Comparison of the everolimus eluting XIENCE-V* stent with the paclitaxel eluting TAXUS* stent in all-comers: a randomized open label study.

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The main objective of the study is a head tot head comparison of the everolimus coated XIENCE-V* stent with the paclitaxel coated TAXUS* stent in order to observe whether there is a difference in clinical outcome between both stents. Efficacy of...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON35195

Source
ToetsingOnline

Brief title
MCRZ-COMPARE

Condition

- Coronary artery disorders

Synonym
outcome PCI treatment

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Rijnmond-Zuid

Source(s) of monetary or material Support: Abbott,Boston Scientific ,Research grants industrie en eigen bijdrage wetenschapsstichting maatschap cardiologie

Intervention

Keyword: drug eluting stents, everolimus, paclitaxel, percutaneous coronary intervention (PCI)

Outcome measures

Primary outcome

The primary end point of the study is the composite end point of: all death,

non fatal myocardial infarction, target vessel revascularization at 1 year.

Secondary outcome

The secondary end points of the study are:

A) The combined endpoint of cardiac death, non fatal myocardial infarction,

ischemic driven target lesion revascularization (TLR) rate at 1, 6 and 12

months follow-up.

B) The combined endpoint of all death, non fatal myocardial infarction, target

vessel revascularization (TVR) rate at 2, 3, 4 and 5 years.

Study description

Background summary

In stead of treating in-stent restenosis, the best strategy for patients is preventing in-stent restenosis. Recent advances in the understanding of the cellular mechanism responsible for smooth muscle cell proliferation (neointimal hyperplasia), together with improvement in stent coating and eluting technology have provided the scientific background to develop drug eluting stents. Drug eluting stents (DES) are now the most promising development in interventional cardiology. Different classes of drugs mounted in a polymer layer on the surface of the stent have shown to be very effective in preventing neointimal hyperplasia. Currently there are 7 DES stents CE marked and commercially available on the market. Two stents, respectively the sirolimus eluting Cypher*

stent and the paclitaxel eluting Taxus* stent, are in clinical use since 2002.
The Cypher* stent consists of the Bx sonic stent/balloon platform. The stent is coated with a non-degradable biocompatible PBMA/PEVA polymer which elutes sirolimius. The Taxus* stent consists of the Express2 balloon/stent platform coated with non-degradable biocompatible Translute* polymer which elutes paclitaxel.
Recent large randomized trials like RAVEL, SIRIUS, E-SIRIUS C-SIRIUS (Cypher* versus bare metal BX sonic* stent), TAXUS II, IV, V, VI (Taxus versus bare metal Express* stent) have shown that DES dramatically reduce the incidence of in-stent restenosis and subsequently the need for target lesion revascularization in patients with non complex and moderate long de-novo coronary lesions in vessels with a diameter between 2.5 -3.5 mm.1-11
Considering the very encouraging results of these early clinical trials with so far mid long term follow-up, there is the need to explore the utilization of DES in the other subsets of coronary lesions like: long lesions, chronic total occlusions, venous graft lesions, thrombotic lesions, restenosis lesions, ostial and bifurcation lesions and lesions in large vessels.
As the result from the previous reported randomized trials, FDA and other regulatory institutes require that new DES are now being evaluated against one of the former DES (Cypher or Taxus). The XIENCE-V stent is a second generation DES, with thinner and more flexible Cobalt-Chromium stent struts, compared to the first generation Stainless Steel stent struts of Cypher and Taxus. This study addresses the questions whether the XIENCE-V* stent has superior clinical results as the Taxus* stent in the general population that is being referred for PCI.

Study objective

The main objective of the study is a head tot head comparison of the everolimus coated XIENCE-V* stent with the paclitaxel coated TAXUS* stent in order to observe whether there is a difference in clinical outcome between both stents. Efficacy of both stents will be assessed by the composite end point of: all death, non fatal myocardial infarction and target vessel revascularization.

Study design

Single center, randomised, open label study in all-comers referred for PCI

Study burden and risks

The burden for the patient consists of filling in 8 questionaires (1 A4 per questionaire) in 5 years time.
The first 3 questionaires in the first year are also requested for monitoring purposes by the Ministry of Health and the Dutch Cardiology Society (Nederlandse Vereniging Voor Cardiologie; NVVC).

There is no risk for the patient related to participation in this study.
Thepatient will receive a Taxus or Xience-V stent anyhow, if the indication for a DES stent exsists.

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

All patients referred for PCI according to dutch and european guidelines
Age between 18-85 years

Exclusion criteria

1 Expected non-adherence to dual antiplatelet therapy for 1 year (e.g: known allergy to ASA or thienopyridines like clopidogrel)
2 Expected major surgery within 30 days (these patients will receive bare metal stents)
3 Expected loss for follow up
4 Enrollment in another stent study with different stents
5 Inability to implant Taxus or Xience-V stent(s)

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2007
Enrollment:	1600
Type:	Actual

Ethics review

Approved WMO Date:	01-02-2007
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	03-05-2010
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (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	NL15206.101.06