Amsterdam Investigator-initiated Absorb trial the bifurcation strategy

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Primary Objective: To compare the fate of the struts in front of the side-branch and intimal bridge formation after treatment with optical coherence tomography between the bioresorbable everolimus eluting vascular scaffold and XIENCE family…

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

Summary

ID

NL-OMON41341

Source
ToetsingOnline

Brief title
AIDA bifurcation strategy

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: Ministerie van OC&W

Intervention

Keyword: Bifurcation, Bioresorbable Vascular Scaffold, Optical Coherence Tomography, Xience drug-eluting stent

Outcome measures

Primary outcome

o Incomplete strut apposition in the bifurcation region at 25 months

Secondary outcome

OCT endpoints

o Incomplete strut apposition in the bifurcation region at baseline

o Number of embedded and protruded struts per region at baseline and 25 months

o Incomplete strut coverage in the bifurcation region at 25 months

o Number of jailed side branch struts (2D-OCT) at baseline and at 25 months

o Tissue in-between non-apposed side branch struts at 25 months

o Number of jailed side branch struts (3D-OCT) at baseline and at 25 months; V,

T, H, double V, double T, and double H.

o Mean/Minimal Lumen diameter/area at baseline and 25 months

o Mean/Minimal Stent/Scaffold diameter/area at baseline and 25 months

o Neointima thickness in the bifurcation region at 25 months

o Scaffold pattern irregularities at baseline and 25 months

Angiographic endpoints

o In-segment Late Loss (LL) postnitrate at 25 months

o Proximal LL postnitrate at 25 months

o Distal LL postnitrate at 25 months

o In-scaffold/in-stent, in-segment, proximal and distal MLD postnitrate at

baseline and at 25 months

o In-scaffold/in-stent, in-segment, proximal and distal % diameter stenosis

(DS) postnitrate at baseline and at 25 months

o Proximal 5mm SB% diameter stenosis (DS) postnitrate at baseline and at 25

months

o In-scaffold/in-stent, in-segment, proximal and distal angiographic binary

restenosis rate postnitrate at 25 months

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 in Europe. Since this release there is lot of discussion 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 were excluded from 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 assess 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 after treatment with optical coherence tomography between the bioresorbable everolimus eluting vascular scaffold and XIENCE family everolimus

eluting coronary stent system in the treatment of (a) coronary bifurcation lesion(s) with and without side-branch fenestration.

Secondary Objective:
To compare the angiographic result between the bioresorbable everolimus eluting vascular scaffold and XIENCE family everolimus eluting coronary stent system in the treatment of (a) coronary bifurcation lesion(s) with and without side-branch fenestration.

Study design

The AIDA bifurcation strategy study is a substudy of the Amsterdam Investigator-intiateD ABSORB all-comers trial (AIDA). This study is a prospective, randomized (1:1) evaluation of consecutive patients undergoing PCI in (a) coronary bifurcation lesion(s) participating in the AIDA trial. Patients will first be randomized according the AIDA protocol (ABSORB BVS vs Xience Family DES), hereafter a second randomization will be performed to either side-branch fenestration

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 complication 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 coronary angiography after 25 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 is enrolled in the Amsterdam Investigator-InitiateD Absorb strategy trial
o Subject has a bifurcation lesion involving a side-branch greater than 2 mm (excluding Medina class 0,0,1 where the is no main-branch involvement)
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 known hypersensitivity or contraindication to contrast 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 is belonging to a vulnerable population (per investigator*s judgment, 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):	23-10-2014
Enrollment:	40
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	30-07-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-06-2015
Application type:	Amendment
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	NL47960.018.14