Performance of bioresorbarble scaffold in primary percutaneous intervention of ST elevation myocardial infarct

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Study goal is to compare the performance of the Absorb bioresorbable scaffold with a metallic drug eltuting stent in the STEMI patient.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON43286

Source
ToetsingOnline

Brief title
BVS in STEMI

Condition

- Coronary artery disorders

Synonym
coronary artery disase. myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Helse Bergen ,St. Jude Medical

Intervention

Keyword: BVS, OCT, STEMI

Outcome measures

Primary outcome

Minimum flow area by OCT after 12 months

Secondary outcome

OCT endpoints

1. Area stenosis

2. Lumen late loss

3. Crushed stent segments

4. Malapposition of stent struts

5. Minimum expansion of the stents expressed as absolute area and percentage of

the closest reference area,

6. Vessel ostial stent area (acute and at FU)

7. Thrombus burden

Angiographic endpoints

1.TIMI flow pre and post PCI,

2.Blush grade

3.Thrombus burden

4. Angiographic complications

5. Contrast use

6. Procedure time

7. Radiation skin dose

Clinical endpoints

Index admission:

1. Total death

2. Cardiac death

3. Non-index procedure myocardial infarction

4. Stent thrombosis (definite and probable)

5. TLR and TVR

6. non-TVR

Follow up:

1. Total death

2. Cardiac death

3. Non-index procedure myocardial infarction

4. Stent thrombosis (definite and probarble)

5. TLR and TVR

6. non-TVR

7. CCS angina class

8. Vascular cerebral events

9. Admissions for congestive heart failure or arrhythmia

Study description

Background summary

In patients presenting with myocardial infarct with ST elevation, Primary percutaneous coronary intervention (PCI) is the preferred treatment (ESC guidelines recommendation I A). Stenting has I A recommendation, and preferably with drug eluting stents (DES) in patients who are likely to be

compliant to dual antiplatelet therapy (DAPT) and are not at an increased bleeding risk (II A recommendation). Thrombus aspiration with specialized catheter has an equally strong II A recommendation[1]. Thrombus aspiration followed by direct stenting without any further balloon dilatation has been shown to give better 1 year survival. Metallic drug eluting stents are being challenged by new stents made from biodegradable platforms. The Absorb BVS (Abbott Vascular, Santa Clara, CA) is the first of these being commercially available in Norway. The second-generation Absorb BVS is a balloon-expandable device consisting of a polymer backbone of poly-L-lactide (PLLA) coated with a thin layer of a 1:1 mixture of an amorphous matrix of poly-D, L-lactide (PDLLA) polymer and 100 *g/cm2 of the antiproliferative drug everolimus. Two platinum markers located at each Absorb BVS edge allow for accurate visualization of the radiolucent Absorb BVS during angiography or other imaging modalities. The PDLLA controls the release of everolimus, 80% of which is eluted within the first 30 days. Both PLLA and PDLLA are fully bioresorbable. The polymers are degraded via hydrolysis of the ester bonds, and the resulting lactate and its oligomers are quickly transformed to pyruvate and metabolized in the Krebs energy cycle. Small particles, less than 2 *m in diameter, have also been shown to be phagocytized and degraded by macrophages. According to preclinical studies, the time for complete bioresorption of the polymer backbone is 2 to 3 years. It has been proven to be safe and non-inferior to metallic everolimus stents in the ABSORB II, cohort B trial [7, 8]. The bioresorbable scaffold has obvious advantages over metallic, as it will not hinder any future revascularization. However there are concerns regarding the strength of the scaffold. It is therefore recommended with more rigorous lesion preparation, using balloons for predilatation. Currently only one small study has been published studying specifically BVS in STEMI patients. This study is not randomized and does not address the issue of predilatation.

Study objective

Study goal is to compare the performance of the Absorb bioresorbable scaffold with a metallic drug eltuting stent in the STEMI patient.

Study design

The study is a prospective, randomized, controlled, non-blinded, single center study comparing metallic drug eluting stent with bioresorbable scaffold in STEMI patients. Primary endpoint is minimum flow area (MinFA) measured by OCT after 12 months.

Intervention

Randomization between Xience metallic stent and bioresorbable scaffold

Study burden and risks

The additional risk of complications from using the OCT catheter is very low. There is a small change that the catheter will cause a dissection, 1 at 1000 patients. Usually this will heal by itself without further invasive actions, sometimes another stent needs to be placed to close this dissection. The risk of death, cerebrovascular accident or myocardial infarction is expected to be similar to an angiography without OCT measurements. Furthermore patients will be asked to undergo an extra angiography after 2 years with additional OCTmeasurements, this is an extra burden for the patient. After this follow-up, there are no additional visits or examines for this substudy.

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) History of chest pain < 12 hrs

2) ST elevation of * 2 mm in *2 contiguous precordial leads (V1-V6), and/or * 1 mm in * 2 contiguous standard leads (I, II, III, aVf, aVr,aVl).
3) Clinical decision to treat with primary PCI
4) > 18 years
5) Oral informed consent

Exclusion criteria

1) Contraindications to long term DAPT
2) Known kidney failure with GFR < 45
3) Cardiac arrest or severe cardiogenic shock (Persistent BP <90 mmHg, despite adequate treatment)
4) Other severe illness with life expectancy of less than 12 months (eg. malignancy, severe malnutrition, degenerative disease);Procedural contra-indications:
1) Heavy calcification, tortuous vessel or large side branch (> 2,5 mm) at culprit lesion.
2) TIMI 0-1 flow after aspiration
3) Unable to advance thrombus aspiration catheter

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	ABSORB bioresorbable Vascular Scaffold

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-09-2016
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	NL57201.018.16