# PRospective Evaluation of complete revascularization in patients with multiveSsel disease Excluding chroNic Total occlusions

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To compare OCT guided complete revascularization to the predefined objective performance goal (OPG) for all-cause death, stroke, myocardial infarction, or repeated revascularization namely 7% at 12 months. The OPG is derived from the most recent (9-…

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Coronary artery disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON51096

**Source**
ToetsingOnline

**Brief title**
PRESENT

### Condition

- Coronary artery disorders

**Synonym**
stable coronary artery disease and non-ST ACS

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** MedtronicBakken Research Center B.V.

## Intervention

**Keyword:** coronary imaging (OCT), Functional assessment (FFR), multivessel disease, PCI

## Outcome measures

### Primary outcome

The main study endpoint is defined as the composite of death from any cause, stroke, myocardial infarction, or repeat revascularization (MACCE) at 1-year post index procedure, which was compared with a pre-specified objective performance goal (OPG).

### Secondary outcome

• Composite outcome of death from any cause, stroke, myocardial infarction, or repeat revascularization (MACCE) at 30 days, 2 and 5 years post intervention.

• All-cause mortality at 30 days, 1, 2 and 5 years

• Myocardial Infarction at 30 days, 1, 2 and 5 years

• Any revascularization at 30 days, 1, 2 and 5 years

• Stroke at 30 days, 1, 2 and 5 years

• Major bleeding at 30 days and 12 months

• Need for renal replacement therapy at 30 days

• Feasibility on on-line complete functional assessment using FFRangio

Other study parameters:

Secondary imaging endpoint

• Minimal lumen diameter (QCA)

• Percent diameter stenosis (QCA)

• Acute lumen gain post-intervention (QCA)

• Maximum stent size/reference vessel diameter ratio (QCA)

• Angiographic Dissection >= NHLBI type B (QCA)

• Angiography-defined procedural success rate:

- Defined as a final lesion angiographic diameter stenosis <30% (QCA) and TIMI III flow (QCA) without dissection >= NHLBI type C, perforation, prolonged chest pain or ST segment elevation or depression changes (>30 minutes), or procedural death.

• OCT device success rate (site reported):

- Successful OCT imaging obtained pre and post PCI

• Peri-procedural myocardial infarction according to the Society of Cardiovascular Angiography and Intervention definition

• Post-PCI stent expansion (OCT):

- Defined as the minimum stent area divided by the average of proximal and distal reference lumen areas x 100

• Untreated reference segment disease (OCT):

- Defined as untreated MLA <=60% of adjacent reference segment lumen area up to 10 mm from the proximal and distal stent edges.

- Sub-classified by amount of untreated lipidic plaque, divided into 3 grades:

A) Low (<= 90° of lipid arc)

B) Medium (>90°-<180° of lipid arc)

C) High (>=180° of lipid arc)

• Edge dissections (OCT):

- Major (%): >=60 degrees of the circumference of the vessel at

site of dissection and/or >=3 mm in length

- Minor (%): any visible edge dissection <60 degrees of the

circumference of the vessel and < 3 mm in length

- All (Major and Minor) (%)

• Edge dissections will be further classified as:

- Intimal (limited to the intima layer, i.e. not extending beyond

the internal elastic lamina)

- Medial (extending into the media layer)

- Adventitial (extending through the external elastic lamina)

• Stent malapposition (OCT):

- Frequency (%) of incompletely apposed stent struts (defined as

stent struts clearly separated from the vessel wall (lumen border/plaque

border) without any tissue behind the struts with a distance

from the adjacent intima of >=0.2 mm and not associated with any side

branch).

- Malapposition will be further classified as:

Major: If associated with stent underexpansion

(unacceptable stent expansion as defined above)

Minor: If not associated with significant

underexpansion (optimal or acceptable stent expansion as defined above)

# Study description

### Background summary

Previous studies comparing coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI) showed superiority of CABG over PCI in patients with multivessel disease particularly driven by a higher need for repeat revascularizations. Incomplete revascularization has been associated with a higher rate of events and the presence of a chronic total occlusion has been demonstrated as to be the most important independent predictor of incomplete revascularization in patients with multivessel disease. The present study aims at investigating the clinical results of complete revascularization (complete revascularization of all significant lesion in vessels >= 2.5 mm and in any case residual syntax score <6). Imaging (OCT) optimization should be performed at least for the left anterior descending artery. FFR guidance will be at operator discretion and should be performed according to current guidelines. Guidance by a complete 3D-QCA based pre procedural functional assessment (FFRangio) might be considered

### Study objective

To compare OCT guided complete revascularization to the predefined objective performance goal (OPG) for all-cause death, stroke, myocardial infarction, or repeated revascularization namely 7% at 12 months. The OPG is derived from the most recent (9-11-2021) publication of the FAME-III trial.

### Study design

Prospective, multicenter, non-randomized, single arm, objective performance goal study.

### Intervention

Patients will be treated in a single arm fashion with:
• Complete revascularization with PCI in all vessels >= 2.5 mm with >=70% stenosis by visual estimation or positive functional assessment and residual syntax score <6.
• At least proximal and mid LAD lesions will be treated with optical coherence tomography (OCT) guided PCI. OCT guided PCI for every lesion is encouraged if feasible.
• Complete functional assessment with online 3D-QCA based fractional flow reserve (FFRangio) ) to assess the hemodynamic relevance of intermediate-grade lesions (40-90% diameter stenosis) could be considered as per operator discretion and availability

**Study burden and risks**

Participation contributes to expansion of the knowledge base with respect to best treatment of patients presenting with an SCAD or NSTE-ACS and more than one narrowed artery, without CTO which may assist physicians in their choice of treating any future patients. When participating in this study, the patient will have more medical check-ups than when he/she would not be participating in the study. In addition, he/she will be treated with a stent that was developed with the latest technology.

Patients will be implanted with two or more Resolute Onyx DES, Zotarolimus-Eluting stent systems. This stent model is approved to be used. Therefore, there is no higher risk associated with implantation of these systems in this study. The risk associated with stent implantation in general is among others dependent on the severity of the narrowing(s) in the coronary arteries, symptoms but also other factors.
For this study data from patients medical files will be gathered. There will be no additional tests as compared to normal procedures.

# 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. Age >= 18 years, <=85 years
2. The patient is an acceptable candidate for treatment with a drug eluting stent in accordance with the applicable guidelines on percutaneous coronary interventions, manufacturer*s Instructions for Use and the Declaration of Helsinki
3. Patient indication, lesion length and vessel diameter of the target lesion(s) are according to the *Instructions for Use* that comes with every Resolute Onyx (Zotarolimus-Eluting stent) system.
4. The patient is willing and able to cooperate with study procedures and required follow up visits
5. The subject or legal representative has been informed of the nature of the study and agrees to its provisions and has provided an EC approved written informed consent, including data privacy authorization

## Exclusion criteria

1. Age <18 years and > 85 years.
2. Single coronary vessel disease.
3. No left anterior descending lesion.
4. Patients in cardiogenic shock.
5. Patients with STEMI.
6. Presence of a chronic total occlusion (CTO) defined as coronary lesion with Thrombolysis in Myocardial Infarction (TIMI) flow grade 0 on initial angiography present for more than or equal to 3 months.
7. Left main coronary artery disease
8. Patients who cannot give informed consent or have a life expectancy of less than 12 months.
9. Absolute contraindications or allergy that cannot be pre-medicated, to iodinated contrast or to any of the study medications, including both aspirin and P2Y12 inhibitors.
10. Patients with an extreme LAD tortuosity imparing OCT catheter advancement
11. Enrollment in another study with another investigational device or drug trial that has not reached the primary endpoint . The patient may only be enrolled once in the PRESENT study.
12. Previous coronary artery bypass grafting (CABG).
13. Patient requiring additional cardiac surgery within 6 months.

14. Women of childbearing potential who do not have a negative pregnancy test result within 7 days before the procedure, women who are known to be pregnant, or who are breastfeeding.

# Study design

## Design

**Study type:** Interventional

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 13-01-2022 |
| Enrollment: | 350 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Generic name: | Optical Coherence Tomography (OCT) |
| Registration: | Yes - CE intended use |

# Ethics review

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| Approved WMO Date: | 16-11-2021 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 21-11-2023 |
| 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 | NL76556.078.21 |