FFR guided PCI optimization directed by high-definition IVUS versus standard of care: the randomized FFR-REACT trial

Published: 26-10-2017
Last updated: 19-08-2024

To assess if PCI optimization using High Definition (HD)-IVUS in patients with a post-PCI FFR below 0.90 will improve target vessel failure.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Interventional

Summary

ID

NL-OMON50576

Source
ToetsingOnline

Brief title
FFR-REACT

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
coronary artery narrowing, coronary artery stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ACIST Medical Systems

Intervention

Keyword: IVUS, PCI optimization, Post procedural FFR

Outcome measures

Primary outcome

Target vessel failure (TVF), a composite of cardiac death, target-vessel

myocardial infarction and clinically driven TVR at 1 year.

Secondary outcome

Secondary safety endpoint (at 6 months, 1, 2 and 3 years follow-up)

(Definitions Appendix IV)

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 stenting proved to be a strong and independent predictor of Major Adverse Cardiac Events (MACE) at 1 year. A number of factors can cause a post Percutaneous Coronary Intervention (PCI) pressure drop over a treated segment. Substantial evidence exists regarding the benefit of Intravascular Ultrasound (IVUS)-guided as compared to angiography-guided PCI. Despite the fact that previous studies demonstrated that FFR after stenting was <0.90 in approximately 45% of the patients, post-PCI FFR is not routinely performed and it is currently unknown if additional interventions to optimize FFR post stenting would improve patient outcome.

Study objective

To assess if PCI optimization using High Definition (HD)-IVUS in patients with a post-PCI FFR below 0.90 will improve target vessel failure.

Study design

Prospective randomized controlled trial

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.

Study burden and risks

Post PCI FFR measurement is safe with an additional risk for complications <0.5%. Previous studies demonstrated that target vessel failure is significantly higher in patients with a post PCI FFR <0.9 as compared to those with a post PCI FFR >=0.90 (3 to 4 fold). IVUS guided PCI optimization after stenting proved to be safe with a low rate of additional complications. Patients in the treatment arm will undergo IVUS assessment of the stented segment with the attempt to visualize the cause of low post-procedural FFR and drive further intervention to correct the final FFR to > 0.90 (e.g. residual disease proximal or distal to the stented segment, stent underexpansion or dissections). Patients in the control arm will receive standard of care excluding additional imaging upon PCI completion according to routine clinical practice. Follow-up burden will be low and will consist of telephone interviews at 6, 24 and 36 months and a clinical follow-up including electrocardiogram (ECG) at 12 months (the latter being routine clinical care).

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
2. Stable- or unstable angina or Non-ST segment elevation myocardial infarction
3. Target lesion stenosis >= 50% by visual estimation or QCA

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. Inability to perform post procedure FFR
5. 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:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-10-2017
Enrollment:	640
Type:	Actual

Medical products/devices used

Generic name:	FFR and IVUS catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-10-2017
Application type:	First submission
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	NL62550.078.17