Drug eluting balloon for in-stent restenosis. Multi-center, randomized trial to study the effect of the SeQuent Please drug-eluting balloon versus the Xience Prime drug-eluting stent for the treatment of in-stent restenosis

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The main objective of the study is to determine whether PCI for in-stent restenosis with a drug eluting balloon is angiographically non-inferior to PCI with a drug eluting stent at 6 month follow up.

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

Summary

ID

NL-OMON34621

Source
ToetsingOnline

Brief title
Drug eluting balloon for in-stent restenosis

Condition

- Coronary artery disorders

Synonym
in-stent restenosis, stenosis of earlier implanted stent

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,B. Braun Medical b.v.

Intervention

Keyword: Drug eluting balloon, Drug eluting stent, In-stent restenosis, Minimal lumen diameter

Outcome measures

Primary outcome

The primary objective of this study is to determine whether PCI with the SeQuent ® Please DEB versus PCI with the Xience* Prime DES for the treatment of patients with in-stent restenosis is non-inferior with respect to minimal lumen diameter (MLD) assessed by quantitative coronary angiography (QCA) at six months.

Secondary outcome

The secondary study parameters are the following parameters:In-stent and in-segment percent Diameter Stenosis (% DS) at 6 months, in-stent and in-segment Angiographic Binary Restenosis (ABR) rate at 6 months, aneurysm, thrombosis and persisting dissection (i.e. dissection post-index-procedure that remained present at follow-up) at 6 months, cardiac death, myocardial infarction, unless originating from a un-treated vessel, target vessel re-vascularization, either by PCI or CABG, stent thrombosis, ischemia driven target vessel re-stenosis, not amenable to re-vascularization.

Study description

Background summary

Coronary in-stent restenosis is commonly treated by using a drug eluting stent (DES). There are, however, some concerns about the safety of drug eluting stents, in particular with respect to delayed healing, chronic inflammatory reaction, and late or very late stent thrombosis. It is unknown whether the current treatment with another layer of stents may add to the risk of stent thrombosis or reoccurrence of restenosis.

Therefore, the relatively new drug-eluting balloons may provide an alternative for treatment of in-stent restenosis, avoiding a double stent layer. The expected advantages of such drug-eluting balloons over stents are the ease of access of the lesion, the absence of a multiple stent layer, and the shorter necessity of the use of dual antiplatelet therapy. Several studies have demonstrated safety and efficacy of the Sequent Please drug-eluting balloon (DEB). Whether the drug eluting balloon is as effective as a drug eluting stent in preventing re-restenosis is not known.

Study objective

The main objective of the study is to determine whether PCI for in-stent restenosis with a drug eluting balloon is angiographically non-inferior to PCI with a drug eluting stent at 6 month follow up.

Study design

The study is designed as an multi-center, randomized, prospective two-arm trial with either PCI with a drug eluting balloon or a drug eluting stent for in-stent restenosis. Blinded evaluation of endpoints by independent core laboratory.

Intervention

PCI with a drug-eluting stent, or PCI with a drug-eluting balloon.

Study burden and risks

Clinical follow-up (telephonically) 30 days, 1, 2, 3, 4 and 5 years post-procedure.
Re-coronairy angiography at 6 months post-procedure. The risks of the re-coronairy angiography are the same as every coronairy angiography.

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

Restenosis of initially stented coronary artery
Restenosis of any type of stent; all drug-eluting stents or bare metal stents
Restenosis must be present > 50% in-stent and < 5 mm out of the stent
Amendable to PCI treatment with either the SeQuent Please DEB or the Xience Prime DES

Exclusion criteria

The impossibility to arrange a follow-up coronary angiography at 6 months (± 1 month) after baseline procedure
Life expectancy less than one year
In-stent re-restenosis already treated with a second stent

Requirement for PCI in the same vessel or expected in the next 6 months

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-04-2010
Enrollment:	270
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	NL31487.018.10
Other	TC=2189