Sirolimus-coated balloon versus drug-eluting stent in native coronary vessels

Published: 07-07-2022
Last updated: 08-02-2025

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

Summary

ID

NL-OMON54209

Source
ToetsingOnline

Brief title
TRANSFORM II

Condition

- Coronary artery disorders

Synonym
Coronary artery disease, stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Fondazione Ricerca e Innovazione Cardiovascolare, No profit organization
Source(s) of monetary or material Support: Nonprofit organization: Fondazione Ricerca e Innovazione Cardiovascolare ETS.

Intervention

Keyword: DCB, Everolimus, Sirolimus, Stent

Outcome measures

Primary outcome

To verify the non-inferiority of Magic Touch SCB hypothesized in target lesion failure (TLF), a composite of cardiac death, ischemia-driven target-lesion revascularization (TLR), target vessel myocardial infarction (MI), at 12 months.

Secondary outcome

-cardiac death;

-all-cause death;

-Q-wave MI;

-any MI;

-TLR;

-target vessel revascularization;

-vessel thrombosis;

-bleedings following BARC classification.

Study description

Background summary

Treatment of lesions allocated in small or mid-sized coronary vessels still represents a challenge for interventional cardiologists and remains an independent predictor for angiographic restenosis, even after the introduction of drug-eluting stents (DES). Several studies have demonstrated the good clinical outcomes of DES, in this particular setting. however even the latest generations of DES are still associated with a higher

incidence of restenosis, vessel thrombosis and myocardial infarction in this setting; without reaching a plateau of adverse events. Lately drug-coated balloons (DCB) have emerged as an attractive alternative for the treatment of coronary de-novo lesions. In the last years, several new generation DCB have been developed, with the aim of improving the trackability and deliverability of these devices, along with an improvement of drug release, especially in tortuous and small vessels. Until 2016, only paclitaxel-eluting DCB were marketed, due to the specific lipophilic
properties of paclitaxel, that render this drug particularly appealing for local delivery.

However, currently available DES all elute sirolimus or analogue drugs (the so called "- limus" class) due to the improved outcome shown when compared to paclitaxel-eluting stents, that were abandoned almost a decade ago due to reduced efficacy and increased thrombotic risk. Despite no specific issues were raised for currently available paclitaxel-eluting DCB used for coronary applications, sirolimus has well recognized
antiproliferative properties and a wider therapeutic window. The main issue with this drug delivered locally without prosthesis implantation is related to its intrinsic lower lipophilia (thus, the ability of penetrating into tissues), that could hamper its ability to exert local antirestenotic effects.

In 2016, the first sirolimus-coated DCB obtained the CE mark and was marketed in Europe and Asia (Magic Touch, Concept Medical, FL, USA); this balloon elutes sirolimus, a powerful cell growth-inhibitory drug, characterized by a low lipophilicity. This device has been studies in several lesion settings till date, but not by means of a study adequately powered for clinical endpoints.

Study objective

To observe and evaluate the efficacy, of Magic Touch SCB compared to one of the gold standard treatment for native vessel disease, (everolimus-eluting stent, EES).

The main OCT subanalysis endpoints are:
- Acute mean and minimum lumen cross-sectional area (CSA) gain between pre- and post-PCI in the SCB and DES groups;
- Late mean and minimum lumen CSA loss from post-PCI to 9 months;
- Change in lumen area stenosis across all timepoints (pre-PCI, post-PCI, and 9 months)
- A series of detailed analyses aiming to evaluate the extension and severity of balloon and stent-induced vascular injury will be performed

Study design

International, multicentric, prospective, investigator-driven, open-label,

randomized (1:1) clinical trial.

Intervention

The included patients will undergo a Percutaneous Coronary Intervention (PCI) with either Magic Touch Sirolimus Coated Balloon or an Everolimus-eluting stent

Study burden and risks

Generally, all patients will receive a higher degree of telephone and clinical follow-up than he/she would outside of the study environment and have a dedicated clinical study team following his/her progress. It is hoped that through this study, information gained on the safety and efficacy of the devices used will help in the management of future patients with similar conditions.

The complications associated with the use of the SCB are the same associated to any intervention of coronary angioplasty (with or without stent) during the first hours after intervention: occlusion of the vessel with the need for new intervention; risk of coronary perforation; risk of spontaneous bleeding or bleeding from the vascular access, or related to the concomitant use of anti-thrombotic drugs; damage to other vessels from the catheter transit and/or arterial thrombosis; allergic reaction to the iodinated contrast medium; contrast induced nephropathy.

The long-term risks are potentially lower with DCB than with DES: with such devices there is no risk of late or very late stent thrombosis; the shorter duration of dual antiplatelet therapy (usually 1 month) can reduce the risk of bleeding events compared with a duration of 6-12 months with the drug-eluting stent; the risk of a new PCI, because of restenosis, is instead comparable to that of drug-eluting stents, but lower compared to bare-metal stents. The absence of exclusion criteria regaring the sickness of the patient (need for surgery, anemia, high bleeding risk) may render this study unique in assessing the role of DCB vs DES in such populations

Contacts

Public
Fondazione Ricerca e Innovazione Cardiovascolare, No profit organization

Lodi, via Sollecito Arisi 14
Lodi 26900
IT
Scientific

Fondazione Ricerca e Innovazione Cardiovascolare, No profit organization

Lodi, via Sollecito Arisi 14
Lodi 26900
IT

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

age >18 years; -all patients with a clinical indication to PCI (stable coronary arterydisease or acute coronary syndromes); -native coronary artery lesion in a vessel with diameter >2.0 mm and *3.5 mm at visual estimation; - maximum lesion lenght: 50 mm. - informed consent to participate in the study

Exclusion criteria

target lesion/vessel with any of the following characteristics: - concomitant PCI at the same vessel with any device (vessels are considered: left anterior descending, circumflex or right coronary artery); - pre-dilatation of the target lesion not performed or not successful (residual stenosis >30%); - severe calcification of the target vessel, at lesion site but also proximally; - highly tortuous vessel which could impair device delivery to the lesion site following Investigator*s judgement; - previous stent implantation at target vessel (left anterior descending artery; circumflex artery; right coronary artery); - bifurcation lesion where side branch treatment is anticipated; - left main stem stenosis >50%; - target lesion is in left main stem. -Lesion is located within asaphenous vein graft

Study design

Design

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):	17-11-2022
Enrollment:	315
Type:	Actual

Medical products/devices used

Generic name:	Magic Touch
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-07-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-07-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	25-09-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-06-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT04893291
CCMO	NL78654.100.22