Drug eluting BALLoon angioplasty to prime bifuRcation lesiOns for stenting: a prOspective randoMized trial

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The study will assess the hypothesis that for treating a bifurcation lesion in a coronary artery the combination of a drug eluting balloon and a bare metal stent is non inferior to the standard provisional T-stenting technique using a drug eluting...

Ethical review	Not approved
Status	Will not start
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON33521

Source
ToetsingOnline

Brief title
BallRoom

Condition

- Coronary artery disorders

Synonym
coronary atherosclerosis, coronay bifurcation lesion

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Biotronic,R&D fonds cardiologie Nieuwegein

Intervention

Keyword: bifurcation, coronary stenosis, drug-eluting balloon

Outcome measures

Primary outcome

The primary end point of the study is the clinical combined end point (MACE) of cardiac death, myocardial infarction, and stent thrombosis or target-vessel revascularization by PCI or coronary artery bypass surgery after 12 months.

Secondary outcome

Secondary study parameters/endpoints (if applicable)

(1) the individual end points of death from any cause, cardiac death, myocardial infarction, target-lesion revascularization, and target-vessel revascularization;

(2) procedure-related biomarker increase (3 times the upper limit of normal of CK-MB mass, troponin-T, or troponin-I); and

(3) the combined angiographic end point of significant restenosis (>50% diameter stenosis) of the main vessel and/or occlusion of the side branch.

(4) The number of major bleedings according to the TIMI -and/or GUSTO criteria.

Study description

Background summary

The optimal endovascular approach to treat coronary artery bifurcation lesions remains challenging. Bifurcation stenting is associated with a high rate of restenosis (1) The use of drug eluting stents has effectuated a major reduction of restenosis in simple and more complicated coronary lesions (2-9) Together with 2 other randomized studies, the Nordic bifurcation study reported excellent clinical and angiographic results using a sirolimus stent in de novo

coronary artery bifurcation lesions. Consequently the simple bifurcation stent strategy (stenting of the main vessel and optional stenting of the side branch) was recommended as a routine bifurcation technique (2,7,10).
Interventional cardiologists are still in search of the optimal treatment of bifurcation lesions. Many techniques have been investigated up till now. The unique anatomical configuration of every bifurcation creates an abnormal flow pattern, which could be considered the cornerstone in the pathofysiology of restenosis (11). Furthermore, in bifurcation lesions a complete coverage of the circumferential vessel with stent struts seems almost inconceivable , once more responsible for a higher restenosis rate (11).
In the Nordic bifurcation trial a provisional T stenting strategy was proven safe and feasible. However, further improvement of the technique is mandated to decrease the restenosis rate consistently. Colombo (presented on the euroPCR congress). demonstrated that the crush technique is not superior to provisional T stenting technique. On the other hand, Bavry emphasized the risk of late stent thrombosis when using a DES(12).

Recently a new technique was introduced using paclitaxel eluting balloons (13). The drug eluting balloon was successfully used for treating in-stent restenosis of bare metal stents (13). Furthermore, it was proven to be feasible and safe to treat a bifurcation lesion with drug eluting balloon angioplasty followed by bare metal stent implantation of the main vessel (11). No late stent thrombosis was reported after angioplasty with a drug eluting balloon.
The OASIS V trial has showed bleeding complications are very important in predicting 1 year survival (14). By using the combination of a drug eluting balloon and bare metal stents the duration of clopidogrel therapy can be reduced significantly to one month.

Study objective

The study will assess the hypothesis that for treating a bifurcation lesion in a coronary artery the combination of a drug eluting balloon and a bare metal stent is non inferior to the standard provisional T-stenting technique using a drug eluting stent. Using this new strategy we intend to combine the advantages of the drugs preventing restenosis and the shorter administration of clopidogrel diminishing major bleeding.

Study design

Open label randomized controlled trial with two groups : group A Elutax drug eluting balloon + bare metal stent, group B conventional provisional T-stenting using a drug eluting stent

Intervention

Group A:

In the drug eluting stent (DES) group, a similar approach ,as used in the Nordic bifurcation study, is requested. The SES "Cypher Select" (Cordis/Johnson & Johnson, Miami Lakes, Fla) is used in the study. The target lesion can be pre -and postdilated at the operators discretion. The operators are requested to avoid predilation not covered by stent in the main vessel segment. Different types of drug-eluting stents in the same vessel will not be allowed.

In the DES group the main treatment principles are (1) stenting of main vessel; (2) side branch dilatation if there is TIMI (Thrombolysis In Myocardial Infarction)flow <3 in the side branch; and (3) side branch stenting if TIMI flow=0 in the side branch after dilatation.

Group B:
In the Elutax drug eluting balloon (DEB)group the main treatment principles are (1) placing of a guide wire in the target vessel and in the side branch, (2) balloon pre-dilatation with standard undersized, compliant, coronary balloons of both vessels at low pressure (6-8 atm), (3) sequential Elutax drug eluting balloon inflations (8atm, 60sec) in the main and side branch respectively, (4) bare metal stent deployment in the main vessel, (5) recrossing wires and performing a final kissing balloon deployment. (6) the procedure is completed when the criterium of angiographic success is achieved (TIMI III flow in the main vessel and side branch with a diameter stenosis < 10% and < 40% respectively). Both operator and patient will be aware of the assigned treatment

Study burden and risks

included patients may be at risk for an instent restenosis if allocated to the group treated with bare metal stent; they are to undergo the risk(allthough low) of second catheterisation; however the latter group of patients wil not be at risk for late stentthrombosis and will be able to stop antiplatelet therapy earlier then patients treated following standard procedure.

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

- 18 years or older
-stable or unstable angina pectoris or silent ischemia
-and a de novo coronary bifurcation lesion. (A bifurcation lesion is defined according to Louvard/Lefevre (15) et al. and can be located in the anterior descending artery and a diagonal, the circumflex artery and an obtuse marginal or the right coronary artery and posterior descending artery/posterolateral artery).
-The diameter of the main vessel and of the side branch should be 2.5 mm and 2.0 mm, respectively, by visual estimate.

Exclusion criteria

- ST-segment elevation acute myocardial infarction within 24 hours,
- life expectancy <1 year,
- S-creatinine > 200 µmol/L,
- allergy to any of the drugs used (aspirin, clopidogrel, sirolimus, and paclitaxel)
- left main bifurcation lesion.
- Inability to cover the lesion in the main vessel with one stent

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:	Will not start
Enrollment:	200
Type:	Anticipated

Ethics review

Not approved

Date:	02-10-2009
Application type:	First submission
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
CCMO	NL28080.100.09