Six-Month Clinical and Angiographic Follow up of Everolimus eluting bioresorbable vascular scaffold in patients presenting with ST-segment elevation myocardial infarction

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The primary objective of the present study is the evaluation of the vascular healing process in patients previously treated with BVS implantation for ST-segment elevation myocardial infarction (STEMI). The healing process will be assessed evaluating...

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

Summary

ID

NL-OMON40314

Source
ToetsingOnline

Brief title
BVS-STEMI

Condition

- Coronary artery disorders

Synonym
stent couverage, strut apposition

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: Angiography, Bioabsorbable scaffold, Myocardial infarction, Optical Coherence Tomography

Outcome measures

Primary outcome

The primary endpoint will be the evaluation of the healing process defined as

scaffold apposition and coverage at 6-month follow-up by invasive coronary

imaging with Optical Coherence Tomography.

Secondary outcome

The secondary OCT objective is the serial assessment of strut apposition from

baseline to 6-month follow-up in a subgroup of patients where an OCT study has

been performed at baseline, as clinically indicated.

Study description

Background summary

Everolimus eluting vascular scaffold (BVS) showed excellent safety and performance for treatment of coronary artery disease, however the vascular healing process following implantation of this device has been evaluated only in stable patients.

Study objective

The primary objective of the present study is the evaluation of the vascular healing process in patients previously treated with BVS implantation for ST-segment elevation myocardial infarction (STEMI). The healing process will be assessed evaluating BVS apposition and coverage at 6 months after implantation using intravascular Optical Coherence Tomography.

Among 50 patients, a subgroup (n=30) will be exclusively comprised by patients who had undergone OCT imaging at baseline, as indicated for clinical reasons.

Study design

A single centre, single arm investigator-driven pilot cohort study

Study burden and risks

The procedure of coronary angiography with the additional use of OCT can be considered a standard procedure with a very low risk of major complications (<2%). The mechanism of action and the safety of the OCT catheter are very well known. OCT is a catheter-based technology 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 imaging modality in human coronary arteries. Very high feasibility and safety of this technique were consistently reported. No effect on the local tissue or on other organs-systems has been observed.
In addition patients with a previous acute coronary syndrome are at high risk of cardiovascular events recurrence, therefore to perform a coronary angiogram at 6-month after a myocardial infarction could be of additional benefit for this patients as it could allow the early detection of a progression of the coronary 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

1. Patient is at least 18 years of age.
2. Patient has been treated, within the previous 6 month, with BVS for primary PCI .
3. For the pre-specified subgroup of 30 patients, an OCT study of the treated culprit lesion after BVS implantation should be available for analysis.
4. Treated target lesion must be a de-novo lesion located in a native vessel.
5. Signed Informed Consent.
6. The patient understands and accepts the meaning and the aims of the study

Exclusion criteria

1. Pregnancy.
2. Known intolerance to contrast material.
3. Known thrombocytopenia (PLT< 100,000/mm3).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	13-08-2013
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	22-07-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-04-2014
Application type:	Amendment
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	NL44619.078.13