Dutch BifUrcaTion Study Evaluating CHaracteristics of the Side Branch Opening with Optical Coherence Tomography after Side Branch FENestration in Patients Treated with COMBO or Xience Stent.

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Primary Objective:To compare the fate of the struts in front of the side-branch using optical coherence tomography after treatment with 1. COMBO or 2. XIENCE stent using single stent strategy with side-branch fenestration in the treatment of (a)...

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

Summary

ID

NL-OMON48918

Source
ToetsingOnline

Brief title
DUTCH OPEN

Condition

- Coronary artery disorders

Synonym
bifurcation lesion;

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: OrbusNeich,OrbusNeich Medical B.V.

Intervention

Keyword: Bifurcation, COMBO stent, coronary artery disease

Outcome measures

Primary outcome

OCT endpoints

o Appearance of overhanging struts in front of the side branch ostium on

three-dimensional OCT post-implantation and post-procedure measured by

cute-plane analysis

o Number of non-apposed side branch (NASB) struts post-implantation and

post-procedure

o Incomplete strut apposition in the bifurcation region post-procedure

o Mean/Minimal Stent diameter/area post-procedure

o Mean/Minimal Lumen diameter/area at baseline

o Stent pattern irregularities post-procedure

Angiographic endpoints

o Acute gain of proximal main branch (MB), distal MB and side branch (SB)

o In-stent, in-segment, % diameter stenosis proximal and distal MB and SB

post-nitrate pre-procedural

o Reference vessel diameter of MB

o In-stent, in-segment Dmax (maximum diameter) proximal and distal MB and

distal SB pre-procedural

3D angiographic endpoints

o The bifurcation angle

o Minimal lumen area (MLA, in mm2)

o Percentage area stenosis (%)

Secondary outcome

Cardiac death

myocardial infarction

revascularization

Study description

Background summary

Coronary artery bifurcation lesions constitute a complex lesion subgroup that is encountered in 15-20% of all percutaneous coronary interventions (1). Percutaneous treatment of coronary bifurcation lesion remain challenging in interventional cardiology, with lower procedural success and increased rates of long-term adverse cardiac events (1). Multiple technical strategies have been proposed, but it has been generally accepted that provisional side-branch (SB) stenting is a favoured approach (2, 3). A two-stent strategy did not have an advantage over a one-stent strategy (4, 5). When SB dilatation is indicated after provision stenting, a frequent used strategy is side branch fenestration followed by proximal optimization technique (POT) (3).

The COMBO dual-therapy stent has not systematically been tested in bifurcation lesions. But, due to the dual helix stent strut design, there is unsurpassed sidebranchability. In addition, the strut width of COMBO is 90 µm and the maximum stent cell opening is 4.50 mm. This all may contribute to a better angiographic result after provisional stenting with COMBO in bifurcation lesions than after XIENCE implantation.

Study objective

Primary Objective:
To compare the fate of the struts in front of the side-branch using optical coherence tomography after treatment with 1. COMBO or 2. XIENCE stent using single stent strategy with side-branch fenestration in the treatment of (a) coronary bifurcation lesion(s).

Secondary Objective:
To compare the angiographic result of the main branch and side-branch after treatment of the main branch with fenestration of the side-branch with 1. COMBO stent to 2. XIENCE stent.

Study design

The DUTCH OPEN trial is a prospective, randomized (1:1), Dutch, multicenter trial of consecutive elective patients undergoing percutaneous coronary intervention in (a) coronary bifurcation lesion(s) with stent placement. This study involves the collection of baseline demographic, clinical, angiographic and optical coherence tomography data, as well as clinical follow-up data.

Study burden and risks

The PCI will take longer, after stent placement an OCT will be made. In addition, patients will be contacted by Phone at 12 months after index procedure. The OCT will come with additional risk: low blood pressure, arithmia, acute vessel closure.

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

Bifurcation lesion involving a side-branch larger than 2 mm and having main branch involvement, which needs percutaneous coronary intervention with stenting.

Exclusion criteria

Patients with a bifurcation lesie which needs a two stent strategy

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-01-2020
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	COMBO stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-11-2019
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	NL65342.018.19