PREdilatation by high-pressure NC balloon catheter for better vessel preparation

Published: 30-12-2013
Last updated: 22-04-2024

Predilatation with high pressure NC balloons results in better lesion preparation for stent implantation and fewer malappositions thanstandard approach with standard balloon predilatation or direct stenting. The risk of late stent thrombosis and...

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

Summary

ID

NL-OMON38851

Source
ToetsingOnline

Brief title
PRE-NC study

Condition

- Coronary artery disorders

Synonym
coronary disease, stenosis

Research involving
Human

Sponsors and support

Primary sponsor: SIS MEDICAL AG
Source(s) of monetary or material Support: SIs Medical

Intervention

Keyword: high pressure balloon, non compliant, OCT, pre dilatation

Outcome measures

Primary outcome

- Stent apposition assessed in OCT post index procedure

- Dissection assessed in OCT post index procedure

Secondary outcome

- Procedural success - succesfull balloon delivery and predilatation, finally

postdilatation without dissection requiring additional stent implantation

- Periprocedural complications assessed in angiography, eg. slowflow, no-flow,

distal embolization, angiographic dissection

- Periprocedural MI

- Death, re-MI in 9M FU

- Re-PCI, TLR / TVR / non-TVR in 9M FU

Study description

Background summary

Proper lesion preparation for stent implantation is considered crucial for percutaneous coronary intervention procedure. Good lesion preparation allows proper stent deployment and apposition, and avoiding kinking or early struts malapposition in the area of implanted stent. However, in the past over 75% of stents were found to not reach their intended diameter.
Nowadays, optimization of lesion preparation becomes a crucial part of PCI procedure. If a lesion is prepared properly, the risk of malapposition is reduced.
New vascular imaging possibilities including OCT are available that can be employed to optimize the stent deployment first time around, avoid malapposition and reduce the need for postdilatation. There are several methods of lesion preparation, used by operators. Standard balloon catheter is most

common device which is used for predilatation. Cutting balloons or rotablation are available for calcified lesions. Also, better stent apposition could be achieved by high pressure postdilatation. In the PRE-NC Study the hypothesis that high pressure predilatation by a
dedicated, non compliant (NC) balloon catheter could help with better lesion preparation will be investigated. If the results of the Study demonstrate
PRE-NC Study Protocol ver 1.0 from 12.04.2013 Page 9 of 33 significant benefit from high pressure predilatation during lesion preparation, this strategy could become a standard part of PCI procedures in future.

Study objective

Predilatation with high pressure NC balloons results in better lesion preparation for stent implantation and fewer malappositions than standard approach with standard balloon predilatation or direct stenting. The risk of late stent thrombosis and need for reinterventions
in long term FU could be reduced.

Study design

1:1 randomized study, two groups - study group treated with BEO and OPN balloons, control group treated with standard balloons.

Study group treatment:
- predilatation with BEO at least 24 atm and optionally with OPN
- coronary stent implantation (DES or BVS) - only currently marketed devices
- optionally low-pressure postdilatation with standard balloon (up to nominal pressure)

Control group treatment:
- optionally predilatation with standard balloon according to Investigator opinion and daily practice in the Center
- coronary stent implantation (DES or BVS) - only currently marketed devices
- optionally postdilatation with standard or NC balloon according to Investigator opinion and daily practice in the Center

Intervention

Study Group - predilatation
Target lesion preparation in study group should be performed by inflation of BEO high pressure NC balloon catheter with pressure at least 24 atm. If this inflation does not prepare target lesion optimally, which is defined as residual stenosis less than 30% (visual estimation), additional predilatation by OPN balloon catheter should be performed up to 35 atm. to obtain optimal lesion preparation.

Control Group - predilatation
Target lesion preparation in control group could be performed by inflation of standard balloon catheter, according to operator decision and local practice. Direct stenting strategy in this group is possible too.

Secondary device treatment - Stenting
For the both, study and control group, stenting with commercially available, CE marked drug eluting stent or bioresorbable vascular scaffold should be performed.

The diameter of stent(s) selected should be as close to a 1:1 ratio vs. vessel RVD as possible. The type of DES or BVS and the inflation pressure/duration parameters used during stenting remain at operator discretion.

Study burden and risks

.

Contacts

Public
SIS MEDICAL AG

Im Holderli 23
Winterthur CH-8405
CH
Scientific
SIS MEDICAL AG

Im Holderli 23
Winterthur CH-8405
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patient must be >18 years of age
- Patient is willing to comply with specified follow-up evaluations;
- Patient has stable or unstable angina diagnosed
- De novo lesion
- Vessel diameter between 2.25 and 4.0 mm
- Lesion qualified for predilatation or for direct stenting strategy are allowed
- Patient has no more than two-vessel disease and no more than one lesion per vessel
- Patient with target lesion localized in bifurcations can be enrolled to the study
- The subject has been informed of the nature of the study and has been provided and signed written informed consent approved by the appropriate Ethics Committee (EC)

Exclusion criteria

- Visible thrombus in angiography
- Total occlusion
- More than one lesion in target vessel
- Diagnosis of myocardial infarction
- Pregnant or nursing patient or planned pregnancy in the period up to 1 year following index procedure
- Patient with contraindications for 12 months of dual antiplatelet therapy
- Patient with contraindications for DES or BVS implantation

Study design

Design

Study phase:	4
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):	25-02-2014
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	High-pressure NC Balloon
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	30-12-2013
Application type:	First submission
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	NL45068.041.13