Comparison of the everolimus eluting (XIENCE-V*/XIENCE-PRIME* or PROMUS* stent) with the biolimus A9 eluting NOBORI* stent in all-comers: a randomized open label study.

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The main objective of the study is to investigate whether of the biolimus eluting and biodegradable polymer NOBORI* stent is non-inferior or even superior to the everolimus eluting XIENCE-V/XIENCE-PRime/PROMUS* stent in daily practice.

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

Summary

ID

NL-OMON35434

Source
ToetsingOnline

Brief title
The COMPARE II trial

Condition

- Coronary artery disorders

Synonym
outcome PCI treatment with stents

Research involving
Human

Sponsors and support

Primary sponsor: Overige Ziekenhuizen
Source(s) of monetary or material Support: Research grants industrie en eigen bijdrage wetenschapsstichting maatschap cardiologie,Terumo

Intervention

Keyword: biolimus A9, drug eluting stents, everolimus, percutaneous coronary intervention(PCI)

Outcome measures

Primary outcome

The primary end point of the study is the composite of safety (cardiac death,

non fatal myocardial infarction) and efficacy (target vessel revascularization)

at 12 months.

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

12 months follow-up.

B) Incidence of Cardiac Death and Post-Procedural (>48h) MI rate at 12 months,

3 and 5 years

C) Target lesion revascularization at 12 months, 3 and 5 years

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

target vessel revascularization (TVR)

rate at 3 and 5 years follow-up.

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

target vessel revascularization at

12 months, 3 and 5 years in STEMI patients, small vessels (<

2.75 mm RVD), long lesions (> 20 mm), Female

patients, DM patients and octogenarians.

F) Procedural performance at the index procedures, measured by the ability to

cross the lesions with the

designated DES stent.

G) Incidence of definite and probable stent thrombosis at 12 months, 3 and 5

years time.

H) Incidence of definite, probable and possible stent thrombosis at 12 months,

3 and 5 years time.

Study description

Background summary

Randomized studies with drug eluting stents (DES), like Taxus (paclitaxel eluting) en Cypher (sirolimus eluting) stents have shown that in almost all indications for percutaneous coronary interventions (PCI) the risk on re-stenosis significantly descrease compared to the use of bare-metal stents. Comparative studies between Taxus and Cypher did not show any clear difference in clinical outcome between both stents.
Since 2002 the Cypher and later the Taxus stent were used as the default stent for all patients referred for PCI in the Rotterdam region (2 intervention centers EMC and Maasstad Ziekenhuis). In the beginning this was done as a registry (RESEARCH and T-SEARCH registry).
In 2006 the XIENCE-V/ PROMUS stent received CE marking and became available on the European market. Compared to the first generation DES , this stent has a different drug (everolimus) that elutes from a different durable polymer coating and the stent has a different metal alloy (cobalt chromium), which makes the stent more flexible.
The Xience-V/Promus stent has in comparison to the Taxus stent a lower angiographic in-stent restenosis (late loss). Whether this surrogate end-point of late loss results in better clinical outcome of the patient needs to be

determined and is part of current studies like the ongoing SPIRIT IV and COMPARE I trials.
Recently a new phenomena in PCI has been identified: late stent thrombosis (> 30 days after stenting). Stent thrombosis is rare (incidence 0.6-1.2 %), but results in severe morbidity (infarction) and mortality. Currently it is unclear whether DES results in an increase of late stent thrombosis. Meta-analysis shows momentarily no clear increase of risk, however several patho-anatomical case reports describe a relationship. In those cases a hypersensitivity reaction of the vessel wall at the site of the DES results in delayed healing and impaired re-endothelization of the stent. The durable polymer of the stent is potentially responsible for this rare complication.
One of the latest development in stents is the biodegradable polymer coating on the DES. The polymer coating and drug resolves within 1-3 months after stent placement. A recent conducted and publicized (Lancet sept 2008) study with this new stent platform in all-comers (LEADERS trial) shows similar good clinical results compared to the first generation Cypher DES. Whether the stent with a biodegradable polymer has a lower incidence of late stent thrombosis needs to be established. This is one of the reasons why the COMPARE II study has a follow-up of 5 years.

Study objective

The main objective of the study is to investigate whether of the biolimus eluting and biodegradable polymer NOBORI* stent is non-inferior or even superior to the everolimus eluting XIENCE-V/XIENCE-PRime/PROMUS* stent in daily practice.

Study design

Prospective, randomized, open-label, multi-center study of consecutive patients referred for PCI.

Study burden and risks

The only requirement of the patient is to fill in a questionaire (1 single A4 form) send by post at 1, 6, 12 months and 2,3,4,5 year. The information within the first 3 questionaire (1 year) is required by the Dutch Ministry of Health (VWS) and the Dutch Society of Cardiology (NVVC).
In case an admission has occurred within the follow-up period, the patient chart will be checked by authorized personel.

There is no risk for the patient related to participation in this study. The patient will receive the CE marked Nobori or Xience-V/Xience-Prime/Promus 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 Cardiogenic shock (Kilip class 4)
4 Previous PCI procedures with implantation of drug eluting stents within 1 year.
5 Expected loss for follow up

6 Enrollment in an investigative stent study with different stents
7 Inability to implant Nobori or Xience-V / Promus 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):	12-01-2009
Enrollment:	2000
Type:	Actual

Ethics review

Approved WMO Date:	18-12-2008
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	28-06-2010
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	30-12-2010
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	NL25754.101.08