A prospective multicenter randomized post market all-comer trial to assess the safety and effectiveness of the SUPRAFLEX sirolimus-eluting coronary stent system for the treatment of atherosclerotic lesion(s).

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

Summary

ID

NL-OMON45959

Source
ToetsingOnline

Brief title
TALENT

Condition

- Coronary artery disorders

Synonym
Stenosis of one or more of the vessels of the heart/ Cardio vascular stenosis

Research involving

Human

Sponsors and support

Primary sponsor: Cardialysis
Source(s) of monetary or material Support: Sponsor ECRI

Intervention

Keyword: Comparison of two stents, Multi centers in Europe, Non inferiority trial, Percutaneous Coronary Intervention

Outcome measures

Primary outcome

The primary endpoint for this trial is a non-inferiority comparison of the

device-oriented composite endpoint Target Lesion Failure of the SUPRAFLEX group

to the XIENCE group at 12 months post-procedure. TLF (DoCE) is a composite of

clinical endpoint of cardiac death, target vessel myocardial infarction (TV-MI)

and clinically-indicated target lesion revascularization (TLR).

Secondary outcome

1. Composite Endpoints

a. Patient Oriented Composite Endpoint (PoCE) defined as all-cause death,

any MI, and any revascularization

b. Target Vessel Failure (TVF) defined as cardiac death, TV MI*, and

clinically indicated Target Vessel Revascularization

c. TLF (DoCE) defined as cardiac death, TV MI* and clinically-indicated

Target Lesion Revascularization (for all follow-up/visits other than 12 months)

2. Mortality

a. All death

b. Cardiac death

c. Non-cardiac death (vascular and non-cardiovascular)

3. Myocardial Infarction*

a. All MI

b.Target Vessel MI

c. Non-Target Vessel MI

4. Revascularization

a. Any revascularization

b.Target Lesion revascularization (TLR) (any, clinically-indicated TLR,

non-clinically indicated TLR)

c.Target Vessel revascularization (TVR) (any, clinically-indicated TVR,

non-clinically indicated TVR)

d.Non-Target Vessel revascularization

5. Stent thrombosis rates according to ARC classification

Study description

Background summary

One of the patient's coronary arteries has a significant narrowing that is causing decreased blood flow to the heart muscle. To prevent damage to the heart muscle, this narrowing has to be resolved. This is commonly done with a percutaneous coronary intervention (PCI). The procedure is performed by entering the arteries with a catheter through the groin or arm. By X-ray, the coronary arteries are made visible. A balloon and then a stent are placed within the narrowing in the artery to achieve the desired result; a reopened artery with good blood flow. Stent placement means that a small metal scaffold (stent) is left behind after the balloon is removed and the stent becomes a permanent part of the artery. Stents have been used for many years to treat narrowing of both coronary arteries. There are simple metal stents and drug eluting stents (DES) In this trial 2 drug eluting stents will be used. The

procedure itself is a standard procedure for this condition.

Study objective

This protocol will compare clinical outcomes of the SUPRAFLEX and XIENCE drug-eluting stents in a broad patient and lesion population and will gain substantial additional information on patients in a real world setting. These data will also provide data on various lesion types that may be treated in order to expand the indications for the SUPRAFLEX Sirolimus Eluting Cobalt Chromium Coronary Stent System.

Study design

This is a prospective, randomized, 1:1 balanced, controlled, single-blind, multi-center study comparing clinical outcomes at 12 months between SUPRAFLEX and XIENCE in a *Real world, all comers* patient population (patients with symptomatic coronary artery disease including patients with chronic stable angina, silent ischemia, and acute coronary syndromes, who qualify for percutaneous coronary interventions). All patients will be (at minimum) contacted at 30 days, 6 months, 12 months, 2 years and 3 years post procedure to assess clinical status and adverse events. The 30 day and 12 month will be a clinic visit.

Intervention

1430 patients will be enrolled to receive treatment with either the study device (SUPRAFLEX) or a control device (XIENCE), in a 1:1 randomization (715 SUPRAFLEX and 715 XIENCE).

Study burden and risks

The potential risks and undesirable effects resulting from the use of these stents are the same as for other stents. These are (but are not limited to): death, stroke, heart attack, renewed narrowing of the coronary artery treated with the stent or of another coronary artery, need for emergency bypass surgery or repeat angioplasty. Undesirable events that may occur due to the procedure, such as artery spasm, lack of oxygen for the heart, or damage to the coronary artery, blood clots in the coronary artery or a side vessel, bleeding, for example at the insertion site for the catheter, and the possible need for a blood transfusion. Additionally, damage may occur to blood vessels from the insertion site of the catheter towards the heart, infection and pain at the catheter insertion site, heart arrhythmias that may be life-threatening, blood pressure changes, allergy reactions to medicines, contrast medium or stent materials.
Fortunately, serious complications are extremely rare, such as clot formation in the arteries that can lead to a stroke or cerebral bleed. In general, a

complication is associated with the severity of the heart disease.
The potential risks for pregnancy associated with this treatment are unknown, and use of adequate contraception during the course of the study is mandatory for women of childbearing potential.

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

1. Male or female patients >=18 years;
2. Presence of one or more coronary artery stenoses of >=50% in a native coronary artery or in a saphenous venous or arterial bypass conduit suitable for coronary stent implantation.
3. The vessel should have a reference vessel diameter ranging from >=2.25 mm to <=4.5 mm (no limitation on the number of treated lesions, vessels, or lesion length)

Exclusion criteria

1. Known pregnancy or breastfeeding at time of randomization;
2. Known contraindication or hypersensitivity to sirolimus, everolimus, cobalt-chromium, or to medications such as aspirin, heparin, bivalirudin, and all of the following four medications: clopidogrel bisulfate, ticlopidine, prasugrel, ticagrelor;
3. Any PCI treatment within 6 months (<6 months) prior to the index procedure.
4. Concurrent medical condition with a life expectancy of less than 12 months.
5. The patient is unwilling/not able to return for outpatient clinic at 1 month and 12 months follow-up.
6. Currently participating in another trial and not yet at its primary endpoint.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-10-2016
Enrollment:	350
Type:	Actual

Medical products/devices used

Generic name:	Coronary Stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	19-10-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-06-2019
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	NL57788.018.16