Multicenter Randomized Study of the MiStent Sirolimus Eluting Absorbable Polymer Stent System (MiStent SES) for Revascularization of Coronary Arteries, the DESSOLVE III Study

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

Summary

ID

NL-OMON50348

Source
ToetsingOnline

Brief title
DESSOLVE III

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 BV
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 a device-oriented composite endpoint (DOCE) or TLF of the MISTENT group to the XIENCE group at 12 months post-procedure. TLF is a composite of clinical endpoint of cardiac death, myocardial infarction (MI, WHO Extended Definition) not clearly attributable to a nontarget vessel and clinically-indicated target lesion revascularization (TLR).

Secondary outcome

Secondary Endpoints (evaluated at each follow-up visit/contact)

1. Composite Endpoints

• POCE defined as all-cause death, any MI, or any revascularization

• MACE defined as all-cause death, any MI, or any TVR

• TVF defined as cardiac death, TV MI, or clinically indicated TVR

• DOCE/TLF defined as cardiac death, TV MI or clinically-indicated TLR (for all follow-up/visits other than 12 months)

2. Mortality

• All death

• Cardiac death

• Non-cardiac death (vascular and non-cardiovascular)

3. Myocardial Infarction

• All MI

• TV-MI

• Non-TV-MI

4. Revascularization

• Target Lesion revascularization (TLR) (any, clinically-indicated TLR,

non-clinically indicated TLR)

• Target Vessel revascularization (TVR) (any, clinically-indicated TVR,

non-clinically indicated TVR)

• Non-TV revascularization

• Any revascularization

5. Stent thrombosis rates according to ARC classification

• ST - Early (Acute, Sub-acute), Late, Very Late.

• ST - Definite, Probable, Possible

• ST - Definite/Probable

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 provide data to comply with regulatory requirements as well as gain substantial additional information on patients in a real world setting. This protocol will compare clinical outcomes of the MISTENT and XIENCE in a broad patient and lesion population. These data may also be used to support regulatory approvals in other countries and provide data on various lesion types that may be treated in order to expand the indications for MISTENT.

Study design

This is a prospective, randomized, 1:1 balanced, controlled, single-blind, multi-center study comparing clinical outcomes at 12 months between MISTENT 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 and 12 months post procedure to assess clinical status and adverse events. The 30 day and 12 month will be a clinic visit.All patients will have phone contact at 6 month, 2 and 3 years follow-up to assess clinical status and adverse events. Additionally, 2 phone calls will be performed in the prolongation of the trial; patients are being called 4 year post procedure and 5 year post procedure.

Intervention

Enrollment of 1400 patients with 700 MISTENT and 700 XIENCE, Approximately 17 sites in Europe will participate.

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 limit 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, allergic 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

Public
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NL
Scientific
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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 2.5 mm to 3.5 mm (no limitation on the number of treated lesions, vessels, or lesion length);

Exclusion criteria

1. Known pregnancy at time of randomization. Female who is breastfeeding at time of randomization;
2. Known contraindication or hypersensitivity to sirolimus, everolimus, cobalt-chromium, or to medications such as aspirin, heparin, bivalirudin, clopidogrel bisulfate, ticlopidine, prasugrel, ticagrelor;
3. Concurrent medical condition with a life expectancy of less than 12 months;
4. The patient is unwilling/ not able to return for outpatient clinic at 1 months and 12 months follow-up;
5. 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):	20-03-2015
Enrollment:	411
Type:	Actual

Ethics review

Approved WMO Date:	27-02-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-03-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-05-2018

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-07-2020
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	NL52025.018.15