# Correlation between 3D Quantitative Angiography Based FFR and luminal obstruction as detected by Optical Coherence Tomography (OCT): the FAST OCT study

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The aim of the FAST OCT study is to define the correlation between 3D-angio-based FFR values and OCT findings in a pre- and post-PCI setting in patients with non-ST segment elevation acute coronary syndromes (NST-ACS). The results will be used to...

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

## Summary

### ID

NL-OMON55347

**Source**
ToetsingOnline

**Brief title**
FAST OCT study

### Condition

- Coronary artery disorders

**Synonym**
Coronary artery disease. Coronary atherosclerosis

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Trialbureau Cardiologie
**Source(s) of monetary or material Support:** Abbott Vascular and Pie Medical Imaging BV,Abbott Vascular, Santa Clara, Ca, US.,Pie Medical Imaging BV, Maastricht, The Netherlands

## Intervention

**Keyword:** Coronary artery disease, Coronary optical coherence tomography, Non-ST elevetation myocardial infarction, vessel fractional flow reserve

## Outcome measures

### Primary outcome

The primary study parameter is the association between 3D-angio-based FFR values and OCT detected minimum luminal area pre- and post-PCI.

### Secondary outcome

The secondary study parameters are: (1) The association between 3D-angio-based FFR values and OCT detected causes of luminal obstruction pre-PCI. (2) The association between 3D-angio-based FFR values and OCT detected causes of luminal obstruction post-PCI. (3) Accuracy of 3D-angio-based FFR to detect intraluminal obstructions pre-PCI. (4) Accuracy of 3D-angio-based FFR to detect intraluminal obstructions post-PCI.

# Study description

### Background summary

Angiography-based fractional flow reserve (3D-angio-based FFR) is an emerging technology with a high diagnostic performance as compared to invasively measured FFR and could provide an easy, safe, and cost-effective solution for functional evaluation of coronary artery stenosis without the need for a costly pressure wire and hyperemic agent. However, 3D-angio-based FFR is still hampered by a significant *grey zone* that might warrant the use of additional diagnostic tools and has not been tested in patients presenting with acute

coronary syndromes (ACS). An important limitation since up to 31% of those cases present with a plaque rupture/erosion or calcified nodules located in *angiographically non-significant* coronary lesions. Optical coherence tomography (OCT) conversely offers high-resolution intracoronary imaging allowing accurate pre- percutaneous coronary intervention (PCI) assessment of lesion and plaque characteristics, and post-PCI results.
Although post stenting low 3D-angio-based FFR values have been associated with a significantly increased risk for future major adverse events, they typically preclude any statements on the exact aetiology of the pressure drop over the intracoronary segment assessment. In this scenario, OCT has the ability to accurately identify specific post-PCI patterns related with significant changes in FFR values in order to improve future outcomes.

## Study objective

The aim of the FAST OCT study is to define the correlation between 3D-angio-based FFR values and OCT findings in a pre- and post-PCI setting in patients with non-ST segment elevation acute coronary syndromes (NST-ACS). The results will be used to power future studies on OCT-based lesion stratification in angiographically proven intermediate lesions to determine indication for PCI and optimize post-PCI long-term outcomes.

## Study design

Prospective, multicentre, single arm, investigator-initiated study.

## Intervention

Coronary angiography and OCT assessment of all epicardial vessels (>=2,5 mm) with intermediate to severe stenosis before and after PCI (if performed). The use of intracoronary physiology (either FFR or pressure wire-derived non-hyperemic pressure ratio indexes(NHPR)) is strongly recommended per clinical practice guidelines. 3D-angio-based FFR analyses before and after PCI (if performed) will be performed offline in all vessels with intermediate to severe stenosis. Patients will be followed up until discharge. No clinical follow-up will be performed after discharge.

## Study burden and risks

Pressure wire-based FFR or NHPR will be used at the discretion of the operator following current clinical practice guidelines.
Previous studies have demonstrated that both FFR- and OCT-guided PCI is safe and improves future clinical outcomes as compared to angiography-guided PCI alone. The potential risks of this study include the known risks of any currently used standard procedure to assess and to treat obstructive coronary artery disease. All patients will receive standard care which includes double

antiplatelet therapy, statins and lifestyle changes recommendations according to current European guidelines. Patients participating in this study will potentially benefit from receiving a more accurate assessment of the severity of the lesions and appropriate guidance of the PCI.

## Contacts

**Public**
Selecteer

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL
**Scientific**
Selecteer

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

### Inclusion criteria

- 18 years or older
- Presenting with non-ST elevation acute coronary syndrome
- One or more coronary vessels with intermediate to severe coronary stenosis (30% to 90% by visual estimation or online quantitative coronary analysis (QCA)).
- Target vessel with a reference vessel diameter (RVD) >=2.5 and <= 5.0 mm as

assessed by QCA or visual estimation.
- The patient is willing to participate in the study.
- Target vessel suitable for optical coherence tomography (OCT) imaging

### Exclusion criteria

- Target vessel with a distal Thrombolysis In Myocardial Infarction (TIMI) flow <3.
- Target lesion located within 5.0 mm of vessel origin.
- Severe tortuosity
- Chronic total occlusion of the target vessel
- Target lesion is located in or supplied by an arterial or venous bypass graft.
- Impaired renal function (eGFR <30ml/min).
- Pregnant or breastfeeding patients.
- Patient has a known allergy to contrast medium.
- Contraindication for the use of nitrates.
- Life expectancy <12 months

## Study design

### Design

**Study type:** Observational invasive

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 14-12-2020 |
| Enrollment: | 140 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | Dragonfly OPTIS Imaging Catheter |
| Registration: | Yes - CE intended use |

# Ethics review

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|---|---|
| Approved WMO Date: | 18-11-2020 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 20-01-2022 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# 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 | NL74296.078.20 |