BVS Calcified: Eighteen months Angiographic and Clinical Follow up of Everolimus eluting bioresorbable vascular scaffold in calcified lesions.

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Primary Objective: The objectives of this study are to assess lumen, scaffold, vessel dimension, malapposition and tissue coverage as assessed by quantitative angiography, intravascular optical coherence tomography and intravascular ultrasound...

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

Summary

ID

NL-OMON42286

Source
ToetsingOnline

Brief title
BVS Calcified

Condition

- Coronary artery disorders

Synonym
Calcified lesion

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bioresorbable vascular scaffold (BVS), Calcified, Coronary artery disease, Follow up, Invasive Imaging

Outcome measures

Primary outcome

The primary parameters for our study are: the scaffold apposition, the strut

coverage, the lumen enlargement, the late lumen loss, the mean and minimum

lumen scaffold area, the stent area and the vessel area.

Secondary outcome

Secondary parameters are clinical outcomes including death, myocardial

infarction, target lesion revascularization and scaffold thrombosis.

Study description

Background summary

Until now, the Absorb bioresorbale vascular scaffold (BVS) was mainly used in non-complex coronary lesions. Little is known about the performance of these scaffolds in calcified lesions.
A calcified lesion is one of the predictors of stent malposition and can preclude late stent thrombosis. There is not much literature about invasive follow up in calcified lesions.

Therefore, for the subgroup of patients with more complex calcified coronary lesions we would like to further investigate scaffold apposition and scaffold performance after BVS placement by, instead of a CT-scan, performing angiography with invasive imaging using both OCT and IVUS at eighteen months post-procedure. Using these techniques, we can superiorly evaluate the scaffold in the calcified lesions since evaluation of calcified lesions by multislice CT are limited due to the blooming artifact.

Study objective

Primary Objective:
The objectives of this study are to assess lumen, scaffold, vessel dimension, malapposition and tissue coverage as assessed by quantitative angiography, intravascular optical coherence tomography and intravascular ultrasound imaging 18 months after implantation of the ABSORB everolimus eluting scaffold in calcified lesions.

Secondary Objective:
The secondary objective of the present investigation is the evaluation of clinical outcomes including death, myocardial infarction, target lesion revascularization and scaffold thrombosis after implantation of the Absorb BVS in calcified lesions.

Study design

We will conduct a single center, single arm, investigator-driven cohort study aiming to evaluate status of the BVS in calcified lesions using invasive coronary imaging 18 months post index procedure.

We will include a total of 30 patients who received BVS in calcified lesion(s) during the index procedure. Patients had to present with NSTEMI, stable or unstable angina or silent ischemia caused by de novo stenotic, calcified lesion(s) in a native previous untreated coronary artery. The investigated subjects will undergo coronary artery catheterization with OCT and IVUS at eighteen months post procedure. There will be clinical follow-up at 30 days, 6 months, 1 year, 18 months and 2, 3, 4, 5 years.

Study burden and risks

Patients will ondergo invasive imaging met OCT and IVUS eightteen months after their indexPCI. Rate of major complications using IVUS/ OCT are low. The risk associated with this study is the standard risk of a diagnostic coronary angiogram with the use of an intravascular imaging catheter and the risk of major complications is reported to be inferior to 2%.
The potential benefit for the patients will be an accurate follow-up 18-months after an index PCI allowing the investigation of the status of the implanted device and the investigation of the possible progression of the atherosclerotic disease.

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

*To be eligible for this study the subject has to be treated for a de novo stenotic, moderate - severely calcified coronary lesion with the BVS in the Erasmus MC and be included in the BVS Expand Registry
*Patient is able to verbally confirm understanding of risks, benefits of the BVS calcified study and he/ she or his/ hers legally authorized representative provides written consent informed consent prior to any clinical investigation related procedure, as approves by the appropriate Ethics Committee of the respective clinical site
*18 years and above

Exclusion criteria

- Previous CABG
- Cardiogenic shock
- Known hypersensitivity or contra-indication to treatment with heparin or contrast that cannot be adequately pre-medicated
- Known renal insufficiency (Creatinine clearance <60ml/min)
- Female patient with child bearing potential not taking adequate contraceptives or currently

breastfeeding
- Expected survival < 1 year
- Age < 18 years
- STEMI patients requiring immediate stent implantation
- Known left ventricular ejection fraction < 30%

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	08-06-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL49407.078.15