Veiligheid en effectiviteit van PCI optimalisatie door het gebruik van hoge resolutie IVUS vergeleken met de standaard behandeling bij patiënten met een lage FFR na de procedure

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25972

Source
NTR

Health condition

FFR, post PCI FFR, IVUS, PCI, atherosclerosis, atherosclerose, dotter, post procedurele FFR

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: ACIST Medical Systems, Inc. Corporate Headquarters

Intervention

Outcome measures

Primary outcome

Target vessel failure, defined as composite of cardiac death, target vessel Q-wave or non-Q

wave myocardial infarction, coronary artery bypass graft and clinically driven target vessel revascularization.

Secondary outcome

The individual components of the primary endpoint (cardiac death, target vessel MI, clinically driven target vessel revascularization)

All-cause death

Target lesion revascularization

Target vessel revascularization

Any coronary revascularization

Non-fatal myocardial infarction

Stent thrombosis (according the ARC criteria)

Peri-procedural MI

Change in post-procedural Pd/Pa and FFR after optimization therapy

Acute kidney injury

Stroke

Periprocedural complications

Correlation outcome of proximal versus stent versus distal FFR drop in categories of 5% pressure drop.

Correlation of FFR segmental drop and minimum luminal area (MLA) on IVUS and 3D QCA

Correlation of Pd/Pa and FFR, both dependent and independent of IVUS findings

Correlation of Pd/Pa and FFR and clinical endpoints

Operators PCI strategy change dependent on the information received from either FFR or IVUS

Study description

Background summary

Fractional flow reserve (FFR) after a percutaneous coronary intervention (PCI) proved to be a strong and independent predictor of Major Adverse Cardiac Events (MACE). A number of factors can cause a post PCI pressure drop over a treated segment which can be revealed by intravascular ultrasound (IVUS). It is currently unknown if optimization of impaired post PCI FFR with IVUS might improve patient outcome.

The objective of the FFR-REACT trial is to assess if FFR guided PCI optimization directed by High Definition (HD)-IVUS in patients with a post-PCI FFR below 0.90 will improve target vessel failure. In this prospective trial 290 patients with a post PCI FFR <0.90 will be randomized (1:1) to either standard of care (no additional intervention) or IVUS-directed optimization to a FFR ≥ 0.90 (treatment arm). Assuming that 45% of patients will have a post PCI FFR <0.90, approximately 640 patients undergoing PCI will need to be enrolled. Post PCI FFR measurements will be performed in all patients. The total follow-up period for all patients will be 3 years.

The primary study end point is defined as target vessel failure, a composite of cardiac death, target-vessel myocardial infarction and clinically driven TVR at 1 year.

This study will provide novel insights for a potentially new patient group where post PCI FFR is followed by IVUS to optimize therapy.

Study design

Patients will be followed-up at 6 months, 1, 2 and 3 years post PCI

Intervention

FFR-guided optimization directed by the ACIST HDi® IVUS System using the Kodama® IVUS catheter will be performed in the treatment arm. Patients will be followed for up to 3 years.

Contacts

Public
P.O. Box 2040, 3000 CA Rotterdam, The Netherlands, internal postal address Ba-593
Joost Daemen
office Ad-342, 's Gravendijkwal 230
Rotterdam 3015 CE
The Netherlands
+31 10 703 56 65/+31 6 205 972 54
Scientific
P.O. Box 2040, 3000 CA Rotterdam, The Netherlands, internal postal address Ba-593
Joost Daemen

office Ad-342, 's Gravendijkwal 230
Rotterdam 3015 CE
The Netherlands
+31 10 703 56 65/+31 6 205 972 54

Eligibility criteria

Inclusion criteria

1. Age ≥18

2. Stable- or unstable angina or Non-ST segment elevation myocardial infarction

3. Target lesion stenosis ≥ 50% by visual estimation or QCA successfully treated by PCI and stenting

4. Written informed consent;

5. The patient agrees to the follow

Exclusion criteria

1. Patients with ST-elevation myocardial infarction (STEMI) or evidence of myocardial infarction within 72 hours before the index procedure

2. Target vessel distal reference diameter <2.25mm

3. Cardiogenic shock or severe hemodynamic instability

4. Unsuccessful stenting

5. PCI without stenting

6. Inability to perform post procedure FFR

7. The patient has other medical illnesses (i.e., cancer) that may cause the patient to be non-compliant with the protocol, confound the data interpretation or is associated with limited life expectancy (i.e., less than one year).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2017
Enrollment:	640
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-09-2017
Application type:	First submission

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
NTR-new	NL6523
NTR-old	NTR6711
Other	METC-Rotterdam : MEC-2017-489

Study results