Functional Lesion Assessment of Intermediate stenosis to guide Revascularisation

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To assess whether the iFR is non-inferior to FFR when used to guide treamtent of coronary stenoses with PCI

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

Summary

ID

NL-OMON38052

Source
ToetsingOnline

Brief title
FLAIR

Condition

- Coronary artery disorders

Synonym
coronary artery disease, coronary narrowing

Research involving
Human

Sponsors and support

Primary sponsor: Imperial College London
Source(s) of monetary or material Support: Ministerie van OC&W,Unrestricted educational grant van Volcano Corp.,Volcano Corporation

Intervention

Keyword: coronary artery disease, fractional flow reserve, functional lesion assessment, instantaneous wave-free ratio

Outcome measures

Primary outcome

Major adverse cardiac events (MACE) rate in the oFR and FFR groups at 30 days,

1, 2, and 5 years.

Secondary outcome

1. Death (all cause) at 30 days, 1, 2, and 5 years.

2. Death (cardiovascular) at 30 days, 1, 2, and 5 years.

3. Myocardial infarction at 30 days, 1, 2, and 5 years.

4. Repeat revascularization by PCI or coronary artery bypass graft surgery

(CABG) at 30 days, 1, 2, and 5 years.

5. Costs associated with iFR or FFR guidance.

6. Quality of Lide (QOL) of patients included in the iFR or FFR guidance groups

7. Cost savings of removing secondary inverigations, by assessing.treating

non-culprit acute coronary syndrome (ACS) at the time of index presentation.

Study description

Background summary

Decisions to perform or defer percutaneous coronary intervention (PCI) on the basis of physiological stenosis severity using fractional flow reserve (FFR) are safe and reduce stent implantation rates. Despite the evidence, this modality of ischemia driven revascularisation is applied only in s small proprtion of patients undergoimg PCI (6-10%). The reaons dor this are multifactorial, including partial or inadequate reimbursement, availability of suitable measurement equipment, or accessibility to pharmocological agents.

Additionally, FFR adds on average 10 minutes to the procedure, which further discourages widespread adoption. This is particularly relevant in multi-vessel disease: multi-vessel assessment is rarely performed and when it is, takes considerably more time.

Recently a new technique for measuring physiological lesion severity, instantaneous wave-free ratio (iFR) was introduced. iFR, is very similar to the conventional measurement technique, but differs crucially as it does not require the administration of pharmacological vasodilators (such as adenosine).

To date, iFR has been assessed extensively over 18 months, being used in over 3000 lesions, principally in comparisons with FFR, wchih is commonly held as the reference standard for classifying stenoses according to haemodynamic severity.

The results of these studies suggest that iFR is a valid diagnostic tool in the catheterisation laboratory. yet, widespread applicability of iFR in clinical practice will require studies investigating the equivalence of iFR to FFR in terms of patient outcomes when used as a clinical decision making tool in patients in whom PCI is considered as a potential treament.

The FLAIR study is designed to thoroughly assess whether iFR-informed treatment decisions are non-inferior to FFR-informed decisions for the treatment or deferral of PCI.

Study objective

To assess whether the iFR is non-inferior to FFR when used to guide treamtent of coronary stenoses with PCI

Study design

Prospective multi-center randomised study.

Intervention

iFR- versus FFR-guided decision making on revascularisation or deferral of coronary stenoses

Study burden and risks

The risks associated with participation in the study are equivalent of those associated with standard FFR-guidance of treatment. De patien burden consists of telephone contact at 6 months, and a clinical visit at 30 days, 1,2,and 5 years after the procedure.

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 of age
2. Willing to participate and able to understand, read, and sign the informed consent document before the planned procedure.
3. Eligible for coronary angiography and/or percutaneous coronary intervention
4. Coronary artery disease in one or more native major epicardial vessels or their branches by coronary angiogram with visually assessed de novo coronary stenosis in which the physiological severity of the lesion is in question (typically 40-70% diameter stenosis).
5. Stable angina or ACS (non-culprit vessels only and outside of primary intervention during acute STEMI)

Exclusion criteria

1. Previous CABG with patents grafts to the interrogated vessel
2. Left main stenosis
3. Tandem stenoses separated by more than 10mm that require separate pressure guide wire interrogation or PCI (not to be interrogated or treated as a single stenosis).
4. total coronary occlusions.
5. Restenotic lesions.
6. Haemodynamic instability at the time of intervention (heart rate<50 beats per minute, systolic blood pressure <90mmHg, balloon pump).
7. Significant contraindication to adenosine administration (e.g. heart block, severe asthma).
8. Contraindications to PCI or drug-eluting stent (DES) implantation.
9. Heavily calcified or tortuous vessels
10. Significant hepatic or lung disease (chronic pulmonary obstructive disease), and/or malignant disease with unfavourable prognosis that may influence survival within the next 5 years.
11. Pregnancy
12. STEMI wihin 48 hours of procedure.
13. Severe valvular disease.
14. ACS patients in whom more than one target vessel is present.

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:	Recruitment stopped
Start date (anticipated):	03-06-2014
Enrollment:	210
Type:	Actual

Ethics review

Approved WMO Date:	31-03-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL46999.018.13