Amsterdam Investigator-initiateD Absorb strategy all-comers trial

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Primary Objective: To compare the strategies of treatment with 1. ABSORB everolimus eluting bioresorbable vascular scaffolds and 2. Xience everolimus eluting coronary stent system in a non-inferiority all-comers trial.

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

Summary

ID

NL-OMON41656

Source
ToetsingOnline

Brief title
AIDA 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: Ministerie van OC&W

Intervention

Keyword: ABSORB, bioresorbable vascular scaffold, randomized controlled trial, Xience drug-eluting stent

Outcome measures

Primary outcome

Composite endpoint Target Vessel Failure (TVF) at 2 years:

- Cardiac death

- Myocardial infarction (MI) according to Third Universal Myocardial Infarction

definitions (unless clearly attributable to a nontarget vessel)

- Target Vessel revascularization

Secondary outcome

Acute success

o Device success: Successful delivery and deployment of the first study

scaffold/stent the intended target lesion and successful withdrawal of the

delivery system with attainment of final in-scaffold/stent residual stenosis of

less than 20% by QCA and TIMI 3 flow grade of the treated vessel.

o Procedural success: Achievement of final in-scaffold/stent residual stenosis

of less than 20% by QCA and TIMI 3 flow grade of the treated vessel with

successful delivery and deployment of at least one study scaffold/stent at the

intended target lesion and successful withdrawal of the delivery system for all

target lesions without the occurrence of cardiac death, target vessel MI or

repeat TLR during the hospital stay.

Clinical endpoints (adjudicated)

o Scaffold/Stent Thrombosis according to ARC definitions (acute, subacute, and late/definite and probable) at 30 days, 1, 2, 3, 4 and 5 years follow-up.

o Target lesion failure (Device-oriented endpoint) according to ARC definitions (cardiac death, MI (not clearly attributable to a nontarget vessel), target lesion revascularization) at 30 days, 1, 2, 3, 4 and 5 years follow-up

o All coronary revascularizations

o Major adverse cardiac events (Patient-oriented composite) according to ARC definitions (all-cause mortality, any MI, any repeat revascularization) at 30 days, 1, 2, 3, 4 and 5 years follow-up.

o Individual clinical endpoints according to ARC definitions (at 30 days, 1, 2, 3, 4 and 5 years follow-up).

Components:

- Death (Cardiac, Vascular, Non-Cardiovascular)

- Myocardial Infarction (Q-wave MI and non Q-wave MI/Target vessel MI and non-target vessel MI)

- Target Lesion Revascularization (TLR):

- Target Vessel Revascularization (TVR)

- Non-Target Vessel Revascularization (NTVR)

Study description

Background summary

The ABSORB everolimus eluting bioresorbable vascular scaffold (BVS) is composed of the polymer poly (L-lactide) (PLLA) backbone which is expected to be fully absorbed in 18 to 24 months. Previous registry studies on the ABSORB BVS showed MACE rates and late lumen losses comparible with the contemporary third

generation drug-eluting stents, which are considered as the standard of care in our institution. Currently, a randomized controlled trial comparing ABSORB BVS with the Xience drug-eluting metallic stent is running, the ABSORB II. In this trial, however, only subject with a small range of stent sizes and relatively simple lesion complexity in an elective setting were included. Therefore, a study is needed in which also patients with lesions with more complexity and in the acute setting should be included and compared with a contemporary drug-eluting stent. We will perform a randomised controlled trial in which we will compare the ABSORB BVS with the Xience drug-eluting metallic stent in an all-comer patients population

Study objective

Primary Objective: To compare the strategies of treatment with 1. ABSORB everolimus eluting bioresorbable vascular scaffolds and 2. Xience everolimus eluting coronary stent system in a non-inferiority all-comers trial.

Study design

Prospective, randomized (1:1), active control, single blinded, single-center, all-comers, non-inferiority trial comparing ABSORB BVS strategy with XIENCE family strategy.

Intervention

The Index Strategy is:
Abbott Vascular ABSORB Everolimus Eluting Bioresorbable Vascular Scaffold strategy (referred to as ABSORB BVS)

The control strategy is:

In the course of the study all repeat interventions will be done with the index strategy device up to 5 years.

Study burden and risks

Since two strategies will be compared which are both practised in daily clinical practice and in both strategies CE-marked devices will be used, we consider all PCI-related risk and burdens not to be related with participation in this study. Potential benefits of being randomised to Xience could be that with Xience there is extensive experience and the design of the stent in combination with its Everolimus drug results in low restenosis rates. The potential benefit of being randomised to ABSORB BVS is that it will be absorbed in 18 to 24 months so there will be no foreign body left behind for the rest of patient's life. Another potential burden for the patient is that he will be

called 7 times in total.

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 an acceptable candidate for treatment with a drug-eluting stent in accordance with the applicable guidelines on percutaneous coronary interventions and the Instructions for Use of the ABSORB BVS strategy and XIENCE family.
o Subject is able to verbally confirm understanding of risks, benefits and treatment alternatives of receiving the ABSORB BVS strategy and he/sheprovides written or in the event of STEMI oral 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 has a true bifurcation lesion where a priori two scaffold/stent strategy is planned.
o Unsuccessful predilation of one or more of the planned lesion to be treated.
o Planned treatment of in-stent restenosis of a previously placed metallic stent.
o Subject has one or more lesion planned to be treated with a scaffold/stent diameter size smaller than 2.5 mm or greater than 4.0 mm.
o Subject has one or more lesion planned to be treated with a stent/scaffold length greater than 70 mm and/or overlapping of four or more scaffolds/stents.
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 Subjects pregnant or nursing subjects and those who plan pregnancy in the period up to 2 years following index procedure. (Female subjects of child-bearing potential must have a negative pregnancy test done within 28 days prior to the index procedure and contraception must be used during participation in this trial)
o Subjects with a limited life expectancy less than one year.
o Subjects with factors that impede clinical follow-up (e.g. no fixed abode).
o Subject is already participating in another clinical investigation that has not yet reached its primary endpoint.
o Subject is belonging to a vulnerable population (per investigator*s judgment, e.g., subordinate hospital staff or sponsor 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)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-08-2013
Enrollment:	1790
Type:	Actual

Medical products/devices used

Generic name:	ABSORB Bioresorbable Vascular Scaffold
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	10-04-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-03-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	17-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-12-2016
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
ClinicalTrials.gov	NCT01858077
CCMO	NL43867.018.13