Intravascular Ultrasound Guidance for Complex High-Risk Indicated Procedures

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To assess the superiority of an IVUS-guided approach versus a qualitative angio-guided approach in patients with complex coronary lesions undergoing PCI.

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

Summary

ID

NL-OMON54377

Source
ToetsingOnline

Brief title
IVUS-CHIP

Condition

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

Synonym
Narrowed or blocked blood vessels

Research involving
Human

Sponsors and support

Primary sponsor: European Cardiovascular Research Institute
Source(s) of monetary or material Support: Boston Scientific Cooperation International,ECRI-14 non profit organisatie

Intervention

Keyword: angiography, cardiology, IVUS, Percutaneous coronary intervention

Outcome measures

Primary outcome

Primary endpoint:

Target-vessel failure defined as a composite of cardiac death, target vessel myocardial infarction*, or clinically indicated target-vessel revascularization

*ARC-2 1; 4th universal definition for spontaneous (>48 hours) MI 2.

Secondary outcome

Secondary endpoints:

1. Composite of target-vessel myocardial infarction and clinically indicated target vessel revascularization

2. Clinically-indicated target vessel revascularization

3. Composite of cardiac death and target-vessel myocardial infarction

4. Target-Lesion Failure (TLF) defined as a composite of cardiac death, target vessel myocardial infarction, or clinically indicated target-lesion revascularization

5. Target-lesion revascularization

6. Cardiac death

Study description

Background summary

The use of intravascular ultrasound (IVUS) during PCI is suggested to give better results than angiographic guided PCI. Clinical trials to confirm a

clinical benefit of IVUS and further define for which patients this method would be most beneficial have not yet been performed. The purpose of this trial is to collect this information for patients with complex coronary lesions

Study objective

To assess the superiority of an IVUS-guided approach versus a qualitative angio-guided approach in patients with complex coronary lesions undergoing PCI.

Study design

The IVUS CHIP trial is a randomized, controlled, multicenter, international, event-driven, post-marketing study. A total of 2020 participants will be randomized in a 1:1 fashion to IVUS-guided PCI versus qualitative angio-guided PCI, stratified by site. Patients will be consented prior to the PCI procedure and then followed up to 2 years after the index procedure.

Intervention

IVUS-guided approach in patients with complex coronary lesions undergoing PCI.

Study burden and risks

No risk outside of standard of care, possible benefits as listed in E1b.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. The patient must be >=18 years of age
2. Patients with an indication for PCI of at least one lesion satisfying any of the following criteria:
a. Angiographic heavy calcification
b. Ostial lesions
c. True bifurcation lesions involving side-branches >2.5mm
d. Left main lesions
e. Chronic total occlusion
f. In-stent restenosis
g. Long-lesions (estimated stent length > 28mm)
OR
Patient with an indication for PCI for any lesion and in need for elective mechanical circulatory support assisted PCI
3. Presenting with silent ischemia, stable angina, unstable angina or recent non-ST-elevation acute coronary syndrome (NSTE-ACS)
4. All lesions must be suitable for treatment with the Synergy stent system, Synergy Megatron system, or other Synergy platform iteration
5. The patient is willing and able to cooperate with study procedures and follow-up until study completion
6. Subject is able to confirm understanding of risks, benefits and treatment alternatives and he/she provides informed consent prior to any protocol-related procedure, as approved by the appropriate Ethics Committee

Exclusion criteria

1. ST-elevation myocardial infarction, cardiogenic shock
2. Known untreated severe valvular heart disease
3. Known contraindication or hypersensitivity to everolimus, platinum-chromium, or to anticoagulants
4. Absolute contraindications or allergy that cannot be pre-medicated, to iodinated contrast or to antiplatelet drugs, including both aspirin and P2Y12 inhibitors

5. Non-cardiac co-morbidities with a life expectancy less than 1 year
6. Currently participating in another trial that is not yet at its primary endpoint. The patient is not allowed to participate in another investigational device or drug study for at least 12 months after enrollment and may only be enrolled once in the study
7. Women of childbearing potential who do not have a negative pregnancy test within 7 days before the procedure and women who are breastfeeding
8. Subject belongs to a vulnerable population (per investigator*s judgment) or subject unable to read or write

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-11-2021
Enrollment:	620
Type:	Actual

Medical products/devices used

Generic name:	Opticross IVUS catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	29-10-2021

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-08-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-09-2024
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
ClinicalTrials.gov	NCT04854070
CCMO	NL76019.078.21