Drug Eluting Balloon in BIfUrcations Trial

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Evaluation of provisional T stenting using a bare metal stent in combination with a paclitaxel eluting balloon compared with a normal balloon. And comparing a bare metal stent in combination with a paclitaxel eluting balloon with a paclitaxel elutin...

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

Summary

ID

NL-OMON31657

Source
ToetsingOnline

Brief title
DEBIUT

Condition

- Coronary artery disorders

Synonym
bifurcations lesion, coronary artery sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bifurcation, PCI

Outcome measures

Primary outcome

Angiographic evaluation of reduction of vessel diameter at 6 months follow-up

at the treated segments (incidence of late Lumen Loss)

Secondary outcome

Target vessel failure at 6 months follow up.

The incidence of Major Adverse Coronary or Cerebral events (MACCE) at 6

month follow up.

Study description

Background summary

Within the field of Percutaneous Coronary Interventions the treatment of bifurcation lesions remains challenging. Not only regarding - acute- technical outcomes but also
long term results regarding an increased risk for restenosis and with the widespread use of DES a higher chance of late stent thrombosis and maybe even higher late mortality.

With the introduction of Drug Eluting Balloons there is the potentially interesting option not only to change the technique (only provisional stenting) but also influencing long term results because the use of only one stented segment reduces complexcity of the procedure. Without using multiple DES the risk of subacute stent thrombosis is also lower and therefore need for prolonged (livelong ?) dual antiplatelet therapy is reduced.

Recently the Dior balloon was CE approved , a paclitaxel coated balloon which showed a remarkebly efficacy in reducing restenosis in patients with in stent restenosis .
(Scheller et al, Treatment of coronary in-stent restenosis with a paclitaxel-coated balloon catheter; New England Journal of Medicine 2006 Nov 16 2149-51).
The study question will be if the incidence of restenosis in bifurcation lesions will be reduced also when using this balloon, without a higher risk of late thrombosis.

Study objective

Evaluation of provisional T stenting using a bare metal stent in combination with a paclitaxel eluting balloon compared with a normal balloon. And comparing a bare metal stent in combination with a paclitaxel eluting balloon with a paclitaxel elutin gstent in combination with a normal balloon.

Study design

Randomised prospective study with 3 arms.

Intervention

Comparison of three groups :

Group A : normal bare metal stent with normal balloons
Group B: normal bare metal stent with paclitaxel balloons
Group C: paclitaxel eluting stent with normal balloons

Study burden and risks

Patients will undergo a standard PCI treatment with the difference that group B will see the use of a paclitaxel eluting balloon in stead of a normal balloon. Systemical side effects of local drug delivery within the artery wall are not to be expected.
Furthermore a 6 month angiografical follow up is required for which informed consent is obtained.

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

- stable angina pectoris or unstable angina and documented ischemia or silent ischemia.
- the target lesion has a major native coronary artery (>2.5 mm) with a stenosis > 50% (on visual assessment) located at a side branch (>2 mm).
- de novo lesion

Exclusion criteria

- in stent restenosis of target lesion
- severe calcifications with an undilatable lesion during balloon predilatation (PTRA could be considered)
- untreated significant lesion greater than 50% diameter stenosis remaining proximal of distal to the target intervention.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-12-2007
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	Drug eluting Stent and Drug Eluting Balloon
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-11-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-01-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-08-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-01-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL18672.041.07