# Optimization of intracoronary functional coronary lesion severity evaluation by simultaneous intracoronary pressure and flow velocity measurements during baseline conditions, and contrast medium- or regadenoson- induced hyperemia.

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The objective of this study is to increase our understanding of the relationship between various parameters of functional lesion severity, to optimize adenosine-free evaluation of functional lesion severity.

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| **Ethical review** | Approved WMO |
| **Status** | Will not start |
| **Health condition type** | Coronary artery disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON36985

**Source**
ToetsingOnline

**Brief title**
IMPROVE

### Condition

- Coronary artery disorders

**Synonym**
cardiac disease, Coronary artery disease

**Research involving**
Human

## Sponsors and support

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

## Intervention

**Keyword:** Adenosine-free, Contrast-induced submaximal hyperemia, Coronary physiology, Functional lesion severity

## Outcome measures

### Primary outcome

To determine the sensitivity, specificity, and diagnostic accuracy of stenosis resistance index (SR) and instantaneous wave free ratio (iFR) during baseline conditions, as well as SR, and the pressure-drop at a fixed velocity (dPv) during contrast-medium induced sub-maximal hyperemia for myocardial ischemia as assessed by intracoronary adenosine-derived (40µg) HSR.

### Secondary outcome

1. To determine the reproducibility and dose-response relationship of SR and dPv during contrast medium-induced sub-maximal hyperemia.

2. To determine the best cut-off value for SR and iFR during baseline conditions, as well as SR and dPv during sub-maximal hyperemia for myocardial ischemia as assessed by intracoronary adenosine-derived (40µg) HSR.

3. To determine the diagnostic accuracy of FFR, CFVR, and SR during regadenoson-induced maximal hyperemia for myocardial ischemia compared to intracoronary adenosine-derived (40µg) HSR.

4. To study the interaction between hemodynamic and mechanical factors

responsible for the morphology of the coronary flow velocity and pressure waveforms during maximal coronary vasodilation compared to resting conditions,,and during a Valsalva maneuver.

5. To compare the results derived from high and low-dose intracoronary adenosine to contrast-derived and baseline parameters.

6. To relate the effect of different vasodilators on microvascular resistance, as well as the relationship between the objectified microvascular resistance and the parameters of functional lesion severity.

7. To relate parameters of functional lesion severity to long-term clinical outcome

# Study description

### Background summary

Contemporary evaluation of functional lesion severity by means of pressure- or flow-velocity equipped guide wires per definition requires a maximal vasodilated state. The use of potent vasodilators may however be cumbersome in daily clinical practice, and there is a large debate on their optimal dose and route of administration. Vasodilator-free evaluation of functional lesion severity is expected to improve feasibility, as well as adoption of these measurements in daily clinical practice.

### Study objective

The objective of this study is to increase our understanding of the relationship between various parameters of functional lesion severity, to optimize adenosine-free evaluation of functional lesion severity.

### Study design

Observational study with invasive measurements

### Study burden and risks

The burden consists of 15 to 20 minutes enlenghtening of the PCI procedure, with a minimal increase in radiation dose and contrast agent exposure. The patient is furthermore contacted 6 times by telephone for follow-up. The risks of participation with this study are considered negligible.

## 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

1. Stable angina (CCS class I to 3, or Braunwald class I)
2. Scheduled for PCI or intracoronary evaluation of functional lesion severity (diagnostic catheterization) of at least one coronary lesion in a native coronary vessel of 40 * 80% diameter stenosis on visual estim

### Exclusion criteria

1. Younger than 18 or older than 80 years of age
2. Multiple coronary lesions in the same coronary artery
3. Recent myocardial infarction or revascularization (less than 6 weeks prior to procedure)
4. Previous revascularization of the vessel of interest
5. Severe left ventricular dysfunction (LV ejection fraction less than 30%)
6. Severe renal insufficiency (eGRF according to sMDRD less than 30 mL/min/m2)
7. 50% or more diameter stenosis in left main coronary artery
8. Severe valvular abnormalities
9. Women of childbearing age without a negative pregnancy test or active birthcontrol

## Study design

### Design

**Study type:** Observational invasive

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Will not start |
| Enrollment: | 200 |
| Type: | Anticipated |

### Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Adenocor |
| Generic name: | adenosine |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |
| Brand name: | Rapiscan |
| Generic name: | Regadenoson |
| Registration: | Yes - NL intended use |

# Ethics review

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| Approved WMO Date: | 08-01-2013 |
| 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 |
|---|---|
| EudraCT | EUCTR2012-004759-35-NL |
| CCMO | NL42381.018.12 |