DEBuT-LRP study: Intravascular Identification and Drug-Eluting Balloon Treatment of Vulnerable Lipid-Rich Plaques

Published: 21-12-2020
Last updated: 08-04-2024

To determine the change in plaque characteristics after treatment with DEB of additional LRPs, as measured by IVUS / NIRS, in ACS patients.

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

Summary

ID

NL-OMON54017

Source
ToetsingOnline

Brief title
DEBuT-LRP

Condition

- Coronary artery disorders

Synonym
myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Academisch Medisch

Centrum,B.Braun Melsungen,Infraredx

Intervention

Keyword: Drug-eluting balloon, Lipid-rich plaques, Near-infrared spectroscopy

Outcome measures

Primary outcome

The difference in LCBImm4 between baseline and 9 months in DEB-treated LRPs

Secondary outcome

• The change in lipid-core burden index in a 4 mm segment (LCBImm4) as measured with IVUS + NIRS from baseline to 9 month follow-up in identified additional LRPs that are not treated with DEB.

• Flow-limiting dissection necessitating bail-out stent implantation;

• Periprocedural myocardial infarction;

• LRP lesion failure, defined as cardiac death, myocardial infarction, or ischemia-driven revascularization related to an identified non-culprit LRP lesion up to one-year follow-up;

• Patient-oriented composite outcomes, defined as all-cause mortality, myocardial infarction, or any repeat revascularization up to one-year follow-up;

• Additional IVUS + NIRS lesion characteristics (plaque volume, minimal lumen area).

Study description

Background summary

Two thirds of the intracoronary thrombi that cause acute coronary syndrome (ACS) result from the rupture of lipid-rich plaques (LRP). After treatment of

the culprit in ACS patients, additional LRPs are found in approximately 50% of patients. Near-infrared spectroscopy (NIRS) in combination with intracoronary ultrasound (IVUS) can identify these vulnerable plaques during coronary angiography (CAG) and is able to assess plaque characteristics and the lipid core burden index in a segment of 4 mm (LCBImm4). It is currently unknown whether treatment of LRPs results in plaque stabilization, possibly reducing the number of subsequent ACS. Previous imaging and animal studies have shown that paclitaxel has a stabilizing effect on plaques with a possible reduction in lipid content.
We hypothesize that LRPs can be treated with balloons coated with paclitaxel (i.e., drug-eluting balloons; DEB) to provide a selective pharmacotherapeutic treatment to arrest the local atherosclerotic process.

Study objective

To determine the change in plaque characteristics after treatment with DEB of additional LRPs, as measured by IVUS / NIRS, in ACS patients.

Study design

Prospective single-arm clinical trial

Intervention

DEB-treatment of LRP, as detected with IVUS/NIRS

Study burden and risks

Patients participating in this study are exposed to extra measurements during their primary intervention for ACS, a possible DEB treatment, and an extra coronary angiography after 9 months.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9

Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patient has an acute coronary syndrome without ST-segment elevation on the ECG (NSTE-ACS), includingnon-ST-elevation myocardial infarction and unstable angina pectoris.
2. An invasive revascularization strategy for NSTE-ACS with PCI is chosen.

Exclusion criteria

Angiographic exclusion criteria:
1. Previous coronary artery bypass-grafting;
2. A chronic total occlusion is present;
3. Too many (complex) coronary lesions requiring staged PCI procedure(s);
4. Procedural complication of the index PCI;

Clinical exclusion criteria:
5. Unstable patients (the presence of cardiogenic shock, need for intubation, need for inotropes);
6. Patients with ST-segment elevations on the ECG requiring immediate primary PCI;
7. Body weight > 250 kg;
8. Known renal insufficiency (estimated Glomerular Filtration Rate [eGFR] <30 mL/min/1.73m2 or subject on dialysis);
9. Hypersensitivity or allergy to contrast with inability to properly pre-hydrate;
10. Presence of a comorbid condition with a life expectancy of less than one

year;
11. Participation in another trial;
12. Subject is belonging to a vulnerable population (per investigator*s judgment, e.g., subordinate hospital staff) or is unable to read or write.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-01-2021
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	drug-eluting balloon
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-12-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-03-2022
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

No registrations found.

In other registers

Register	ID
CCMO	NL75566.018.20