Fractional Flow Reserve or 3D-Quantitative-Coronary-Angiography Based Vessel-FFR guided revascularization

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To determine the safety and effectiveness of a vFFR guided strategy versus an invasive FFR guided strategy for coronary revascularization.

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

Summary

ID

NL-OMON54348

Source
ToetsingOnline

Brief title
FAST III

Condition

- Coronary artery disorders

Synonym
Intermediate coronary artery stenosis

Research involving
Human

Sponsors and support

Primary sponsor: European Cardiovascular Research Institute
Source(s) of monetary or material Support: ECRI-15 (non-profit organisatie),Pie Medical

Imaging,Siemens

Intervention

Keyword: 3D-Quantitative-Coronary-Angiography, Cardiology, Fractional Flow Reserve, Percutaneous coronary intervention

Outcome measures

Primary outcome

Composite of all-cause death, any myocardial infarction, or any revascularization at 1 year.

Secondary outcome

1. Patient-oriented Composite Endpoint (POCE) defined as all-cause death, any stroke, any myocardial infarction, and any revascularization
2. Device-oriented Composite Endpoint (DOCE) defined as the composite of cardiovascular death, target-vessel MI, clinically indicated repeat revascularization of the target lesion
3. Study-oriented Composite Endpoint (SOCE) defined as the composite of cardiovascular death, study-vessel or target vessel MI, or study-vessel or target vessel revascularization
4. Target-vessel failure defined as a composite of cardiac death, target vessel myocardial infarction, or clinically indicated target-vessel revascularization
5. Target-lesion Failure defined as a composite of cardiac death, target vessel myocardial infarction, or clinically indicated target-lesion revascularization
6. Study-vessel failure defined as a composite of cardiac death, study vessel myocardial infarction, or clinically indicated study-vessel revascularization
7. Definite and probable stent thrombosis

Study description

Background summary

Invasive coronary angiography has served as the cornerstone for the diagnosis of patients with known or suspected coronary artery disease (CAD). Unfortunately, the technique is limited in its ability to assess the hemodynamic impact of intermediate coronary artery stenosis resulting in under- or overestimation of disease severity. In order to overcome this limitation, Fractional Flow Reserve (FFR) has emerged as the gold standard to assess the hemodynamic importance of intermediate coronary artery lesions and to guide revascularization.
FFR assessment requires the use of a dedicated guidewire or microcatheter along with the administration of a hyperemic agent associated with temporary patient discomfort. Recently a new method was validated which calculates FFR based on blood pressure and a 3D reconstruction of the routinely obtained coronary angiogram (vFFR).

Study objective

To determine the safety and effectiveness of a vFFR guided strategy versus an invasive FFR guided strategy for coronary revascularization.

Study design

The FAST III is a randomized controlled, open-label, multicenter, international, non-inferiority, strategy trial. A total of 2228 participants will be randomized in a 1:1 fashion to either vFFR or FFR guided revascularization. Patients will be consented prior to the procedure and then followed up to 12 (+1) months after randomization. The primary endpoint is analyzed at 12 months after randomization.

Intervention

(v)FFR guided revascularization

Study burden and risks

Participating in the study does not impose additional risks to those compared to patients undergoing standard coronary angiography, percutaneous coronary intervention and coronary artery bypass grafting.
There are no risks associated with the use of 3D-angio-based FFR analysis since it is performed from routinely obtained angiographic data.
Benefits from participating in this study are no different from when standard of care is followed. However, potential benefits of randomization to the vFFR

arm might include the benefit of avoiding vessel manipulation. Possible benefits may be found for future patients treated with vFFR guided PCI based upon results of the study.

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

2. Presenting with silent ischemia, stable angina, non-ST-elevation acute coronary syndrome (NSTE-ACS), or stabilized STEMI (>72h post culprit treatment)
3. Coronary artery disease with at least one native artery in which the stenosis severity is questionable (typically 30-80% stenosis)
4. vFFR guided revascularization considered feasible (see vFFR training manual)

Exclusion criteria

1. Acute treatment of ST-elevation myocardial infarction (STEMI)
2. Cardiogenic shock or severe hemodynamic instability at the time of intervention (as defined by the interventionalist) or use of left ventricular assist device
3. A study lesion cannot be in a vessel with a distal Thrombolysis In Myocardial Infarction (TIMI) flow <3.
4. A study lesion cannot have evidence of thrombus.
5. Known untreated severe valvular heart disease
6. A study lesion cannot be located in or supplied by an arterial or venous bypass graft
7. History of cardiac allograft transplantation
8. A study lesion cannot be aorto-ostial with an estimated diameter stenosis >50%
9. Severe tortuosity precluding the acquisitions of 2 orthogonal projections of the target vessel with minimal overlap or foreshortening

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-11-2021
Enrollment:	800
Type:	Actual

Medical products/devices used

Generic name:	vFFR software (CAAS;Pie Medical;The Netherlands) for angio-based analysis of fractional flow reserve
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-10-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-04-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-12-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-08-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-02-2024
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
Other	ClinicalTrials.gov: NCT04931771
CCMO	NL77863.078.21