Inclusive physiological assessment: impact of location of flow velocity assessment

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Flow velocity measurements are more feasible proximal to a coronary stenosis than distal to a stenosis. The conservation of mass principle dictates that proximal flow velocity measurements can be used as a substitute for distal flow velocity…

Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON50864

Source
ToetsingOnline

Brief title
ILIAS Location

Condition

- Coronary artery disorders

Synonym
atherosclerosis, Coronary artery Disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: AMC Medical Research

Intervention

Keyword: CAG, Coronary, Flow, physiology

Outcome measures

Primary outcome

- To document the relationship between coronary flow reserve assessed proximal and distal to a stenosis.

Secondary outcome

- To document the relationship between hyperaemic coronary flow assessed proximal and distal to a stenosis.

- To document the relationship between baseline coronary flow assessed proximal and distal to a stenosis.

Study description

Background summary

Patients with stable angina complaints and suspected coronary artery disease are often treated with percutaneous intervention (PCI). However, not all epicardial stenosis benefit from treatment with PCI and are often better treated with medication alone. To stratify epicardial stenosis that need treatment, physiological assessment is necessary. Coronary pressure and flow indices are able to distinguish significant stenosis and physiological guided therapy improves outcomes and prognosis.

However, flow measurements are technically difficult and measurements distal of a stenosis are suspectable for noise and failure of measurements. Hypothetically, flow measurements proximal to a stenosis are equal to distal measurements in absence of major branches. This study aims to assess this hypothesis.

Study objective

Flow velocity measurements are more feasible proximal to a coronary stenosis than distal to a stenosis. The conservation of mass principle dictates that

proximal flow velocity measurements can be used as a substitute for distal flow velocity measurements. We hypothesize that proximal measurement of coronary flow reserve can be used as a substitute for distal measurement of coronary flow reserve.

Study design

Multi-centre, double-blind, randomized, cross-over study.

Study burden and risks

Compared to local practice standards that recommend physiological-guided revascularization, no additional risks are related to the present study. It is in general considerate that the use of sensor-equipped guide wires is safe. The appearance of vessel wall damaging occurs in approximately 1 of 1000 procedures, hence the adoption of sensor-equipped guide wires is considered as local standard 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

* Age > 18 years
* Presentation with chronic coronary syndrome (Canadian Cardiovascular Society (CCS) Class I-III)
* At least one epicardial stenosis in a native coronary artery with a clinical indication for physiological measurements to inform decision-making.
* Ability to understand and the willingness to sign a written informed consent.

Exclusion criteria

* Left main involvement requiring revascularization, ostial lesions, tandem stenosis.
* Prior CABG to target vessel.
* Extremely tortuous or calcified coronary arteries precluding intracoronary physiologic measurements.
* Visible collateral flow to the target vessel
* Recent (within 3 weeks prior to cardiac catheterization) ST-segment elevation myocardial infarction (STEMI) in any arterial distribution (not specifically target lesion).
* Renal failure (MDRD calculated eGFR of <30).
* Pregnancy.
* Severe valvular abnormalities that require surgery
* Severely impaired left ventricular (LV) function (ejection fraction < 30%)
* Known severe LV hypertrophy (> 13 mm septal wall thickness) Inability to sign an informed consent, due to any mental condition that renders the subject unable to understand the nature, scope, and possible consequences of the trial or due to mental retardation or language barrier.

Study design

Design

Study type:	Observational invasive

Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2021
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Date:	26-04-2021
Application type:	First submission
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	NL75970.018.20