Bifurcation ABSORB OCT Trial

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Primary Objective:To compare the fate of the struts in front of the side-branch and intimal bridge formation using optical coherence tomography after treatment with the bioresorbable everolimus eluting vascular scaffold of coronary bifurcation...

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

Summary

ID

NL-OMON44338

Source
ToetsingOnline

Brief title
BISORB OCT Trial

Condition

- Coronary artery disorders

Synonym
Coronary Artery Disease, Coronary Atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Abbott,Bedrijven

Intervention

Keyword: Bifurcation, Bioresorbable Vascular Scaffold, Optical Coherence Tomography

Outcome measures

Primary outcome

OCT endpoints

o Incomplete strut apposition in the bifurcation region at baseline, at 12 months, 24 months and 36 months

o Number of embedded and protruded struts per region at baseline, 12, 24 months and 36 months

o Incomplete strut coverage in the bifurcation region at 12, 24 months and 36 months

o Number of non-apposed side branch (NASB) struts at baseline at 12, 24 months and 36 months

o Tissue in-between NASB struts at 12 and 36 months

o Appearance of jailed side branch struts on three-dimensional OCT at baseline, 12, 24 months and 36 months including the V, T, H, double V, double T and double H shapes.

o Mean/Minimal Scaffold diameter/area at baseline, 12, 24 months and 36 months

o Mean/Minimal Lumen diameter/area at baseline, 12, 24 months and 36 months

o Neointima thickness at 12 and 36 months; in total and per segment (proximal end distal main branch; bifurcation region).

o Scaffold pattern irregularities at baseline, 12, 24 months and 36 months

o Incomplete strut apposition in the bifurcation region at baseline, 12 months, 24 months and 36 months between re-crossing through the distal compartment and other compartments.

o Number of non-apposed side branch (NASB) struts at baseline 12 months, 24 months and 36 months between re-crossing through the distal compartment and other compartments.

o Appearance of jailed side branch struts on three-dimensional OCT at baseline 12 months, 24 months and 36 months including the V, T, H, double V, double T and double H shape between re-crossing through the distal compartment and other compartments.

Angiographic endpoints

o Proximal 5mm SB% diameter stenosis (DS) postnitrate at baseline, 12, 24 months and 36 months

o In-segment Late Loss (LL) postnitrate at 12 months, 24 months and at 36 months

o Proximal LL postnitrate at 12 months, 24 months and at 36 months

o Distal LL postnitrate at 12 months, 24 months and at 36 months

o In-scaffold/in-stent, in-segment, proximal and distal MLD postnitrate at baseline, 12 months, 24 months and at 36 months

o In-scaffold/in-stent, in-segment, proximal and distal % diameter stenosis (DS) postnitrate at baseline, 12 months, 24 months and at 36 months

o In-scaffold/in-stent, in segment, proximal and distal angiographic binary restenosis rate postnitrate at 12 months, 24 months and at 36 months

Secondary outcome

nvt

Study description

Background summary

Based on previous studies on the ABSORB BVS, the scaffold received C.E. mark in December 2010 and is since then
commercially available (n Europe. Since this release there is lot of discuss ion whether bifurcation lesions, with a sidebranch of >2mm, can be treated with ABSORB BVS in the same way as with metallic stents. This discussion is mainly driven by the fact that lesions with a sidebranch of 2mm ware excluded trom previous trials, some observational data has been presented, however no expert consensus exist about the use of ABSORB BVS in bifurcation lesions. The use of bioresorbable vascullar scaffold in coronary bifurcation lesions could have substantial advantages compared to metallic stent, it could prevent permanent obstruction of a side branch after resorption of the struts in front of a sidebranch.
To increase insight in the use of the ABSORB BVS in coronary bifurcation lesions we will perform a a randomised study between ABSORB BVS and Xience metallic stent in coronary bifurcation lesions and asses the fate of the struts in front of the sidebranch in patient with or without fenestation towards the sidebranch with intravascular imaging (optical coherence tomography).

Study objective

Primary Objective:
To compare the fate of the struts in front of the side-branch and intimal bridge formation using optical coherence tomography after treatment with the bioresorbable everolimus eluting vascular scaffold of coronary bifurcation lesions with and without side-branch fenestration.

Secondary Objectives:
To compare the angiographic result in the side-branch ostium after treatment of the main branch with the bioresorbable everolimus eluting vascular scaffold 1. with and 2. without fenestration and post-dilatation of the side-branch.

Study design

Prospective, randomized (1:1), international, multicenter, evaluation of consecutive patients undergoing an elective percutaneous coronary intervention in (a) coronary bifurcation lesion(s) with ABSORB BVS placement. This study involves the collection of baseline demographic, clinical, angiographic and optical coherence tomography data, as well as angiographic and optical coherence tomography follow-up data.

Intervention

Intervention of interest is either fenestration or no fenestration of the stent towards the sidebranch.

Study burden and risks

Patients will undergo an OCT pullback after stent placement, to allow this pullback a wire will be placed in the coronary artery.The risk of a wire is a dissection of the coronary artery of spasm of the artery, this occurs in 2-3% of the patients. Very severe complications, like a myocardial infarction, stroke or death occur in les than 0.1% of the patients (1:1000). These complications occur mostly in patients known with severe cardiac conditions, we expect no severe complications in our study given the fact that we will not include patients with severe cardiac illnesses.

The coronaryangiography after 12 or 24 or 36 months there is also a small risk of bleeding, especcially at the access site of the guiding catheter (wrist or groin).

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

o Subject has a bifurcation lesion involving a side-branch larger than 2 mm and having main branch involvement (Medina 0,0,1 lesions are excluded)
o Subject must agree to undergo all clinical investigation plan-required follow-up visits and to undergo follow-up angiography and optical coherence tomography
o Subject is able to verbally confirm understanding and he/she or his/her legally authorized representative provides written informed consent prior to any Clinical Investigation related procedure,as approved by the appropriate Ethics Committee.

Exclusion criteria

o Subject is younger than 18 years of age
o Subject is presenting with a STEMI
o Subject has a true bifurcation lesion where a priori two scaffold/stent strategy is planned.
o Subject has known hypersensitivity or contraindication to aspirin, both heparin and bivalirudin, antiplatelet medication specified for use in the study (clopidogrel, prasugrel and ticagrelor, inclusive), everolimus, poly (L-lactide), poly (DL-lactide), cobalt, chromium, nickel, tungsten, acrylic and fluoro polymers or contrast sensitivity that cannot be adequately pre-medicated.
o Known renal insufficiency (eg. estimated Glomerular Filtration Rate (eGFR) <60mL/min/1.73m2 or serum creatinine level of >2.5mg/dL or subject on dialysis)
o Subject with a limited life expectancy less than one year.
o Subject is belonging to a vulnerable population (per investigator*s , e.g., subordinate hospital staff) or subject unable to read or write.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-03-2016
Enrollment:	26
Type:	Actual

Medical products/devices used

Generic name:	Optical Coherence Tomography (OCT)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	22-03-2016
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	NL50172.018.14