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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22515

Source
Nationaal Trial Register

Brief title
TRANSFORM II

Health condition

Coronary artery disease

Sponsors and support

Primary sponsor: Fondazione Ricerca e Innovazione Cardiovascolare ETS
Source(s) of monetary or material Support: Fondazione Ricerca e Innovazione Cardiovascolare ETS

Intervention

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

The hypothesis of the TRANSFORM II study is the non-inferiority of Sirolimus Coated Balloon versus Everolimus Eluting Stent in terms of Target Lesion Failure

Study design

- Visit 1 (phone) at 6 Months: Recording of medications and Adverse Events
- Visit 2 (in person) at 12 Months: Clinical Follow-up
- Visit 3 (phone) at 24 Months: Recording of medications and Adverse Events
- Visit 4 (phone) at 36 Months: Recording of medications and Adverse Events
- Visit 5 (phone) at 48 Months: Recording of medications and Adverse Events
- Visit 6 (phone) at 60 Months: Recording of medications and Adverse Events

Intervention

Percutaneous Coronary Intervention

Contacts

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Eligibility criteria

Inclusion criteria

- age >18 years;
- all patients with a clinical indication to PCI (stable coronary artery disease or acute coronary syndromes);
- native coronary artery lesion in a vessel with diameter >2.0 mm and ≦3.0 mm at visual estimation;
- maximum lesion lenght: 40 mm.

- informed consent to participate in the study.

Exclusion criteria

- patients with known (and untreatable) hypersensitivity or contraindication to aspirin, heparin, clopidogrel, prasugrel, ticagrelor, sirolimus or contrast media, which cannot be adequately pre-medicated;
- patients participating in another clinical study;
- subject is a woman who is pregnant or nursing (pregnancy test, either urine or blood test must be performed within 7 days prior to the index procedure in woman of child-bearing potential, and must not commit to initiating a pregnancy for 12 weeks after implantation, using effective contraception);
- creatinine clearance <30 ml/min;
- left ventricular ejection fraction <30%;
- life expectancy <12 months;
- ST-elevation myocardial infarction in the previous 48 hours;
- visible thrombus at lesion site;
- culprit lesion stenosis >99% and/or TIMI flow <2;
- 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-09-2021
Enrollment:	1130
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9678
Other	Medical research Ethics Committees United (MEC-U) : Will follow

Study results