Drug-Coated Balloons versus Drug-Eluting Stents for Treatment of De-Novo Coronary Artery Lesions in Patients with Stable Coronary Artery Disease - the COATED Trial.

Published: 06-09-2022
Last updated: 19-04-2025

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

Summary

ID

NL-OMON51852

Source
ToetsingOnline

Brief title
The COATED 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: Top Medical BV

Intervention

Keyword: Drug-coated balloon, Drug-eluting stent, Randomized controlled trial, Stable coronary artery disease

Outcome measures

Primary outcome

The primary objective is to investigate percentage diameter stenosis at 1-year follow-up as assessed by coronary angiography in patients with a single de-novo lesion in a native coronary artery successfully treated with DCB as compared to treated with DES.

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

Stenting has significantly reduced the need for revascularization procedures as compared to plain old balloon angioplasty. Additionally, drug-eluting stents (DES) have significantly decreased in-stent restenosis compared to bare-metal stents and its use is recommended in current guidelines. Nevertheless, using DES carries te risk of in-stent restenosis and stent thrombosis, and requires the use of dual antiplatelet therapy during an extensive period of time. With the use of drug-coated balloons (DCB), all these problems can be either avoided or attenuated, while maintaining the anti-proliferative properties of DES.

However, data on the use of DCB for treatment in a general population of patients with stable coronary artery disease (CAD) is currently lacking.

Study objective

The aim of the study is to investigate the value of DCB treatment of single de-novo coronary artery lesions in patients with stable coronary artery disease, as compared to treatment with DES in a randomized fashion.

Study design

This is an investigator-initiated, randomized,open-label, single-center, non-inferiority clinical trial. Patients with a single de-novo lesion in a native coronary artery and accepted for percutaneous intervention (PCI) will be randomized in a 1:1 ratio to treatment with DCB or DES. Patients in DES group receive DAPT for 6 months (clopidogrel + aspirin), followed by life-long treatment with a single platelet inhibitor (aspirin). Patients in DCB group receive DAPT for 3 months, followed by life-long treatment with a single platelet inhibitor.

Intervention

After inclusion, patients will be randomized (1:1) to treatment with DCB or DES. Patients in DES group receive DAPT for 6 months (clopidogrel + aspirin), followed by life-long treatment with a single platelet inhibitor (aspirin). Patients in DCB group receive DAPT for 3 months, followed by life-long treatment with a single platelet inhibitor.

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:
Using DCB for the treatment of single de novo coronary artery lesions may obviate the use of DES, and therefore reduce the risk on in-stent restenosis and stent thrombosis and shorten the use of dual antiplatelet therapy. However, data on the use of DCB for treatment in a general population of patients with stable coronary artery disease is currently lacking. This trial could provide this data and therefore influence current guidelines on the application of DCBs in patients with stable coronary artery disease.

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

• Age >= 18 years

• Stable angina or dyspnea and the presence of a single de-novo lesion in a native coronary artery causing myocardial ischemia, eligible for PCI based on a formal local heart team decision
• Reference diameter of the vessel is 2.5-4.0 mm
• The lesion is suitable for both treatment with DCB and DES

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 a two-stent technique
• In-stent restenosis
• Unprotected left main lesion
• Chronic total occlusion
• Acute cononary 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:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2025

Enrollment:	230
Type:	Anticipated

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:	06-09-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-03-2025
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	NL80988.029.22