HYBRID SIROLIMUS-ELUTING STENT WITH BIORESORBABLE POLYMER VERSUS EVEROLIMUS-ELUTING STENT WITH DURABABLE POLYMER FOR TOTAL OCCLUSIONS IN NATIVE CORONARY ARTERIES
Primary Stenting of Occluded Native Coronary Arteries IV (PRISON IV)

Published: 30-01-2012
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The main objective of the present study is to investigate whether the ORSIRO coronary stent is non-inferior compared to the Xience coronary stent in patients with total coronary occlusions.

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

Summary

ID

NL-OMON38171

Source
ToetsingOnline

Brief title
PRISON IV

Condition

- Coronary artery disorders

Synonym
angina pectoris, stenosis of coronary arteries

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Bedrijven,Biotronik

Intervention

Keyword: Coronary artery disease, Coronary occlusion, coronary restenosis, drug eluting stent

Outcome measures

Primary outcome

in-segment late luminal loss at 9 months follow-up angiography

Secondary outcome

-angiografische in-stent late luminal loss, in-stent en in-segment restenose na

9 maanden

- targetvessel en target lesion revascularisatie

- Major adverse cardiac events

- acute en subacute stent thrombose

Study description

Background summary

Primary intracoronary stent placement after successfully crossing chronic total coronary occlusions (CTO) decreases the high restenosis rate at long-term

follow-up compared with conventional balloon angioplasty. Several studies have shown the efficacy of drug-eluting stents in selected groups of patients. In the PRISON II AND III study we demonstrated that drug-eluting stents were superior to bare metal stents in CTO. In this prospective randomized trial, implantation of ORSIRO sirolimus-eluting stents with bio-resorbable polymer coating will be compared to Xience everolimus-eluting stent with permanent polymer coating implantation for the treatment of total coronary occlusions.For a complete overview: see http://www.clinicaltrials.gov

Study objective

The main objective of the present study is to investigate whether the ORSIRO coronary stent is non-inferior compared to the Xience coronary stent in patients with total coronary occlusions.

Study design

prospective, randomized, single blinded, controlled, multi-center

Intervention

recanalization of the occluded coronary artery with placement of either the ORSIRO or XIENCE stent

Study burden and risks

Additional investigations for patients in this study include a standard angiography at 9 months follow-up, in 60 patients an OCT, informed consent procedure and once a year telephone follow-up. All other procedures during the study are standard treatment procedures. Participation in the study has little additional risk compared to standard treatment.

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) the estimated duration of the occlusion is at least 4 weeks.
2) signs of ischemia related to the occluded coronary artery.
3) successful recanalization of the occluded artery is achieved.

Exclusion criteria

1) primary or rescue PCI for acute myocardial infarction
2) the lesion could not be crossed.
3) lesions with complex anatomy making successful stent deployment unlikely.

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-02-2012
Enrollment:	250
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	30-01-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-06-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-08-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-10-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-11-2012
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-02-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-04-2013
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	NCT01516723
CCMO	NL37520.100.11