Pre-emptive, OCT guided angioplasty of vulnerable, intermediate coronary lesions: a randomized trial, the ‘PECTUS’ Trial

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26010

Source
Nationaal Trial Register

Brief title
PECTUS

Health condition

Coronary artery disease; vulnerable plaque

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: Abbott Vascular, St. Jude Medical

Intervention

Outcome measures

Primary outcome

A composite of major adverse cardiovascular events (all cause mortality, non-fatal

myocardial infarction (STEMI or NSTEMI), or unplanned revascularization) at one year follow-up

Secondary outcome

The same composite at 2 and 5 years

Study description

Study objective

Stenting with a bioabsorbable vascular scaffold of intermediate, vulnerable coronary lesions in patients with residual non-obstructive CAD after myocardial infarction will prevent future Major Adverse Cardiac Events (MACE)

Study design

1, 2 and 5 years

Intervention

After inclusion, patients will undergo coronary CT and OCT to determine if the residual stenosis is vulnerable. In case of vulnerable plaques at OCT, patients will be randomized to PCI with BVS placement or to conservative (optimal medical) therapy.

Contacts

Public
Department of Cardiology, VU University
de Boelelaan 1117
Niels Royen, van
Amsterdam 1081 HV
The Netherlands
+31 (0)20 4442244
Scientific
Department of Cardiology, VU University
de Boelelaan 1117
Niels Royen, van
Amsterdam 1081 HV
The Netherlands
+31 (0)20 4442244

Eligibility criteria

Inclusion criteria

· Informed consent must be obtained

· Patients with STEMI or NSTEMI and residual, non-obstructive CAD, with the possibility of plaque vulnerability.

· The coronary lesion must be suitable for PCI with a commercially available BVS.

Exclusion criteria

· Refusal or inability to provide informed consent.

· < 18 years of age

· Previous CABG.

· Indication for revascularization by CABG.

· Target vessel diameter < 2,5 mm or >4.0 mm

· Anatomy or lesions unsuitable for OCT catheter crossing or imaging (aorta-ostial lesions, small diameter segment, severe calcifications)

· Anatomy unsuitable for BVS placement (left main, bifurcation stenting, sidebranch (> 2 mm) involvement).

· Target lesion is instent restenosis

· Target lesion is chronic total occlusion

· Severe kidney disease defined as an eGFR < 30 ml/min.

· Pregnancy.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-03-2016
Enrollment:	500
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-12-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43561
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4177
NTR-old	NTR5590
CCMO	NL55011.029.15
OMON	NL-OMON43561

Study results