Pressure Guidewire Comparative In Patients Study

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Compare the stability of the FFR measurement and the handling performance of the St. Jude Pressure Wire X compared to the Opsens OptoWire Deux.

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

Summary

ID

NL-OMON45355

Source
ToetsingOnline

Brief title
FFR COMP-IP-02 study

Condition

- Coronary artery disorders

Synonym
Coronary artery disease, Intravascular blood pressure

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Opsens Inc.,TOP Medical BV Elsloo

Intervention

Keyword: Diagnostic angiography, Drift, Fractional flow reserve (FFR), intravascular blood

pressure

Outcome measures

Primary outcome

The FFR measurement reliability is assessed by two measures. First reliability is assessed by tracking and recording the drift caused by the pressure guidewire residing within the coronary artery. This is determined by the value of Pd/Pa before and after the procedure when pulled back just outside the guiding catheter.

Secondly, FFR reliability is assessed by the stability of Pd/Pa during constant hyperemia.

Secondary outcome

The wire handling performance is assessed by scoring both wires by the same investigator in the same patient. The following characteristics are scored on a 5 point scale: torquability, steerability, pushability and support. The wire performance is also assessed by measuring the time it takes to reach and cross the lesion.

Study description

Background summary

Fractional Flow Reserve (FFR) is an index that is used to determine the functional significance of coronary artery disease (CAD) during cardiac catheterization. FFR requires measurement of aortic and distal coronary pressure. The latter is usually determined by a pressure sensor mounted guide wire. The challenge with current pressure guidewires is that they measure pressure using piezo-resistive pressure sensors that are sensitive to moisture

which influences the stability of the transmitted pressure signal. Potentially, unreliable measurements with consequent erroneous clinical decisions could be made. Moreover, wire handling with these pressure mounted guide wires is different from regular guidewires due to the design. This fact limits adoption of functional assessment of CAD in the cathlab. Therefore, there is a clinical need for a FFR wire providing reliable pressure measurement and whose performance would be closer to standard angioplasty-wire.

Study objective

Compare the stability of the FFR measurement and the handling performance of the St. Jude Pressure Wire X compared to the Opsens OptoWire Deux.

Study design

Observational study, two-center, two-arm study

Study burden and risks

In this study the small additional small risk arises from the elongation of the procedure due to the repetition of the FFR measurement. FFR measurement is standard of care and has a Class 1A recommendation for lesion assessment pre-percutaneous coronary intervention in the European Society of Cardiology guidelines for revascularization. The risks of a FFR measurement are small in experienced hands and almost always temporary. There is no direct benefit for the patient when participating in this 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

Patients with at least one lesion indicated for FFR

Exclusion criteria

More than 3 lesions indicated for FFR measurements
Type C lesions
Lesions with angiographic 'haziness' or suspected to contain thrombus

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-03-2018
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Optical FFR Guidewire
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-12-2017
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL60721.028.17