A Clinical PeRformancE EVAluatIon of a new Medtronic Coronary Drug-Coated BaLloon Catheter for the treatment of De Novo Lesions, In-Stent Restenosis and Small Vessel Disease in Coronary Arteries; The PREVAIL study.

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To evaluate the clinical safety and efficacy of the Drug-Coated Balloon Catheter in the treatment of de novo lesions, small vessel disease or ISR with coronary lesions previously treated with drug-eluting or bare metal stents in native coronary...

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

Summary

ID

NL-OMON48662

Source
ToetsingOnline

Brief title
PREVAIL Study

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

coronary artery disease, coronary stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic Trading NL BV
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: Drug coated ballon catether, Pre-market study, Procedure is standard of care, Safety and efficacy

Outcome measures

Primary outcome

In-stent (in balloon) Late lumen loss (LLL) at 6 months post-procedure as measured by quantitative coronary angiography (QCA).

Secondary outcome

1. All deaths including cardiac death.

2. Target Vessel Myocardial infarction (TVMI).

3. Major adverse cardiac event (MACE) defined as composite of death, myocardial infarction (Q-wave and non Q-wave), emergent coronary bypass surgery, or repeat target lesion revascularization (clinically driven) by percutaneous or surgical methods.

4. Target vessel failure (TVF) defined as cardiac death, target vessel myocardial infarction, or clinically-driven target vessel revascularization (TVR) by percutaneous or surgical methods.

5. Target lesion failure (TLF) defined by a composite of cardiac death, target vessel myocardial infarction, or clinically-driven target lesion revascularization (TLR) by percutaneous or surgical methods.

6. All revascularizations (target lesion revascularization (TLR), target vessel revascularization (TVR) and non-TVR).

7. Stent Thrombosis rate as defined as definite, probable, possible, and overall stent thrombosis (according to Academic Research Consortium (ARC) definition).

8. Acute success (device, lesion and procedure success).

Angiographic Endpoints:

Angiographic parameters to be assessed at 6 months post-procedure including:

1. In-stent (balloon) and in-segment LLL

2. In-stent (balloon) and in-segment percent diameter stenosis (%DS).

3. In-stent (balloon) and in-segment Binary Angiographic Restenosis (BAR) rate [defined as *50% diameter stenosis (DS)].

4. In-stent (balloon) and in-segment Minimal luminal diameter (MLD).

Study description

Background summary

To evaluate the clinical safety and efficacy of a new Medtronic Coronary Drug-Coated Balloon Catheter in the treatment of de novo lesions, small vessel disease or ISR with coronary lesions previously treated with drug-eluting or bare metal stents in native coronary arteries.

Study objective

To evaluate the clinical safety and efficacy of the Drug-Coated Balloon Catheter in the treatment of de novo lesions, small vessel disease or ISR with coronary lesions previously treated with drug-eluting or bare metal stents in native coronary arteries.

Study design

This is a prospective, multicenter, single-arm study with up to 50 subjects enrolled in up to 15 qualified centers in- and outside of Europe. The enrollment period is anticipated to be approximately 8 months. Subjects will remain in the study and continue with follow-up clinical assessments through 12 months, study exit, or death, whichever comes first.

Intervention

A PTCA will be performed with the Medtronic drug-coated ballon to evaluate the safety and efficacy.

Study burden and risks

Patients may not have immediate medical benefits. The information obtained from this research may be beneficial to other patients with coronary artery disease in the future.
Since the Medtronic Coronary Drug-coated Balloon Catheter is an investigational device, the risks are not entirely known but are believed to be the similar to those that are associated with the standard, customary angioplasty with a commercially available drug-coated balloon of a stenosed coronary artery. The risks associated with using this device are related to the drug, and risks associated with standard percutaneous coronary diagnostic and treatment procedures.

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

- Subject with documented stable or unstable angina, and/or clinical evidence of ischemia
- Subject is an acceptable candidate for treatment with a Drug-Coated Coranary Balloon in accordance with the applicable guidelines on percutaneous coronary interventions, manufacturer*s Instructions for Use and the Declaration of Helsinki.
- Successful pre-dilatation of the (entire) target lesion(s) that will be treated with the investigational device. Success being documented by angiographic visual estimate of <30% residual stenosis of the target lesion and no major (> Grade B) flow-limiting dissection.
- Subject has a life expectancy >1 year in the Investigator*s opinion.
- Subject is willing and able to cooperate with study procedures and required follow up evaluations.
Angiographic Inclusion:
- The patient requires treatment of either:
A. At least a single lesion* amenable to treatment with the Medtronic Coronary Drug-Coated Balloon (* if two lesions can be treated by one Drug-Coated Balloon covering both lesions, it will be considered as a single target lesion).
OR
B. A maximum of four lesions in a maximum of 3 vessels. In case 3 vessels require to be treated, at least one should receive a non-DCB treatment, i.e. treatment with a Drug Eluting Stent (DES); this will be called a non-target lesion. Lesions (max. 3) treated with the DCB are considered target lesions.
Note: For subjects with a planned treatment of two to four lesions, the first lesion must be treated successfully and the subject must be clinically stable before treatment of the following one to three lesions are attempted. The lesion(s) in each vessel that is (/are) planned to be treated with the DES should be treated first.
- Target lesion(s) must be * 25 mm in length.
- Target lesion(s) must have a stenosis of * 50% and < 100%.
- Target lesion(s) to be treated with the investigational device must have an RVD between 2.0 and 4.0 mm in diameter.
- Target vessel(s) must have a thrombolysis in myocardial infarction (TIMI) flow * 2.
Note: Measurements may be made by careful visual estimate, on-line QCA, IVUS, or OCT

Exclusion criteria

- Known hypersensitivity or contraindication to aspirin; heparin; bivalirudin; clopidogrel; prasugrel; ticagelor and structurally related compounds; or a sensitivity to contrast media, which cannot be adequately pre-medicated.
- History of an allergic reaction or significant sensitivity to paclitaxel or any other analogue or derivative.
- Platelet count < 100,000 cells/mm³ (i.e. 100 x 109/L) or > 700,000 cells/mm³ (i.e. 700 x 109/L), or a white blood cell (WBC) count < 3,000 cells/mm³ within 7 days prior to index procedure.
- Serum creatinine level > 2.5 mg/dl (i.e. 221 *mol/L) within 7 days prior to index procedure
- Evidence of an Acute Myocardial Infarction within the previous 72 hours of the study procedure.
- Planned treatment of the left main coronary artery, internal mammary artery, aorto-ostial, and sapheneous vein grafts with the investigational device.
- Planned treatment of more than one lesion in one target vessel, or more than two lesions in two target vessels.
- Planned treatment involves a bifurcation.
- Previous percutaneous coronary intervention (PCI) of the target vessels(s)
- within 3 months prior to the procedure for In-Stent Restenosis;
- within 9 months prior to the procedure for de novo lesions.
- Planned PCI of any vessel within 30 days post-index procedure and/or planned PCI of the target vessel within 6 months post-procedure.
- During the index procedure, the target lesion(s) require(s) treatment with a cutting/scoring balloon, atherectomy, laser, or thrombectomy procedure.
- History of a stroke or transient ischemic attack (TIA) within the prior 6 months (any prior stroke or TIA, if prasugrel is used).
- Active peptic ulcer or upper gastrointestinal (GI) bleeding within the prior 6 months.
- History of bleeding diathesis or coagulopathy or will refuse blood transfusions.
- Any previous treatment of the target vessel for restenosis, including brachytherapy.
- Pregnant or breast-feeding woman.
- Documented left ventricular ejection fraction (LVEF) <30% at the most recent evaluation, within 3 months.

Angiographic Exclusion Criteria

- Target lesion(s) is/are located in a bypass graft (including but not limited to saphenous vein graft or a left/right internal mammary artery.
- Target vessel(s) has/have other lesions with greater than 40% diameter stenosis based on visual estimate or on-line QCA.
- Target vessel(s) has/have evidence of thrombus.
- Target vessel(s) is/are excessively tortuous (any bend >90º to reach the target lesion).
- Target lesion(s) has/have any of the following characteristics:

a. Lesion location is aorto-ostial, an unprotected left main lesion, or within 5mm of the origin of the left anterior descending (LAD) or left circumflex (LCX)
b. Involves a side branch >2.0mm in diameter
c. Is at a >45º bend in the vessel
d. Is severely calcified

- Unprotected left main coronary artery disease is present (an obstruction greater than 50% in the left main coronary artery).
- Lesion that is planned to be treated is longer than 25 mm in length or RVD is smaller than 2 mm.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-02-2018
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Medtronic Coronary Drug-Coated Balloon catheter
Registration:	No

Ethics review

Approved WMO Date:	06-10-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-01-2018
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-02-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-02-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-09-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-02-2019
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	NCT03260517
CCMO	NL62055.100.17