Influence of over-the-wire microcatheters on coronary haemodynamics and the accuracy of physiological indices for assessing the functional significance of intermediate coronary stenoses.

Published: 30-10-2015 Last updated: 19-04-2024

This study is designed to objectively document the physiological impact of a micro-catheter on coronary physiology parameters compared with a contemporary 0.014* sensor-equipped guide wire during both basal and hyperaemic conditions, and to identify...

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

Summary

ID

NL-OMON42425

Source ToetsingOnline

Brief title IMPACT

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:** Ministerie van OC&W

Intervention

Keyword: Coronary Artery Disease, Functional stenosis severity, over-the-wire microcatheter, sensor-equipped guide wires

Outcome measures

Primary outcome

The resistance induced by the epicardial coronary segment with and without the

presence of an over-the-wire micro-catheter during coronary vasodilation.

Secondary outcome

The resistance induced by the epicardial coronary segment with and without the

presence of an over-the-wire micro-catheter during resting conditions.

The available coronary vasodilatory reserve with and without the presence of an over-the-wire micro-catheter using the coronary flow reserve, and the resistive reserve ratio.

Stenosis severity with and without the presence of an over-the-wire micro-catheter by means of the distal coronary to aortic pressure ratio during resting conditions.

Stenosis severity with and without the presence of an over-the-wire micro-catheter by means of the distal coronary to aortic pressure ratio during coronary vasodilation.

The delta stenosis resistance between wire-only and micro-catheter based assessment during vasodilation as a function of stenosis severity identified by angiographic diameter stenosis, resting Pd/Pa and basal stenosis resistance index.

Study description

Background summary

The adoption of physiologic indices as fractional flow reserve (FFR) remains limited, part of which can be attributed to practical ambiguities related to the use of contemporary sensor-equipped guide wires. Since the mechanical properties of sensor-equipped guide wires are less refined than routine guide wires used for PCI, many operators prefer to use their workhorse guide wire for stent placement. This could be addressed by an over-the-wire system capable of measuring coronary pressure, while allowing the use of routine flexible workhorse guide wires to provide stable positioning of the pressure sensor, and limiting guide wire manoeuvres necessary for physiological assessment and PCI. However, micro-catheter systems are larger in diameter than guide wires, and it is unclear to what extend coronary haemodynamics and physiological properties of the stenosis might be altered by over-the-wire micro-catheters systems compared to contemporary sensor-equipped guide wires.

Study objective

This study is designed to objectively document the physiological impact of a micro-catheter on coronary physiology parameters compared with a contemporary 0.014* sensor-equipped guide wire during both basal and hyperaemic conditions, and to identify boundary conditions for micro-catheter based physiology-guided coronary intervention.

Study design

A multi-center, single-blinded, randomized , cross-over study.

Study burden and risks

Compared to local practice standards that recommend FFR-guided revascularization, no additional risks are related to 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

Public

Academisch Medisch Centrum

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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.;Presence of at least one epicardial stenosis in a native coronary artery, requiring physiological assessment according to the European Society of Cardiology Myocardial Revascularization Guidelines.;Vessel size at least 2.5mm in diameter as visually assessed on the diagnostic angiogram.;Presence of stable; Canadian Cardiovascular Society (CCS) score I-III.;Willing to participate and able to understand, read and sign the informed consent document before the scheduled procedure.

Exclusion criteria

Left main involvement requiring revascularization.;Cardiac arrhytmia.;Extremely tortuous or calcified coronary arteries that impede adequate physiologic measurements.;Recent (<6 weeks) myocardial infarction (STEMI or NSTEMI).;Severe valvular abnormalities that require surgery. ;Severely impaired left ventricular (LV) function (LV ejection fraction < 30%);LV hypertrophy (>13mm septal wall thickness). ;Unable to undergo percutaneous intervention or receive adenosine (severe reactive airway disease, severe hypotension or high-grade Atrio-Ventricular (AV) block in the absence of a pacemaker. ;Collateral formation in target vessel.;CABG to target vessel.;Tandem stenoses.;Ostial lesions.;Renal failure (MDRD calculated eGFR of <30). ;Pregnancy or planned pregnancy within 12 months after the procedure.

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

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NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2015
Enrollment:	32
Туре:	Actual

Ethics review

Approved WMO	
Date:	30-10-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO	
Date:	31-05-2016
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 CCMO **ID** NL54889.018.15