Identification of risk factors for acute coronary events by Optical Coherence Tomography after STEMI and NSTEMI in patients with residual non-flow limiting lesions: the PECTUS-obs Trial (observational cohort)

Published: 10-12-2018
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To assess the clinical outcome in NSTEMI and STEMI patients with vulnerable plaque characteristics in non-culprit vessels as assessed by OCT.

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

Summary

ID

NL-OMON48078

Source
ToetsingOnline

Brief title
the PECTUS-obs trial

Condition

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

Synonym
Atherosclerosis, vulnerable plaque

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Abbot Vascular en St Jude Medical,Abbott,St. Jude Medical

Intervention

Keyword: OCT, 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 2 year follow-up.

Secondary outcome

The primary outcome at 1 and 5 year follow-up. Also target lesion/vessel

failure and target lesion/vessel revascularisation at 1,2, and 5 years.

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. These new events can be largely attributed to residual vulnerable lesions. Possible detection of vulnerable lesions by means of OCT imaging may help to determine which lesions need additional treatment in order to reduce adverse cardiac events.

Study objective

To assess the clinical outcome in NSTEMI and STEMI patients with vulnerable plaque characteristics in non-culprit vessels as assessed by OCT.

Study design

This is a multicenter, prospective cohort, clinical trial. After PCI for myocardial infarction (STEMI or NSTEMI), patients with residual, hemodynamically non-obstructive plaque will be analyzed for plaque morphology and vulnerability by means of OCT. Structured clinical follow-up will be performed at 1, 2 and 5 years. Primary analysis wil be performed at 2 years follow-up.

Study burden and risks

Patiënts included in the trial will undergo OCT imaging to assess plaque morphology and vulnerability. Patients are exposed to radiation as part of the invasive coronary angiography and fractional flow reserve (FFR) measurement which is clinically indicated. The procedural risks of intracoronary imaging are below 1%. An extra blood sample will be taken. Patient will be followed by telephonic follow-up, 3 times during the study, which will take about 10 minutes each. The expected benefit is a structured clnical follow-up at 1, 2 and 5 years.

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

Inclusion criteria for the main trial:
- Informed consent must be obtained.
- Patients are hospitalized with a STEMI or NSTEMI (or have been in the last 6 weeks), for which they are subjected to invasive coronary angiography.
- Invasive coronary angiography shows residual non-culprit CAD (target lesion(s))
- Patient has >= 1 target lesion(s) on angiography with following additional characteristics:
- Lesion has visual stenosis of 30-90%.
- Lesion is non-obstructive (FFR>0.80).
- Lesion is not in-stent restenosis.

Inclusion criteria for the registry:
Inclusion criteria for the registry are the same as for the main trial, except:
- All target lesions are obstructive (FFR<=0.80).

Exclusion criteria

- Refusal or inability to provide informed consent.
- < 18 years of age
- Hemodynamic instability, respiratory failure, or Killip class >= 3 at time of inclusion.
- Previous CABG.
- Indication for revascularization by CABG.
- Anatomy of target lesion(s) unsuitable for OCT catheter crossing or imaging (aorta-ostial lesions, too small diameter segment, severe calcifications, chronic total occlusion, lesions located to distally)
- Pregnancy.
- Estimated life expectancy < 3 year

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-12-2018
Enrollment:	329
Type:	Actual

Ethics review

Approved WMO Date:	10-12-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-08-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-11-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-11-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-10-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
ClinicalTrials.gov	NCT03857971
CCMO	NL67426.091.18