Pre-emptive, OCT guided angioplasty of vulnerable, intermediate coronary lesions: a randomized trial

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To determine the effect of the stenting of intermediate, vulnerable coronary lesions on the prevention of future ACS, in patients with residual non-obstructive CAD after PCI for myocardial infarction.

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

Summary

ID

NL-OMON43561

Source
ToetsingOnline

Brief title
the PECTUS trial

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Atherosclerosis, vulnerable plaque

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Abbott,Abbott Vascular en St Jude

Medical,St. Jude Medical

Intervention

Keyword: BVS, OCT, Stenting, Vulnerable plaque

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 primary outcome at 2 and 5 year follow up

Study description

Background summary

Recently, major advances in the treatment of acute coronary syndromes have been made, but still there is a large proportion of patients at risk for new coronary events after experiencing ACS. In addition to medical treatment, detection of residual vulnerable plaques after ACS and local treatment by means of coronary intervention can further reduce adverse cardiac events in this group of unstable patients.

Study objective

To determine the effect of the stenting of intermediate, vulnerable coronary lesions on the prevention of future ACS, in patients with residual non-obstructive CAD after PCI for myocardial infarction.

Study design

This is a multi center, randomized clinical trial. After PCI for myocardial infarction patients with residual, hemodynamically non-obstructive plaque will be analysed for vulnerability by means of CCTA (optional) and OCT. Patients with vulnerable coronary segments on OCT wil be randomized to biovascular

scaffold (BVS) placement or medical treatment.

Intervention

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

Study burden and risks

Patients included in the trial will undergo coronary CTA, unless there are logistical or clinical issues hindering the use of CTA. If CTA shows features of plaque vulnerability or if CTA is not performed, patients will undergo FFR. After FFR (if there is a hemodynamically important stenosis, patients will undergo PCI according to the guidelines), OCT will be performed to confirm plaque vulnerability. If this is the case, half of these patients will undergo PCI with BVS placement. Thus patients will be admitted to the hospital for 1-2 days and exposed to radiation (CTA and ICA), the risks of intracoronary imaging and possibly to PCI. Extra bloodsamples will be taken after informed consent and when patients are randomised to intervention extra bloodsamples will be taken after PCI. Patients will be followed by telephonic follow-up at 1, 2 and 5 years for 10 minutes. Furthermore, the first 25 randomized patients will be followed by telephonic contact after 30 days (±7 days). Risk/benefit: expected benefit is a reduction in major adverse cardiac events, at the cost of an expected low amount of procedure related complications.

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

- patients with acute myocardial infarction 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.
- Target lesion in the same vessel as the treated culprit lesion
- Target lesion in the same segment as a previously implanted stent/scaffold
- Estimated life expectancy < 1 year

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-03-2016
Enrollment:	1000
Type:	Actual

Medical products/devices used

Generic name:	Absorb GT1 stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	03-02-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-05-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-01-2017
Application type:	Amendment
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

ID: 26010
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL55011.029.15
OMON	NL-OMON26010