardiac catheterisation. If, however, it would be certain that such measurements could be performed immediately following primary PCI of myocardial infarction, this second catheterisation could be avoided.

### Study objective

The aim of the present study is to investigate if FFR measurement of a stenosis in a remote coronary artery are influenced by the presence of acute myocardial infarction.

### Study design

For that purpose, 50 patients presenting with an acute coronary syndrome and

referred for primary coronary intervention, are investigated. Immediately following successful stent placing in the infarct related artery, FFR will be measured in the stenotic, non-infarct related artery. Five - 28 days later, a second measurement will be performed as in the usual routine whether or not followed by stenting of that concomitant artery if indicated by FFR. Comparing FFR values at both sessions, will answer the study question. All methodology used is standard methodology.

### **Study burden and risks**

The only extra investigation is the FFR measurement in the non-infarct related artery immediately following primary PCI. This extra investigation takes about 10 minutes and is performed by standard techniques. Load for the patient and risks are minimal.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- 1) Patients admitted for primary percutaneous coronary intervention of acute coronary syndrome
- 2) Presence of a stenosis of at least 50% in a concomitant coronary artery
- 3) Stable hemodynamic condition

### Exclusion criteria

- 1) Cardiogenous shock or mechanical complication following primaire PCI
- 2) Extremely tortuous or calcified vessels
- 3) Severe obstructive pulmonary disease

## Study design

### Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2008
Enrollment:	50
Type:	Actual

## Ethics review

Approved WMO

Date: 22-05-2008

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## 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	NL22453.060.08