Safety and Efficacy of the FANTOM ENCORE sirolimus-eluting bioresorbable scaffold for treatment of de-novo coronary artery disease: the ENCORE-I study

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To assess the safety and efficacy of the FANTOM ENCORE sirolimus-eluting BRS.

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

Summary

ID

NL-OMON49058

Source
ToetsingOnline

Brief title
ENCORE-I

Condition

- Coronary artery disorders

Synonym
Coronary artery disease. Coronary atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Trialbureau Cardiologie

Source(s) of monetary or material Support: REVA Medical Inc.,the InSilc project (EU number: 777191)

Intervention

Keyword: Bioresorbable scaffold, Fantom encore sirolimus-eluting bioresorbable scaffold, Percutaneous coronary intervention

Outcome measures

Primary outcome

Device-oriented composite endpoint (DOCE), a composite of cardiac death, target vessel-related non-fatal myocardial infarction and clinically-driven target lesion revascularization.

Secondary outcome

Clinical endpoints:

- Subcomponents of DOCE at 30 days, 6, 12, 24, 36, 48 and 60 months.

- Target vessel revascularization (TVR) at 30 days, 6, 12, 24, 36, 48 and 60 months.

- Definite or probable stent thrombosis (ST) at 30 days, 6, 12, 24, 36, 48 and 60 months.

Angiographic endpoints:

At baseline

- Acute gain

- Acute recoil

- Incidence of procedural complications (dissection >B, perforation, vessel closure, slow flow or no-reflow, intra-procedure scaffold thrombosis)

At 13 months follow-up

- In-device late lumen loss (LLL)

- In-segment LLL

- In-device binary restenosis rate

- In-segment binary restenosis rate

Device performance:

- Device success

- Procedural success

Intracoronary imaging (OCT):

At baseline:

- Incomplete strut apposition (ISA)

- Scaffold expansion

- Scaffold eccentricity index

- Scaffold symmetry index

- Edge dissection

- In-device endothelial shear stress

- In-segment endothelial shear stress

At 13 months follow-up:

- Neointima thickness

- Percentage of patent struts

- Percentage of uncovered struts

- Persistent ISA

- Acquired ISA

- Scaffold eccentricity index

- Scaffold symmetry index

- Changes in scaffold area

- In-device late lumen area loss

- In-segment late lumen area loss

- In-device binary restenosis rate

- In-segment binary restenosis rate

- In-device endothelial shear stress

- In-segment endothelial shear stress

Study description

Background summary

In patients with coronary artery disease who receive metallic drug-eluting coronary stents, adverse events such as late target-lesion failure may be related in part to the persistent presence of the metallic stent frame in the coronary vessel wall. Bioresorbable scaffolds (BRS) have been developed to attempt to improve long-term outcomes. Following the excellent result of the first generation FANTOM BRS up to 2 years, the next generation FANTOM ENCORE BRS received Conformité Européene (CE) mark on June 18, 2018. The available diameters 2.5, 3.0 and 3.5 offer different and smaller strut thickness (95, 105 and 115 micron, respectively) as compared to its predecessor (125 micron), potentially allowing a smoother and faster vessel healing with lower inter-strut flow disturbances, while maintaining similar mechanical properties and x-ray visibility, which could potentially reduce the incidence of future adverse cardiac events. Intracoronary imaging with optical coherence tomography (OCT) will provide a close look at the acute performance and the long-term healing profile of the device.

Study objective

To assess the safety and efficacy of the FANTOM ENCORE sirolimus-eluting BRS.

Study design

Prospective, multicentre, non-randomized, investigator-initiated study.

Intervention

Percutaneous coronary intervention of de-novo non-complex obstructive coronary lesions using the FANTOM ENCORE sirolimus-Eluting BRS. Mechanical behavior and healing pattern of the device will be assessed with optical coherence tomography performed at baseline (pre- and post-procedure) and at 13months follow-up.

Study burden and risks

The FANTOM ENCORE has received CE Mark approval and its use will follow standard practice for PCI and the instructions for use, with careful patient and lesion selection. Available data on the previous FANTOM BRS generation demonstrate that the device is safe with a target lesion failure rate of 5% at 24 months as compared to Absorb BVS or Xience (11% and 7.9% respectively). Patients will receive standard care which includes double antiplatelet therapy, statins and lifestyle changes recommendations according to current European guidelines. OCT will be performed to guide the procedure and at 13-months follow-up according to current ESC-EAPCI task force on the evaluation and use of BRS guidelines; previous studies have demonstrated that OCT guidance of PCI is a safe technique and can potentially improve clinical outcomes when compared to angiography alone; in cases of BRS implantation, OCT enhance vessel and device selection, deployment evaluation and healing profile. The potential risks of this study include the known risks of any currently used standard procedure to assess and to treat obstructive coronary artery disease. Patients participating in this study will potentially benefit from receiving transitory vessel scaffolding with the newest generation of thinner strut BRS.

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

- 18 years or older
- Stable angina, unstable angina or documented silent ischemia (invasive or non-invasive test) or non-ST segment elevation ACS.
- De-novo non-complex coronary obstructive lesions (>50% stenosis as assessed by quantitative coronary analysis (QCA))
- The patient is willing and able to comply with the specified follow-up evaluations.
- Reference vessel diameter (RVD) >= 2.5 mm and <= 4.0 mm by QCA.
- During pre-dilatation, the pre-dilatation balloon is uniformly expanded to the full intended diameter.
- Target segment suitable for OCT imaging

Exclusion criteria

- Target vessel with a distal Thrombolysis In Myocardial Infarction (TIMI) flow 0 or 1.
- Target lesion located within 5.0 mm of vessel origin.
- Lesion type ACC/AHA C.
- Heavily calcified lesion
- Severe tortuosity
- Target lesion is located in or supplied by an arterial or venous bypass graft.
- Target lesion requires treatment with a device other than the pre-dilatation balloon prior to scaffold placement (including but not limited to directional coronary atherectomy, excimer laser, rotational atherectomy, etc.).
- Unsuccessful pre-dilatation, defined as a residual diameter stenosis >= 30%, assessed by QCA.
- Planned future revascularization of non-culprit lesions.

- Presence of another device (stent or scaffold) located within the same segment (5mm from the target lesion borders).
- Patient is currently participating in another study with an investigational device or an investigational drug and has not completed the entire follow-up period.
- Impaired renal function (eGFR <30ml/min).
- Patient has a contraindication for the use of double antiplatelet therapy for at least 12 months.
- Pregnant or breastfeeding patients.
- Patient has a known allergy to contrast medium, sirolimus, Tyrosine-derived polycarbonate or other structurally related compounds.
- Patient is receiving chronic oral or intravenous immunosuppressive therapy or has known life-limiting immunosuppressive or autoimmune disease (diabetes mellitus is not an exclusion criteria).
- Patient has a co-morbidity, which reduces life expectancy to <= 24 months, or social-economic factors making compliance with the study requirements difficult.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-11-2019
Enrollment:	26
Type:	Actual

Medical products/devices used

Generic name:	Fantom Encore sirolimus-eluting bioresorbable scaffold
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	03-09-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-11-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL69644.078.19