OPtical Coherence Tomography (OCT) Guided Coronary Stent IMplantation Compared to Angiography: a Multicenter Randomized TriaL in PCI

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The objective of this clinical investigation is to demonstrate the superiority of an Optical Coherence Tomography (OCT)-guided stent implantation strategy as compared to an angiography-guided stent implantation strategy in achieving larger post-PCI…

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

Summary

ID

NL-OMON54677

Source
ToetsingOnline

Brief title
ILUMIEN IV: OPTIMAL 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: Abbott

Intervention

Keyword: Angiography, Optical Coherence Tomography, Percutaneous Coronary Intervention, Randomized

Outcome measures

Primary outcome

1) Imaging Outcome (powered): Minimal stent area (MSA), continuous measure

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

2) Clinical outcome (powered): Target vessel failure (TVF)

Composite time-to-first event rate of cardiac death, target vessel myocardial infarction (TV-MI) (per-protocol MI definition), or ischemia-driven target vessel revascularization (ID-TVR), assessed at a minimum of 1 year and up to 2 years.

Secondary outcome

Procedural outcomes, OCT-defined

1) Stent expansion

2) Mean stent expansion (%)

3) Intra-stent plaque protrusion and thrombus

4) Untreated reference segment disease

5) Edge dissections

6) Stent Malapposition

7) Border detection (angiography arm post-PCI only, blinded to investigator)

8) Intra-stent lumen area (intra-stent flow area)

9) Effective lumen area (total flow area)

Additional Procedural and Clinical Endpoints

10) Several Angiographic Endpoints (QCA)

11) Several Device Usage Endpoints

12) Procedure time (first wire insertion to guide catheter removal),

fluoroscopy time, radiation exposure

13) Contrast use; contrast induced nephropathy

14) Procedural success

15) Procedural complications

16) OCT performance success

17) OCT imaging-related procedural complications

18) Additional interventions on the basis of the pre-PCI or post-stent

OCT-imaging run that would not have been performed based on angiographic

guidance alone (site reported; assessed per subject; OCT Arm Only)

Clinical outcomes at 30 days, 1 year and 2 years

19) Target lesion failure

20) All-cause mortality

21) Cardiac and non-cardiac mortality

22) All myocardial infarction (MI)

23) TV-MI, non-TV-MI and indeterminate vessel MI

24) Periprocedural MI and non-periprocedural MI

25) All revascularization

26) ID-revascularization and non-ID-revascularization

27) ID-TVR, ID-TLR and ID-non-TLR TVR

28) Definite, probable and definite/probable stent thrombosis (ARC definition)

29) Relationship between immediate post-procedure OCT parameters and 2-year endpoint rates

Patient Reported Outcomes

Patient Reported Outcome questionnaires will be incorporated into this study to provide a complementary evaluation of the effectiveness of OCT-guided stent implantation. The following instruments will be administered during this study in hospital (required at baseline, optional post-procedure), and at 30 day, 12 month and 24 month follow-up:

30) EuroQoL 5D (EQ-5D-5L) survey to assess overall health status

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.

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 and strut coverage. Due to its high resolution and ability to accurately optimize and identify suboptimal results of stent implantation, it is plausible that the use of this OCT-guided algorithm may improve clinical outcome of stent implantation

In the present study we aim to compare the outcomes of OCT-guided stent implantation to those achieved with angiography guided stent implantation, specifically among in high-clinical-risk patients or high-angiographic-risk lesions.

Study objective

The objective of this clinical investigation is to demonstrate the superiority of an Optical Coherence Tomography (OCT)-guided stent implantation strategy as compared to an angiography-guided stent implantation strategy in achieving larger post-PCI lumen dimensions and improving clinical cardiovascular outcomes in patients with high-risk clinical characteristics and/or with high-risk angiographic lesions.

Study design

This is a prospective, single-blind clinical investigation randomizing subjects to OCT-guided coronary stent implantation vs. angiography-guided coronary stent implantation in a 1:1 ratio.
The clinical investigation will be conducted at approximately 125 centers in North America (US and Canada), Europe, Middle East and Asia-Pacific. Up to 3656 randomized subjects and approximately 375 roll-in subjects will be enrolled in the clinical investigation. No site may enroll more than 15% of the total randomized subjects.
Subjects participating in this clinical investigation will be followed for 2 years. The expected duration of enrollment is approximately 2 years.The total duration of the clinical investigation is expected to be approximately 5 years.

Intervention

One group receives the stent implantation guided by OCT where the other group receives the stent implantation guided by angiography.

Both imaging techniques are currently part of the standard of care.

Study burden and risks

For study purposes, an additional OCT catheter is used after the stent placement in patients randomized in the angiography arm. The additional risk of inserting an extra catheter is minimal during this procedure.

Furthermore, the usual risks of a PCI treatment apply.

The burden related to participation in this clinical study is minimal, since the study promotes following the standard of 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

1. Subject must be at least 18 years of age.
2. Subject must have evidence of myocardial ischemia (e.g., stable angina, silent ischemia, unstable angina, or acute myocardial infarction) suitable for elective PCI.
3. Patients undergoing planned XIENCE stent implantation during a clinically indicated PCI procedure meeting one or more of the following criteria:

A) High clinical-risk, defined as;
i. Medication-treated diabetes mellitus, AND/OR
B) High angiographic-risk lesion(s), with at least one target lesion in each target vessel planned for randomization meeting at least one of the following criteria;
i. Target lesion is the culprit lesion responsible for either:
• NSTEMI, defined as a clinical syndrome consistent with an acute coronary syndrome and a minimum troponin of 1 ng/dL (may or may not have returned to normal), and >1 mm ST segment deviation and/or dynamic T wave changes at rest within 7 days, OR
• STEMI >24 hours from the onset of ischemic symptoms
ii. long or multiple lesions (defined as intended total stent length in any single target vessel >=28 mm),
iii. bifurcation intended to be treated with 2 planned stents (i.e. in both the main branch and side branch), and where the planned side branch stent is >= 2.5 mm in diameter.
iv. angiographic severe calcification (defined as angiographically visible calcification on both sides of the vessel wall in the absence of cardiac motion),
v. chronic total occlusion (CTO) (enrolment and randomization in this case performed only after successful antegrade wire escalation crossing and pre-dilatation)
vi. in-stent restenosis (all patterns, as long as the lesion is at or within the stent margin(s) and has an angiographically visually-assessed DS >=70% or DS >=50% with non-invasive or invasive evidence of ischemia)
4. All target lesions (those lesions to be randomized) must have a visually estimated or quantitatively assessed %DS of either >=70%, or >=50% plus one or more of the following: an abnormal functional test (e.g. fractional flow reserve, stress test) signifying ischemia in the distribution of the target lesion(s) or biomarker positive ACS with plaque disruption or thrombus.
5. All target lesions must be planned for treatment with only >=2.5 mm and <=3.5 mm stents and post-dilatation balloons based on pre-PCI angiographic visual estimation. The only exception is for long target lesions (visually estimated as >20 mm), in which after implantation of a <=3.5 mm stent up to half of the stented segment may be post-dilated with balloons >3.5 mm as needed per operator judgment.
6. No more than 2 target lesions requiring PCI are present in any single vessel., and no more than 2 target vessels are allowed. Thus, up to 4 randomized target lesions per patient in a maximum of 2 target vessels are allowed, including branches. The intended target lesions will be declared just prior to randomization.
7. All target lesions intended to be treated by PCI in the target vessel are amenable to OCT-guided PCI.
8. For a female subject of childbearing potential, a pregnancy test must be performed with negative results known within 7 days prior to the index procedure per site standard, and pregnancy must not be intended for at least 2 years.

9. For a female subject with a recent birth, subject is not breast-feeding at the time of the screening visit and will not be breast-feeding for up to 2 years following the index procedure.
10. Subject or a legally authorized representative must provide written Informed Consent prior to any study related procedure.

Exclusion criteria

Clinical Criteria for exclusion:
1. STEMI <=24 hours from the onset of ischemic symptoms.
2. Creatinine clearance <=30 ml/min/1.73 m2 (as calculated by MDRD formula for estimated GFR)5 and not on dialysis. Note: chronic dialysis dependent patients are eligible for enrolment regardless of creatinine clearance.
3. Hypotension, shock or need for mechanical support or intravenous vasopressors
4. CHF (Killip class >=2 or NYHA class >=3)
5. LVEF <=30% by the most recent imaging test within 30 days prior to procedure (echo, MRI, contrast left ventriculography or other)
6. Unstable ventricular arrhythmias
7. Inability to take DAPT (both aspirin and a P2Y12 inhibitor) for at least 12 months in the patient presenting with an ACS, or at least 6 months in the patient presenting with stable CAD, unless the patient is also taking chronic oral anticoagulation in which case a shorter duration of DAPT may be prescribed per local standard of care.
8. Planned cardiac or non-cardiac surgery within 24 months after the index procedure
9. Prior PCI within the target vessel within 12 months (unless the target lesion is the prior PCI site - i.e. in-stent restenosis)
10. Any planned PCI within the target vessel(s) within 24 months after the study procedure, other than a planned staged intervention in a second randomized target vessel.
11. Any prior PCI in a non-target vessel within 24 hours before the study procedure, or within previous 30 days if unsuccessful or complicated.
12. Subject has known hypersensitivity or contraindication to any of the study drugs (including heparin and all P2Y12 inhibitors, one or more components of the study devices, including everolimus, cobalt, chromium, nickel, platinum, tungsten, acrylic and fluoropolymers, or radiocontrast dye that cannot be adequately pre-medicated.
13. Subject has received any solid organ transplants or is on a waiting list for any solid organ transplants.
14. Subject is receiving immunosuppressant therapy or has known immunosuppressive or severe autoimmune disease that requires chronic immunosuppressive therapy (e.g., human immunodeficiency virus, systemic lupus erythematosus, etc.). Note: corticosteroids are not included as immunosuppressant therapy.
15. Subject has previously received or is scheduled to receive radiotherapy to

a coronary artery (vascular brachytherapy), or the chest/mediastinum.
16. Subject has a platelet count <100,000 cells/mm3 or >700,000 cells/mm3.
17. Subject has a documented or suspected hepatic disorder as defined as cirrhosis or Child-Pugh >= Class B.
18. Subject has a history of bleeding diathesis or coagulopathy, or has had a significant gastro-intestinal or significant urinary bleed within the past six months.
19. Subject has had a cerebrovascular accident or transient ischemic neurological attack (TIA) within the past six months, or any prior intracranial bleed, or any permanent neurologic defect, or any known intracranial pathology (e.g., aneurysm, arteriovenous malformation, etc.).
20. Subject has extensive peripheral vascular disease that precludes safe 6 French sheath insertion. Note: femoral arterial disease does not exclude the patient if radial access may be used.
21. Subject has life expectancy <2 years for any non-cardiac cause.
22. Subject is in the opinion of the Investigator or designee unable to comply with the requirements of the study protocol or is unsuitable for the study for any reason.
23. Subject is currently participating in another investigational drug or device clinical study that has not yet completed its primary endpoint6.
24. Subject is part of a vulnerable population who, in the judgment of the investigator, is unable to give Informed Consent for reasons of incapacity, immaturity, adverse personal circumstances or lack of autonomy. This may include: Individuals with mental disability, persons in nursing homes, children, impoverished persons, persons in emergency situations, homeless persons, nomads, refugees, and those incapable of giving informed consent. Vulnerable populations also may include members of a group with a hierarchical structure such as university students, subordinate hospital and laboratory personnel, employees of the Sponsor, members of the armed forces, and persons kept in detention.Angiographic exclusion criteria:
A) Syntax score >=33, unless a formal meeting of the Heart Team, including a cardiac surgeon, concludes that PCI is appropriate.
B) Planned use of any stent <2.5 mm in a randomized vessel based on visual estimation (note: a smaller stent may be used in a bail-out scenario - e.g. to treat a distal dissection - but its use cannot be planned prior to enrolment)
C) Planned use of a stent or post-dilatation balloon >=3.75 mm for the randomized target lesion (see inclusion criteria #2 for the one exception to this exclusion criterion)
D) Severe vessel tortuosity or calcification in a randomized target vessel such that it is unlikely that the OCT catheter can be delivered (note: severe vessel calcification is allowed if it is expected that the OCT catheter can be delivered at baseline or after vessel preparation with balloon pre-dilatation or atherectomy)
E) The randomized target lesion is in the left main coronary artery
F) The randomized target lesion is in a bypass graft conduit. Note: A native coronary artery may be randomized if a prior bypass graft conduit to the vessel is totally occluded, but not if it is patent.

G) The randomized target lesion is an ostial RCA stenosis
H) The randomized target lesion is a stent thrombosis
I) Planned use of any stent other than Xience in a randomized target lesionehoude

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-10-2018
Enrollment:	1096
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	12-09-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	01-04-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-10-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-12-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-01-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-02-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT03507777
CCMO	NL65713.101.18