Comparison of the ABSORB TM Everolimus Eluting Bioresorbable Vascular Scaffold System With a Drug-Eluting Metal Stent (XienceTM) in Acute ST-Elevation Myocardial Infarction

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

Summary

ID

NL-OMON40503

Source
ToetsingOnline

Brief title
ABSORB STEMI: the TROFI II Study

Condition

- Myocardial disorders

Synonym
Infarction due to closure of coronary arteries with ECG changes., ST Elevation Myocardial Infarction

Research involving
Human

Sponsors and support

Primary sponsor: ECRI B.V.
Source(s) of monetary or material Support: Abbott,ECRI-3 - European Cardiovascular Research Institute 3,Terumo

Intervention

Keyword: Bioabsorbable, Neointimal Healing Score, OFDI, STEMI

Outcome measures

Primary outcome

1. Presence of filling defect (%ILD) is assigned weight of *4*,

2. Presence of both malapposed and uncovered struts (%MN) is assigned a weight

of *3*,

3. Presence of uncovered struts alone (%N) is assigned a weight of *2* and

finally,

4. Presence of malapposition alone (%M) is assigned a weight of *1*.

Secondary outcome

Clinical Endpoints (in-hospital/post-procedure, at 1 and 6 months and yearly up

to 3 years follow-up)

* Procedure success (no in-hospital DoCE).

* Device-oriented Composite Endpoints at 1 month and 6 months and annually to 3

years and its individual components. (Device-oriented Composite Endpoint (DoCE)

is defined as cardiac death, MI not clearly attributable to a non-intervention

vessel, and clinically-indicated target lesion revascularization)

* All-cause death at all timepoints

* Any MI at all timepoints

* Non ischemia-driven target lesion revascularization TLR at al timepoints

* Ischemia-driven and non ischemia-driven target vessel revascularization (TVR) at all timepoints

* Scaffold/Stent thrombosis according to ARC definition at all timepoints.

* Angina class at all timepoints

* Other SAEs at all timepoints.

Imaging Endpoints

* Angiographic endpoints (pre- and post-procedure and at 6 months)

o Percent diameter stenosis (%DS) at; in-segment, in-device, proximal and distal

o Minimal lumen diameter (MLD) at; in-segment, in-device, proximal and distal

o Lumen Loss (LL); in-segment, in-device, proximal and distal

o Angiographic binary restenosis (ABR) at; in-segment, in-device, proximal and distal

* OFDI Endpoints (6 months)

o All individual components of the Healing Score at 6 months;

o Mean/minimal scaffold/stent diameter/area/volume at 6 months;

o Mean/minimal lumen diameter/area/volume at 6 months;

o Incomplete strut apposition (ISA) area/volume at 6 months;

o Percentage of covered struts at 6 months;

o Mean/maximal thickness of the struts coverage at 6 months;

o Neointimal hyperplasia area/volume at 6 months;

o Mean Flow area/volume at 6 months;

o Intraluminal defect area/ volume at 6 months;

o Thickness of neointimal tissue developed over lipid rich plaque at 6 months

(*research project*).

Study description

Background summary

We hypothesize that acutely and at intermediate follow-up (i.e. 6 months) implantation of the ABSORB fully bioresorbable everolimus-eluting scaffold is at least as safe as implantation of metallic drug-eluting stent, and that at late follow-up the ABSORB scaffold could improve the arterial healing process and potentially reduce late stent thrombosis in patients presenting with STEMI. Since the previous ABSORB trials as well as ongoing trials only include stable patients with simple lesions, the polymeric device has not been prospectively investigated in patients presenting with STEMI. The purpose of this study is therefore to test the feasibility of the everolimus-eluting bioresorbable scaffold implantation in STEMI and to assess the healing process documented on OFDI 6 months after implantation.

Study objective

The primary objective of this study is to assess the neointimal healing score (as evaluated by intra-coronary OFDI) in patients with STEMI and treated with Abbott Vascular ABSORB everolimus eluting bioresorbable vascular scaffold (BVS) at 6 months follow-up by comparing with a metallic drug eluting stent (XIENCE).

Study design

This is a prospective, randomized, active control, single-blind, non-inferiority, European multi-center clinical trial. Approximately 190 subjects will be registered at up to 8-10 European sites. Subjects will be followed for 3 years.

All eligible patients (STEMI <24 hours from onset of chest pain) will be randomized to
* Abbott Vascular ABSORBTM everolimus eluting bioresorbable vascular scaffold system (BVS) or
* XIENCE Everolimus Eluting Coronary Stent System (XIENCE Xpedition)

All patients will undergo optical frequency domain imaging (OFDI) investigation of the culprit lesion at 6 months follow-up.

Intervention

All eligible patients (STEMI <24 hours from onset of chest pain) will be randomized to
* Abbott Vascular ABSORBTM everolimus eluting bioresorbable vascular scaffold system (BVS) or
* XIENCE Everolimus Eluting Coronary Stent System (XIENCE Xpedition)

All patients will undergo optical frequency domain imaging (OFDI) investigation of the culprit lesion at 6 months follow-up.

Study burden and risks

There is extensive clinical and commercial experience worldwide with cardiac catheterization and interventional procedures and it is expected that the procedural risks in this study and existing stenting procedure will not be significantly different.

Potential benefits of study device:
1. Decrease of late ischemic adverse events
Complete biodegradation of stent struts prevents the risk of thrombus formation at sites of impaired endothelialization and may reduce the risk of very late stent thrombosis
2. Restoration of vascular biology during follow-up. Normalization of vasomotion and compensatory remodeling were observed following implantation of BVS suggesting restoration of normal vessel physiology after complete biodegradation of the stent struts. Culprit lesions of STEMI patients are frequently localized in the proximal segments of the coronary artery tree. Restoration of physiological vasomotion may therefore have a greater impact in patients with STEMI as compared to patients with stable coronary artery disease.
3. No interference with diagnostic or therapeutic measures in case of disease progression As the scaffold disappears, non-invasive diagnostic imaging is not hampered by the presence of metallic stents. In case of a progression of a coronary artery disease, no foreign body material will limit the selection of the distal anastomosis of coronary artery bypass grafts.
4. Improved vascular healing after stent implantation into vulnerable plaques
The vulnerable plaque composition in STEMI lesions interferes with vascular healing after metallic stent implantation 13, and may lead to coronary evagination formation or late acquired malapposition, features which have been correlated with adverse ischemic outcomes. Complete biodegradation of the scaffold may reduce long-term stent related adverse events.
5. Discontinuation of longterm antiplatelet therapy in patients with single-vessel coronary artery disease Patients with STEMI often present with single-vessel coronary artery disease and would eventually not necessitate long-term antiplatelet therapy. Following the implantation of a metallic DES, lifelong antiplatelet therapy is recommended because of the presence of a

foreign body. With the assurance of a completely resorbable scaffold, discontinuation of antiplatelet therapy after 1-2 years may result in decreased rates of bleeding events.

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. Primary PCI within 24 hours of symptom onset;
3. ST-segment elevation of > 1mm in > 2 contiguous leads, or (presumably new) left bundle branch block, or true posterior MI with ST depression of >1mm in >2 contiguous anterior leads;
4. Presence of at least one acute infarct artery target vessel with one or more coronary artery stenoses in a native coronary artery within planned device deployment segment (Dmax) by

visual estimation of * 2.5 mm and * 3.8 mm;
5. Subject agrees to not participate in any other investigational or invasive clinical study for a period of 6 months following the index procedure.

Exclusion criteria

1. Inability to provide informed consent;
2. Known pregnancy at time of randomization. Female who is breastfeeding at time of randomization;
3. Known intolerance to aspirin, heparin, PLLA, everolimus, contrast material;
4. Cardiogenic Shock;
5. Unprotected left main coronary artery stenosis;
6. Distal occlusion of target vessel;
7. Acute myocardial infarction secondary to stent thrombosis;
8. Mechanical complications of acute myocardial infarction;
9. Severe tortuous, calcified or angulated coronary anatomy of the study vessel that in the opinion of the investigator would result in sub-optimal imaging or excessive risk of complication from placement of an OFDI catheter;
10. Fibrinolysis prior to PCI;
11. Active bleeding or coagulopathy or patients at chronic anticoagulation therapy;
12. Subject is currently participating in another clinical trial that has not yet completed its primary endpoint.

Study design

Design

Study phase:	4
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):	15-04-2014
Enrollment:	64
Type:	Actual

Ethics review

Approved WMO Date:	03-03-2014
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	26-05-2014
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NCT01986803
CCMO	NL46160.099.13