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

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1. To determine the change in plaque characteristics of non-culprit LRPs, as measured with IVUS/NIRS, after treatment with DEB in patients with ACS.2. To develop a non-invasive algorithm that is able to detect LRPs with CT.

Ethical review	Not approved
Status	Will not start
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON49521

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: Computed tomography coronary angiography, Drug-eluting balloon, Lipid-rich plaques, Near-infrared spectroscopy

Outcome measures

Primary outcome

The difference in LCBImm4 between baseline and 9 months

Secondary outcome

* Changes in plaque volume and characteristics of LRPs treated with DEB

measured by CTCA at 9-month follow-up, as compared to baseline;

* Changes in perivascular fat as measured by CTCA at 9-month follow-up, as

compared to baseline;

* 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);

* Correlation of vulnerable plaque characteristics on CTCA with IVUS + NIRS at

9-months follow-up.

Study description

Background summary

Two-thirds of intracoronary thrombi causing acute coronary syndrome (ACS) result from rupture of lipid-rich plaques (LRP). After treatment of the culprit lesion in ACS patients, additional LRPs are found in approximately 50% of patients. Near infrared spectroscopy (NIRS) combined 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 4mm segment (LCBImm4). Computed tomography coronary angiography (CTCA) may be an alternative, non-invasive method to detect vulnerable plaques. This additional imaging technique, combined with artificial intelligence-based analysis, could contribute to earlier detection and treatment of LRPs, providing reduced disease burden, and generate insight into the underlying pathogenesis. It is currently unknown whether treatment of LRPs leads to plaque stabilization, potentially reducing the number of subsequent ACS. We hypothesize that LRPs can be treated with balloons coated with an antiproliferative drug (i.e. drug-eluting balloons; DEB) to deliver both mechanical and selective pharmacotherapeutic treatment to halt the local atherosclerotic process.

Study objective

1. To determine the change in plaque characteristics of non-culprit LRPs, as measured with IVUS/NIRS, after treatment with DEB in patients with ACS.
2. To develop a non-invasive algorithm that is able to detect LRPs with CT.

Study design

Prospective single-arm clinical trial

Intervention

If an LRP is detected with IVUS/NIRS, these are treated with DEB

Study burden and risks

Patients participating in this study are exposed to extra measurements during their primary intervention for ACS, as well as an extra coronary angiography after 9 months. Moreover, patients undergo CTCA at baseline and 9 months.

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

1. Patient has an acute coronary syndrome without ST-segment elevation on the ECG (NSTE-ACS), including non-ST-elevation myocardial infarction and unstable angina pectoris.
2. An invasive revascularization strategy for NSTE-ACS with PCI is chosen.
3. The coronary arteries are open and patent on CTCA, thus feasible to scan all major coronary arteries with IVUS/NIRS.

Exclusion criteria

Angiographic exclusion criteria:
1. Patient has additional lesions that cannot be treated during the index PCI

and need staged PCI;
2. A chronic total occlusion is present;
3. Previous coronary artery bypass-grafting;
4. Patient has a major procedural complication of the index PCI (coronary perforation, coronary dissection);

Clinical exclusion criteria:
5. Irregular heart rhythm, affecting the CT quality (i.e. atrial fibrillation or frequent premature ventricular contractions);
6. Technical aspects hampering appropriate CT assessment (i.e. the presence of extreme calcifications or extreme tortuosity);
7. Unstable patients (the presence of cardiogenic shock, need for intubation, need for inotropes);
8. Patients with ST-segment elevations on the ECG requiring immediate primary PCI;
9. Body weight > 250 kg;
10. Known renal insufficiency (estimated Glomerular Filtration Rate [eGFR] <30 mL/min/1.73m2 or subject on dialysis);
11. Hypersensitivity or allergy to contrast with inability to properly pre-hydrate;
12. Presence of a comorbid condition with a life expectancy of less than one year;
13. Participation in another trial;
14. 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:	Will not start
Enrollment:	40

Type:	Anticipated

Medical products/devices used

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

Ethics review

Not approved
Date:	01-10-2020
Application type:	First submission
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	NL73933.018.20