Randomized "all-comer" evaluation of a permanent polymer zotarolimus eluting stent versus a polymer free amphilimus stent

Published: 08-10-2014
Last updated: 20-04-2024

The study objective is to assess the safety and efficacy of the Permanent Polymer Zotarolimus-Eluting Stent Resolute Integrity* to the Polymer Free Amphilimus-Eluting Stent Cre8* compared in an all-comer patient population. 1 month of dual...

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

Summary

ID

NL-OMON47737

Source
ToetsingOnline

Brief title
The ReCre8 trial

Condition

- Coronary artery disorders

Synonym
Coronary stenosis, Stent thrombosis

Research involving
Human

Sponsors and support

Primary sponsor: R&D Cardiologie

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Percutanous coronary intervention, Polymer Free Stent

Outcome measures

Primary outcome

The primary endpoint will be evaluated at 12 months of follow up post-procedure:

* Target-Lesion Failure (TLF), consisting of: cardiac death, Target-Vessel Myocardial Infarction (QWMI and NQWMI), or Target-Lesion revascularization Revascularization by CABG or PCI

Secondary outcome

Net Adverse Clinical Events (NACE) defined as composite of: any death, myocardial infarction, stroke, any unplanned repeated revascularization and bleeding (BARC 3a and above), and separate components of the endpoints at 12-months post-procedure:

* Target-Vessel revascularization by CABG or PCI (TVR)

* Stent thrombosis

* Device-, lesion-, and procedure success at time of baseline procedure

Study description

Background summary

Could possible reduce the antiplatelet duration period with a new generation stent after PCI, retaining efficacy regarding restenosis etc.

Study objective

The study objective is to assess the safety and efficacy of the Permanent

Polymer Zotarolimus-Eluting Stent Resolute Integrity* to the Polymer Free Amphilimus-Eluting Stent Cre8* compared in an all-comer patient population. 1 month of dual antiplatelet duration will be applied in stable angina pectoris patients. Myocardial infarction patient population will be treated with 12 months of dual antiplatelet therapy.

Study design

A Prospective, Single-Center, Open Label, Randomized Controlled, two-arm Study to Evaluate the Safety and Efficacy of the Permanent Polymer Zotarolimus Eluting Stent *Resolute Integrity** Compared to Polymer Free Amphilimus Eluting Stent *Cre8* .Dual Antiplatelet Therapy duration of 1 Month will be applied in stable angina pectoris patient population. Myocardial infarction patient population will be treated with 12 months of dual antiplatelet therapy (DAPT).

For the primary endpoint of 12-month TLF randomizing 525 patients 1:1 to Amphilimus-eluting stent Cre8TM and zotarolimus-eluting stent Resolute IntegrityTM affords at least 80% power to show clinical non-inferioirty, assuming a TLF rate of 5.5% in both arms, and using a 1-sided binomial test of proportions with a significance level of *=0.05, and a non-inferioirty margin of 3.5%.

For the secondary endpoint of 12-months NACE, randomizing 1486 subjects 1:1 to Amphilimus-eluting stent Cre8TM and zotarolimus-eluting stent Resolute IntegrityTM affords at least 80% power to show non-inferioirty, assuming a NACE rate of 8% in both arms, and using a 1-sided binomial test of proportions with a significance level of *=0.05, and a non-inferioirty margin of 3.5%.

To ensure a sufficient level of power for the secondary endpoint and to account for possible uncertainty regarding the estimated event rate of the primary endpoint, the lager sample size of 1486 subjects was considered preferable.

Hence, One thousand five hundred thirty-two (1532) patients (1:1 randomization Cre8 stent:Resolute Integrity* stent) will be enrolled in the study, with clinical follow-up at 12 months to assess the primary end point.

After a period of 12 months, a clinical registry will be implemented Information will be collected at 3-years post procedure.

Intervention

The *Cre8** stent is a polymer-free stent with a thin (80-µm) cobalt-chromium alloy L605, integrally coated by an ultra-thin (0.3-µm) passive carbon coating (i-Carbofilm, CID, Saluggia, Italy). The amphilimus formulation, constituted by sirolimus (0.9 µg/mm2) formulated with an excipient composed of long-chain fatty acids mixture, to modulate the drug (Sirolimus) release, is loaded into

abluminal reservoirs to obtain a targeted elution toward the vessel wall.

The *Resolute Integrity** stent, made from advanced cobalt alloy, is a permanent-polymer stent with a BioLink biocompatible polymer, which allows rapid, complete and functional healing. The polymer is a drug vehicle to Zotarolimus, a potent antiproliferative drug, which allows effective inhibition of neointimal growth.

Study burden and risks

This study carries no additional burden to the subject as daily clinical practice (regarding site visits, blood samples, physical examination and other tests) will be applied.
The risk associated with study participation is moderate.
Expected benefits are associated with lower bleeding complications associated with lower DAPT duration

Contacts

Public
Selecteer

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Selecteer

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

General Inclusion Criteria
a. All-comer patients 18 years and older;
b. Patient has been informed of the nature of the trial and agrees to its provisions and has provided either oral during emergency procedure, followed by written informed consent, or written informed consent in case of an elective procedure as approved by the Medical Research Ethics Committee (MREC)
c. Patient is eligible for percutaneous coronary intervention (PCI) with implantation of a drug-eluting stent
d. Patient has clinical evidence of ischemic heart disease, stable or unstable angina, NSTEMI or STEMI, silent ischemia, or a positive functional studyAngiographic Criteria
a. All de-novo and restenotic lesions (whether native coronary or bypass graft) not amenable for treatment with drug eluting balloons
b. All lesions types are allowed: calcified lesions (lesion preparation with scoring/cutting and rotational atherectomy is allowed), thrombus, chronic total occlusion (CTO; randomized after successful wire crossing and pre-dilatation), bifurcation lesions, ostial lesions and left main.
c. There is no limit for lesion length, or number of lesions or diseased vessels.
d. Target vessel reference size (visual estimation) between 2.5 and 4.5 mmumwaar

Exclusion criteria

Exclusion Criteria
a. Inability to provide informed consent
b. Participation in another study for intracoronary stents that had not reached its primary endpoint
c. Planned surgery within the next 3 months
d. Known intolerance to P2Y12 receptor antagonist that would prevent adherence to DAPT, or intolerance to aspirin, Clopidogrel, Ticagrelor, Prasugrel, Heparin/Bivalirudin, contrast agent (that cannot be adequately premedicated) or component of drug-eluting stents
e. Female of childbearing potential, who are pregnant or are planning to become pregnant
f. Life expectancy of less than 12 months
g.Patients undergoing revascularization prior to planned TAVI procedure
Angiographic Criteria:

a. Lesions amenable for treatment with drug eluting balloons

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-11-2014
Enrollment:	1100
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	08-10-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	07-04-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	22-12-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-02-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-07-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-09-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-05-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-12-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	05-12-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-04-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL48472.041.14

Study results

Results posted: 28-06-2021

First publication
07-06-2021