Drug-COated Balloon Coronary Angioplasty versus Stenting for Treatment of Disease Adjacent to a Chronic Total Occlusion - The Co-CTO Trial.

Published: 25-05-2021
Last updated: 07-02-2025

The aim of the study is to investigate the value of DCB treatment in the residual disease of the coronary artery after successful recanalization and stenting of the actual CTO body as compared with complete stenting in a randomized fashion.

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

Summary

ID

NL-OMON51074

Source
ToetsingOnline

Brief title
The Co-CTO trial

Condition

- Coronary artery disorders

Synonym
arteriosclerosis, coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Boston Scientific Cooperation International,Boston Scientific Corporation

Intervention

Keyword: Chronic Total Occlusion, Drug-coated balloon, Drug-eluting stent, Randomized controlled trial

Outcome measures

Primary outcome

The primary objective is to investigate percentage diameter stenosis at 1-year follow-up as assessed by intravascular ultrasound (IVUS) in patients successfully treated with PCI CTO randomized to stenting of the CTO body in conjunction with DCB of residual disease compared to stenting of residual disease adjacent to the CTO body.

Secondary outcome

Secondary invasive imaging objectives are minimal lumen diameter, late luminal loss, in-segment binary restenosis, and target vessel re-occlusion at 1-year follow-up. Secondary clinical objectives are evaluation of the occurrence of major adverse cardiac events (MACE) at 1-year follow-up.

Study description

Background summary

Chronic total coronary occlusions (CTO) are documented in approximately 20% of diagnostic coronary angiograms. New developments such as retrograde approach and dissection re-entry techniques have resulted in more widespread application of percutaneous coronary intervention (PCI) of CTOs, and this technique now serves as a viable alternative to optimal medical therapy alone or coronary

artery bypass surgery. In general, PCI CTO is accompanied by extensive stenting of the coronary artery beyond the original occlusive segment itself. Unfortunately, stent length and diameter are directly related to poorer outcome, which is related to an increased rate of in-stent restenosis and thrombosis. An alternative to stenting is the application of drug-coated balloons (DCB). This strategy may prove beneficial, as it could significantly reduce stent length, among other things. However, data on the use of DCBs in the context of PCI CTO are currently lacking.

Study objective

The aim of the study is to investigate the value of DCB treatment in the residual disease of the coronary artery after successful recanalization and stenting of the actual CTO body as compared with complete stenting in a randomized fashion.

Study design

This is an investigator-initiated, randomized, single-blind (patients will be masked), multi-center, non-inferiority clinical trial.
Patients with a CTO who are eligible for PCI will be randomized in a 1:1 ratio to additional DCB treatment or stenting of residual disease.

Intervention

After inclusion, patients will be randomized (1:1) to additional DCB treatment or stenting of residual disease.

Study burden and risks

All patients included in the trial will have a clinical indication for percutaneous revascularization. Since there are no randomized controlled trials which advocate the use of either DES or DCB over one another in this setting, patients will not be exposed to extra risk due to randomization in the trial. Contemporary native vessel PCI is associated with low in-hospital events rates, i.e. in-hospital mortality of 0.9%, vascular complication in 0.7%, procedural complications in 4.7% and bleeding requiring transfusion in 3.3%.
All patients will undergo coronary angiography after 1 year follow-up and will thus be exposed to the risks of invasive coronary angiography. Coronary angiography is characterized by a low complication rate (<0.5%) of e.g. bleeding, stroke, coronary dissection, myocardial infarction, or death (<0.1%). Radiation exposure of a repeat coronary angiography is estimated at 5-10 mSv.

Patients participating in the CCTA substudy will be exposed to an effective dose equivalent ~2.1 mSv. Impact CT Dosimetry software package version 1.04 was used to calculate the radiation dosage. Furthermore, ionized contrast agents

will be used during CCTA, which can be nefrotoxic and may elicit allergic reactions.

Expected benefit of this study:
A DCB facilitated minimal stenting strategy for treatment of chronic total occlusions may significantly reduce stent length, number of used stents, as well as compression of the distal lumen with undersized stents and consequently may avoid potential late detrimental complications of a permanent metallic cage. However, data on the use of DCBs in the context of PCI CTO are currently lacking. This trial could influence current guidelines on the application of DCBs in CTO procedures, and facilitate its use in patients with high bleeding risk.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Age >= 18 years
• Clinical indication for revascularization of the CTO as determined by the local heart team (based on symptoms, documented ischemia, and viability)
• Successful recanalization of the CTO with residual disease adjacent to the initial lesion

Exclusion criteria

• Dissection affecting the flow (TIMI score <3), significant recoil (>30%) or coronary perforation after predilation
• Reference diameter of the vessel is <2.5 mm or >4.0 mm
• Bifurcation lesion requiring the stenting of the side branch
• Left main lesion
• Acute coronary syndrome
• Cardiogenic shock
• Severe kidney disease defined as an eGFR < 30 ml/min
• Pregnancy
• Life expectancy < 12 months
• Inability to give written consent

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	17-06-2021
Enrollment:	144
Type:	Actual

Medical products/devices used

Generic name:	(1) Agent paclitaxel drug-coated balloons. (2) Synergy everolimus-eluting platinum chromium coronary
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-05-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-11-2024
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	NL75646.029.20