Vascular Response to Everolimus-eluting Bioresorbable Vascular Scaffold Implantation in patients with Diabetes Mellitus

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The primary objective of the present study is the evaluation of the vascular healing process in patients with diabetes mellitus treated with BVS implantation for NSTEMI, stable or unstable angina, or silent ischemia. The healing process will be...

Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON38428

Source
ToetsingOnline

Brief title
BVS-DM First

Condition

- Coronary artery disorders

Synonym
angina pectoris, coronary sclerosis

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 scaffold, Coronair sclerose, Diabetes Mellitus, PCI

Outcome measures

Primary outcome

The primary endpoint is the evaluation of the scaffold coverage at 6-month

follow-up by invasive coronary imaging with Optical Coherence Tomography.

Secondary outcome

Secondary objectives of the present investigation include OCT, QCA, NIRS

imaging (baseline and 6 month) and clinical endpoints (until 5 years follow-up)

Study description

Background summary

The everolimus eluting bioresorbable vascular scaffold (BVS) demonstrated excellent safety and performance for treatment of coronary artery disease, however, the vascular healing response following implantation of this device in high-risk patients, in particular patients with diabetes mellitus, has not been evaluated

Study objective

The primary objective of the present study is the evaluation of the vascular healing process in patients with diabetes mellitus treated with BVS implantation for NSTEMI, stable or unstable angina, or silent ischemia. The healing process will be assessed evaluating BVS coverage 6 months post-implantation by intravascular Optical Coherence Tomography.

Study design

A single centre, single arm investigator-initiated observational pilot cohort study

Study burden and risks

The procedure of coronary angiography with the additional use of OCT and NIRS imaging can be considered a standard procedure with a very low risk of major complications (0.4%). The mechanism of action and the safety of the OCT and NIRS imaging catheters are very well known. The OCT and NIRS imaging systems are both catheter-based technologies producing ultra-high resolution, cross-sectional, intravascular images from backscattered infrared light-signals. A relevant amount of data has been produced on the use of the OCT and NIRS imaging modalities in human coronary arteries. Very high feasibility and safety of these techniques are consistently reported. No effect on the local tissue or on other organs-systems has been observed.
In addition, patients with a previous coronary syndrome are at high risk of recurrence of cardiovascular events, therefore to perform a coronary angiogram with additional intracoronary imaging pre, post and 6 months post-scaffold implantation could be of additional benefit as it could allow the evaluation of the early (pre- and post-procedure) and longer-term (6 months) effects of scaffold implantation and it could allow the early detection of a progression of the coronary atherosclerotic disease (6 months imaging).

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. Patient is at least 18 years of age.
2. Patient is know with diabetes mellitus
3. Patient presenting with NSTEMI, stable or unstable angina , or silent ischemia caused by a de novo stenotic lesion in a native previous untreated coronary artery
4. Dmax (proximal and distal mean lumen diameter) within the upper limit of 3.8 mm and the lower limit of 2.0 mm by online QCA (at the moment only for the 2.5 mm and 3.5 mm devices)
5. The patient understands and accepts the meaning and the aims of the study
6. The patient is willing to comply with specified follow-up evaluation and can be contacted by telephone (Signed Informed Consent)

Exclusion criteria

1. Previous CABG
2. Cardiogenic shock
3. STEMI patients requiring immediate stent implantation
4. Bifurcation lesion requiring kissing balloon postdilatation
5. Allergies or contraindications to antiplatelet medication or contrast material
6. Female patient with child bearing potential not taking adequate contraceptives or currently breasfeeding
7. Expected survival of < 1 year

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2013
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Date:	14-01-2014
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	NL45678.078.13