OPtical Coherence Tomography (OCT) Compared to Intravascular Ultrasound (IVUS) and Angiography to Guide Coronary Stent Implantation: a Multicenter RandomIZEd Trial in PCI

Published: 20-08-2015
Last updated: 19-04-2024

Primary Objective: To demonstrate the safety and efficacy of an OCT guided strategy for stent implantation.Trial Hypothesis: OCT-guided stent placement with application of a novel algorithm is non-inferior to IVUS-guided stent placement and superior…

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

Summary

ID

NL-OMON42441

Source
ToetsingOnline

Brief title
ILUMIEN III: OPTIMIZE PCI

Condition

- Coronary artery disorders

Synonym
Coronary Artery Disease - Disease of the heart vessels

Research involving
Human

Sponsors and support

Primary sponsor: St. Jude Medical
Source(s) of monetary or material Support: St. Jude Medical

Intervention

Keyword: IVUS, OCT, PCI, Randomized

Outcome measures

Primary outcome

Primary Efficacy Endpoint (powered).

Post-PCI MSA assessed by OCT in each randomized arm, measured at the independent OCT core laboratory blinded to imaging modality assignment.

Testing will be done in a hierarchal manner as follows:

1. Non-inferiority of OCT guided stenting vs. IVUS guided stenting

2. Superiority of OCT guided stenting vs. Angiography guided stenting

3. Superiority of OCT guided stenting vs. IVUS guided stenting

Primary Safety Endpoint (non-powered).

Procedural MACE defined as procedural complications (angiographic dissection, perforation, thrombus, and acute closure) requiring active interventions (prolonged balloon inflations, additional stent implantation, or pericardiocentesis).

Secondary outcome

Imaging measures by OCT in each study arm

1) Acute procedural success

2) Post-PCI stent expansion (%)

3) Mean stent expansion (%)

4) Intra-stent plaque protrusion and thrombus

5) Untreated reference segment disease

6) Edge dissections

7) Stent Malapposition

8) Border detection (OCT arm only)

9) Altered clinical decision making on the basis of the post-stent imaging run

10) Intra-stent Lumen Area (Intra-stent Flow Area)

11) Effective Lumen Area (Total Flow Area)

12) IVUS vs. OCT detected:

A) Malapposition (Major, Minimal, All) (%)

B) Dissection (Major, Minor, All) (%)

C) Protrusion (Major, Minor, All) (%)

Non OCT Secondary Endpoints

Angiographic Endpoints (QCA)

1) Minimal lumen diameter

2) Percent diameter stenosis

3) Acute lumen gain post-intervention

4) Maximum stent size/reference vessel diameter ratio

5) Angiographic Dissection >= NHLBI type B

Procedural Endpoints (site reported):

1) Total Stent Length

2) Total number of stents

3) Maximal Stent Size

4) Post dilatation inflations (yes/no)

5) Maximum inflation pressure (atm.)

6) Additional interventions on the basis of the post stent imaging run:

A) Use of larger balloon

B) Use of higher inflation pressures

C) Use of additional inflations

D) Use of additional stent(s)

E) Thrombus aspiration

F) Other interventions

Additional Procedural and Clinical Endpoints

1) Angiography defined procedural success rate

2) Device success rate (site reported)

3) Target Lesion Failure at 1 year defined as cardiovascular death, target vessel myocardial infarction, or ischemia driven target-lesion revascularization.

4) Peri-procedural myocardial infarction.

Study description

Background summary

Angiography remains the primary method of imaging the coronary artery vasculature to guide clinical decision-making and PCI strategy. However angiography has a number of well-known limitations. Angiography provides a 2-dimensional representation of a complex 3-dimensional structure. Moreover, the angiogram displays only luminal dimensions and characteristics, without information on vascular remodeling, plaque distribution and eccentricity, or detailed delineation of the extent of disease. The ability of angiography to accurately characterize plaque and tissue types including calcification, lipid and thrombus is poor. Operator assessment of lesion severity both before and after PCI is notoriously inaccurate. Although quantitative coronary angiography is able to reduce intra-observer and inter-observer variability, it is cumbersome and rarely performed (at least in the US), and is unable to overcome other inherent limitations of the technique.Angiography is also suboptimal in its ability to identify post PCI complications such as stent underexpansion or malapposition, residual dissections or thrombus, and plaque prolapse.

These limitations of angiography may be overcome in part by intravascular ultrasound (IVUS), which allows tomographic cross-sectional imaging of the vessel wall. IVUS determination of the minimum stent area as well as residual plaque burden and dissections at the stent margins have been shown in numerous studies to be independent predictors of both restenosis and stent thrombosis. Meta-analyses of randomized and registry studies of IVUS-guided vs. angiography-guided PCI have suggested that IVUS guidance may decrease restenosis and TVR (Target Vessel Revascularisation) after treatment with BMS, and restenosis, TVR, stent thrombosis, and death after treatment with DES. The large-scale ADAPT-DES study demonstrated that IVUS guidance leads to larger stent expansion and use of longer stents, with associated reductions in stent thrombosis, MI, TLR (Target Lesion Revascularisation) and cardiac death. Nonetheless, IVUS has limited axial resolution (150-200 µm), is unable to image behind calcium, poorly discriminates thrombus and other plaque subtypes, is unable to assess fibrous cap thickness with resolution sufficient to identify vulnerable plaque, and is limited by the photoacoustic properties of sound and therefore requires slow pullback. Radiofrequency IVUS is more accurate than grayscale IVUS for plaque characterization, but is currently used principally as a research tool, and has not been demonstrated to further enhance stent procedures.

Optical coherence tomography (OCT) is a newer intravascular imaging modality that provides high-resolution (10-20 µm) cross-sectional images of plaque microarchitecture, stent placement and size, apposition, and strut coverage. Second-generation frequency domain (FD)-OCT allows for rapid pullback during blood clearance of the vessel, and has been used to image microstructural details, which correlate closely to histopathology. Specifically, compared to IVUS, OCT offers greater dimensional measurement accuracy, and is able to more accurately identify thrombus, lipid, calcium, fibrous cap thickness, dissections, plaque prolapse, stent malapposition and strut coverage. However, despite the greatly improved resolution of OCT compared to IVUS, the

penetration depth of OCT is limited, and as such the full thickness of the vascular wall may not be visible. The impact of this limitation is unclear.

In a cross-over study design, Habara and colleagues reported that compared to OCT-guided PCI, IVUS-guided PCI resulted in a significantly greater minimum stent area (MSA), the most important single determination of restenosis and stent thrombosis. Multiple strategies to optimize stent implantation using OCT have been proposed but none as of yet has gained universal agreement among interventional cardiologists and broad adoption. The lack of randomized studies demonstrating that patient outcomes of OCT-guided stenting are at least as good as with IVUS-guided stenting represents major hurdles for the adoption of this technology. We therefore developed an algorithm to use OCT to optimize coronary stent implantation and in this study will compare its outcomes to those achieved with IVUS as well as those achieved with angiography.

Study objective

Primary Objective:
To demonstrate the safety and efficacy of an OCT guided strategy for stent implantation.

Trial Hypothesis:
OCT-guided stent placement with application of a novel algorithm is non-inferior to IVUS-guided stent placement and superior to Angiography, all as measured by post-PCI minimum stent area (MSA).

Study design

The present study is a prospective, post-market, international, multi-center, randomized trial aimed at demonstrating whether a practical strategy of OCT-guided stent implantation can result in similar immediate post-PCI stent lumen dimensions as achieved with IVUS-guidance, and superior results to those achieved with angiography.
Approximately 35 sites in the United States and outside the United States will participate in this study of 420 subjects.

Study burden and risks

An extra OCT catheter is used after stent placement in patients who will be randomized to the Angiography and IVUS arm. This is done to generate additional OCT images for study purposes. The risk of the insertion of an additional catheter is minimal during this procedure.

For the rest of the procedure the usual risks of PCI treatment apply.

Participation is justified because the research brings almost no extra burden

for the patient. The extra-OCT catheter which is used in the angiography and IVUS arm gives a minimal additional risk during the PCI procedure. The randomization to different standard of care visualization techniques brings no additional risk to the patient. These three techniques are already widely used in hospitals.
It could be that the PCI procedure takes longer because more measurements are done.

The burden for the patient is minimal compared to the scientific value of this study.

Contacts

Public
St. Jude Medical

Standaardruiter 13
VEENENDAAL 3905 PT
NL
Scientific
St. Jude Medical

Standaardruiter 13
VEENENDAAL 3905 PT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

General Inclusion Criteria:
1) Age >= 18 years.
2) Patient with an indication for PCI
3) Patients will undergo cardiac catheterization and possible or definite PCI with intent to stent using any non-investigational metallic drug-eluting stent (DES);Angiographic Inclusion Criteria:
1) The target lesion must be located in a native coronary artery with visually estimated reference vessel diameter of >=2.25 mm to <=3.50 mm.
2) Total lesion length <40mm

Exclusion criteria

General Exclusion Criteria:
1) Estimated creatinine clearance <30 ml/min using Cockcroft-Gault equation, unless the patient is on dialysis
2) STEMI within 24 hours of initial time of presentation to the first treating hospital, whether at a transfer facility or the study hospital
3) PCI within 24 hours preceding the study procedure
4) PCI of a lesion within the target vessel within 12 months prior to the study procedure
5) Planned use of bare metal stent (BMS)
6) Planned use of bioresorbable vascular scaffold (BVS)
7) Cardiogenic shock or requiring pressors or hemodynamic support, including IABP, at time of procedure
8) Mobitz II second degree or complete heart block
9) Malignant ventricular arrhythmias requiring treatment
10) Pulmonary edema defined as patient with shortness of breath, evidence of volume overload on physical exam, and crepitations on physical exam (>1/3 of lungs) or radiographic interstitial or alveolar pulmonary edema
11) Subject is intubated
12) Known LVEF <30%
13) Severe valvular disease (e.g. severe mitral regurgitation or severe aortic stenosis)
14) Cerebrovascular accident or transient ischemic attack within the past 6 months, or any permanent neurologic defect attributed to CVA

Study design

Design

Study type:	Observational invasive

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):	02-09-2015
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	OCT;Optimal Coherence Tomography
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-08-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-05-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL53487.078.15