FAVOR III (Functional Assessment by Virtual Online Reconstruction). Comparison of quantitative flow ratio (QFR) and conventional pressure-wire based functional evaluation for guiding coronary intervention. A randomized clinical non-inferiority trial

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To investigate if a QFR-based diagnostic strategy yields non-inferior 12-month clinical outcome compared to a standard pressure-wire guided strategy in evaluation of patients with stable angina pectoris and intermediate coronary stenosis.

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

Summary

ID

NL-OMON54747

Source
ToetsingOnline

Brief title
FAVOR III

Condition

- Coronary artery disorders

Synonym
angina, coronary stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Aarhus University and AarhusUniversity Hospital, Skejby
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: FFR (Fractional Flow Reserve), QFR (Quantitative Flow Reserve)

Outcome measures

Primary outcome

Major Adverse Cardiac Events (MACE): All-cause mortality, any myocardial

infarction, and any unplanned revascularization at 12 months.

Secondary outcome

A composite of cardiac death, target vessel myocardial infarction and ischemic

driven target vessel revascularization.

Individual clinical endpoints• Major adverse cardiac events (MACE): all cause mortality, any myocardial

infarction, and any unplanned revascularization at 24 months.

* All-cause mortality at 30 days, one year and two years

* Stroke at 30 days, one year en two years

• Cardiac death at 30 days, one year and two years

• Any myocardial infarction at 30 days, one year and two years

• Target vessel myocardial infarction at 30 days, one year and two years

• Any revascularization at 30 days, one year and two years

• Ischemia driven target vessel revascularization at 30 days, one year and two

years

• Ischemia driven treated target lesion revascularization at 30 days, one year

and two years

• Ischemia driven measured segment target vessel revascularization at 30 days,

one year and two years

• Ischemia driven de novo revascularization at 30 days, one year and two years

• Ischemia driven measured segment de novo revascularization at 30 days, one

year and two years

Procedural endpoints:

• Feasibility of QFR

• Feasibility of FFR

• Number of lesion interrogated

• Procedure time

• Contrast volume

• Fluoroscopy time

• Number of stents implanted

Study description

Background summary

Evaluation of coronary artery stenosis requires objective evidence of its ischemic potential. Current official guidelines indicate assessment of the physiological significance of a coronary stenosis by fractional flow reserve (FFR) (class 1A indication by European Society of Cardiology official guidelines on myocardial revascularization (1)). FFR is the reduction in flow induced by a stenosis and a pressure drop exceeding 20% (FFR<= 0.80) indicates

that a stenosis may cause ischemia in the supplied territory. FFR is assessed as the pressure drop across a stenosis during medically induced hyperaemia. The pressure distal to the stenosis is measured by a pressure transducer on a thin wire. The need for using a pressure wire limits this approach due to potential difficulties advancing the wire, risk of dissections, and the associated costs.
Quantitative flow ratio (QFR) is a novel diagnostic tool to compute FFR based on angiographic images. QFR allows for *wire free* FFR assessment as it does not require a pressure transducer to be placed in the coronary artery. Medical induced hyperaemia is required for standard FFR and causes patient discomfort and, in rare cases, arrhythmia and impaired breathing. With QFR, hyperaemia is modelled by the application and medical induction is not needed.
QFR is based on a combination of coronary anatomy assessed by X-ray angiography and estimated flow velocity in the vessel based on modified frame count analysis.
The FAVOR II study demonstrated that QFR is feasible in clinical practice and lesions are classified comparable to FFR with diagnostic precision of 88%-92% (FAVOR II Europe-Japan and FAVOR II China) for intermediate lesions. QFR has the potential to reduce procedural costs substantially compared to the pressure wire-based FFR strategy, but it is unknown if QFR assessment results in clinical outcome comparable to that of the pressure wire based approach.
To demonstrate the clinical value of a QFR based diagnostic approach a randomized, adequately powered, non-inferiority trial is required; the FAVOR III trial.

Study objective

To investigate if a QFR-based diagnostic strategy yields non-inferior 12-month clinical outcome compared to a standard pressure-wire guided strategy in evaluation of patients with stable angina pectoris and intermediate coronary stenosis.

Study design

Investigator initiated, 1:1 randomized, prospective, clinical outcome, non-inferiority, multi-center trial performed at up to 40 international sites.

Intervention

randomization (1:1) to QFR based evaluation of FFR based evaluation of intermediate coronary stenosis.

Study burden and risks

For patients randomized to the QFR based strategy, obtaining 1-2 extra angiographic recordings per vessel interrogated might be necessary. The potential extra amount of contrast is estimated to be up to 15mL and the

radiation exposure can increase by up to 0.1 mSv per analyzed vessel, equaling up to 0.3 mSv increase in total for each patient. The radiation dose for a standard diagnostic coronary angiography is 1-2 mSv. This limited additional contrast load and radiation exposure is not supposed to cause any measurable increased risk for the patient. A total dose of 2 mSv is associated with an increased risk of 0.01% for developing incurable cancer. Interventional cardiologists and support staff at the participating sites are well trained to manage and reduce any procedural risks.

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

• Indication for invasive coronary angiography
• Diameter stenosis of 40-90% and a vessel diameter of at least 2.5 mm and

supplying viable myocardium
• Patients with stable angina pectoris, or assessment of secondary lesions in stabilized non-STEMI patients or assessment of secondary lesions in patients with prior STEMI and staged evaluation of secondary lesions.
• Patients with restenosis in a native coronary artery

Exclusion criteria

• Severely impaired renal function: GFR < 20 mL/min/1.73m²
• Life expectancy less than one year
• Cardiogenic shock or unstable haemodynamic state (Killip class III and IV)
• Myocardial infarction within 24 hours
• Bypass graft to any target vessel
• Atrial fibrillation at the time of the procedure
• Chronic total occlusions of any vessel with possible or established indication for treatment
• LVEF < 30%
Angiographic exclusion critera:
• Ostial right coronary artery > 50% diameter stenosis
• Left main coronary artery > 50% diameter stenosis

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):	04-05-2020
Enrollment:	130
Type:	Actual

Ethics review

Approved WMO Date:	11-06-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	13-02-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	21-01-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	24-02-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	17-04-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL68927.098.19