EXpansion of stents after Intravascular lithoTripsy versus conventional predilatation in CALCified coronary arteries

Published: 15-04-2020
Last updated: 17-01-2025

To compare stent expansion after plaque modification by IVL or balloon predilation in severely calcified coronary lesions assessed by optical coherence tomography (OCT).

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

Summary

ID

NL-OMON49291

Source
ToetsingOnline

Brief title
EXIT-CALC

Condition

- Coronary artery disorders
- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Coronary atherosclerosis, heart artery calcification

Research involving
Human

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: OLVG

Intervention

Keyword: Coronary atherosclerosis, Intravascular lithotripsy, Optical coherence tomography

Outcome measures

Primary outcome

Stent expansion measured by OCT

Secondary outcome

1. Periprocedural and in-hospital complications

a. Coronary dissection type D-F,

b. Coronary perforation,

c. Periprocedural infarction (Troponin T rise of >5 times ULN, or a 20%

increase if already elevated but stable or falling); assessment if indicated

2. MACE at 1 month, 1- and 2-year FU, comprised of death, myocardial

infarction, or target-lesion revascularization and each of its individual

components

3. Stent thrombosis according the ARC criteria: defined as

a. Definite or confirmed stent thrombosis: Angiographic confirmation of vessel

occlusion or thrombus formation within, or adjacent to, the stented segment or

proven stent thrombosis at autopsy.

b. Probable stent thrombosis: Unexplained death within 30 days or target vessel

recurrent MI without angiographic confirmation.

c. Possible stent thrombosis: Unexplained death after 30 days.

Study description

Background summary

In percutaneous coronary intervention (PCI), severe coronary artery calcification is associated with stent underexpansion, which is an independent predictor for future adverse cardiac events. Intravascular lithotripsy (IVL) is a promising modality for plaque modification that may improve stent expansion.

Study objective

To compare stent expansion after plaque modification by IVL or balloon predilation in severely calcified coronary lesions assessed by optical coherence tomography (OCT).

Study design

Prospective, randomized pilot study

Intervention

IVL or balloon dilatation, followed by stenting with DES in all patients

Study burden and risks

The burden for this study is negligible. Indication for treatment by PCI is already set before inclusion in the study. Available data on IVL have shown no additional risks are associated with this device. No *new* or developmental techniques are used. Follow-up is by telephone, no extra visits nor associated costs are necessary.

Contacts

Public
OLVG

Oosterpark 9
Amsterdam 1091AC
NL
Scientific
OLVG

Oosterpark 9
Amsterdam 1091AC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Age >= 18 years
2. An indication for PCI of a calcified lesion in an native coronary artery
3. Main OCT criterium is a calcification score of 4 defined as maximum calcium angle of >180 degrees, maximum calcium thickness >0.5mm, and a minimal calcium length of 5mm, as measured at the target lesion
4. Written informed consent with agreement of follow-up visits.
5. Eligible for PCI with a target vessel reference diameter between 2.5 and 4.0 mm (by visual estimation).

Exclusion criteria

1. Severe congestive heart failure, severe heart failure NYHA IV
2. ST-elevation myocardial infarction as indication for PCI
3. Severe renal impairment with a glomerular filtration rate of <30ml/min/1.73m2
4. Lesion related exclusion criteria
5. Stent occlusion / restenosis
6. OCT images not fulfilling inclusion criteria
7. Inability to cross the lesion with an OCT catheter
8. Large side branch (>2.0mm) originating from the target lesion
9. Contraindication for dual antiplatelet therapy.
10. Recent history of major bleeding, hematologic disease and/or platelet count < 100.000 per 1 mm3
11. Planned major surgery within 3 months after the procedure.

12. Participation in another clinical study, interfering with this protocol.
13. The inability to provide written informed consent.
14. Expected life expectancy of less than two years.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-06-2020
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	15-04-2020
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	NL72279.018.20

Study results

Results posted: 11-09-2023

First publication
01-02-2023