# The accuracy, feasibility and safety of Fractional Flow Reserve in patients with acute ST-elevation myocardial infarction

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The objective is to investigate the accuracy, feasibility and safety of FFR in patients presenting with STEMI and MVD.

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|---|---|
| **Ethical review** | Not approved |
| **Status** | Will not start |
| **Health condition type** | Coronary artery disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON34319

**Source**
ToetsingOnline

**Brief title**
FFR in STEMI

### Condition

- Coronary artery disorders

**Synonym**
Coronary artery disease, multivessel disease

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** multivessel disease, myocardial infarction, percutaneous coronary intervention

## Outcome measures

### Primary outcome

Accuracy defined as difference between FFR in the acute phase and second procedure (delta FFR).

### Secondary outcome

Feasibility defined as completion of the FFR protocol and safety measured as procedural time, contrast volume used and procedural complications (bleeding, dissection, perforation, reinfarction).

# Study description

### Background summary

Fractional Flow Reserve(FFR)-guided percutaneous coronary intervention (PCI) in elective patients with multivessel disease (MVD) has proven to limit unnecessary PCIs in clinical irrelevant lesions. It is currently unclear whether FFR is also accurate, feasible and safe when used in the acute phase of a ST-elevation myocardial infarction (STEMI).

### Study objective

The objective is to investigate the accuracy, feasibility and safety of FFR in patients presenting with STEMI and MVD.

### Study design

A prospective, non-randomized, longitudinal study. Investigator driven.

### Study burden and risks

As with any invasive coronary procedure the risks of a PCI procedure include; bleeding, perforation of a coronary vessel, infarct extension, and arrhythmias.

Current used FFR wires have comparable safety profiles as standard angioplasty wires. In the largest trial to date, usage of FFR was not associated with prolongation of the interventional procedure nor with more usage of contrast agent as compared with the normal angiography group.

# 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

- A diagnosis of a STEMI defined by 1/A diagnosis of acute MI defined by chest pain suggestive for myocardial ischemia for at least 30 minutes, with a time from onset of symptoms of less than 12 hours, before hospital admission, 2/ ECG with ST- segment deviation of more than 0.1 mV in 2 or more leads and 3/Positive cardiac troponin T >0.01 *g/l.
- Clinical indication for urgent PCI of the infarct related lesion as identified at coronary

angiography
- Planned staged PCI for a lesion in a non-infarct related vessel
- Verbal followed by written informed consent
- 18 years or older

### Exclusion criteria

- Presence of cardiogenic shock
- Implantation or planned implantation of an intra-aortic balloon pump
- Failed reperfusion of the infarct related vessel (>30% residual stenosis and less than TIMI 3 coronary flow)
- No staged PCI possible
- Need for coronary artery bypass grafting
- No suitable anatomy of the non-IRV (Left main stenosis of >50%, Diameter <2.5mm, Extremely tortuous or calcified coronary arteries, Chronic total occlusion, Collaterals visible, Previous CABG
- Contra-indications for adenosine intracoronary (Second or third degree AV block, Sick sinus syndrome, Asthma, Hypersensitivity to adenosine)
- Inability to provide informed consent

## Study design

### Design

**Study type:** Observational invasive

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 50 |
| Type: | Anticipated |

### Medical products/devices used

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|---|---|
| Generic name: | Fractional Flow Reserve measurements |
| Registration: | Yes - CE intended use |

# Ethics review

Not approved

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|---|---|
| Date: | 04-11-2010 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

# 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 | NL33668.042.10 |