Dual source multi-slice CT angiography for non-invasive evaluation of coronary stent patency at 6 months comparing two abluminal coated drug eluting stents: Synergy* versus Nobori*.

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To test the non-inferiority of the Synergy* abluminal coated everolimus eluting stent with bio-absorbable polymer from Boston Scientific compared to the Nobori* abluminal coated biolimus eluting stent with bio-absorbable polymer from Terumo in the...

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

Summary

ID

NL-OMON37096

Source
ToetsingOnline

Brief title
DELICATE

Condition

- Coronary artery disorders

Synonym
Atherosclerosis, coronaropathy

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Boston Scientific Cooperation International,De producerende firma's van beide stents gebruikt in het onderzoek.,Jeroen Bosch Ziekenhuis,Terumo International

Intervention

Keyword: Drug eluting stents, Dual source multi-slice CT, stent patency

Outcome measures

Primary outcome

The primary outcome is the difference in in-stent late lumen loss at 6 months

between the Synergy* DES and the Nobori* DES .

Secondary outcome

1. In-stent late lumen loss at 6 months detected by dual source MSCT compared

to IVUS

2. Stent related target vessel failure rate (cardiac death, myocardial

infarction (MI) related to target vessel and target vessel re-intervention

(TVR)) at 12 months post stent implantation.

3. Stent thrombosis (ST) rate using Academic Research Consortium (ARC)

definition (definite/probable with no censoring for Target Lesion

Re-vascularization).

4. Overall mortality

Study description

Background summary

Cardiovascular disease (CVD), of which coronary heart disease (CHD) is the most

common, is the major cause of death in adults in most European countries.1 By the year 2000, CVD caused more than 4.35 million deaths annually in Europe (1.9 million in the European Union) and accounted for 43% of all deaths in men and 55% in women of all ages. One-year mortality in subgroups may be up to 20% per year.2 Although CHD mortality is declining in the majority of European countries, the actual number of patients with CHD has been increasing. This is caused by several factors: aging of the populations, later onset of clinical manifestation of the disease, and improved prognosis of individuals afflicted. CVD is an important cause of disability and contributes substantially to the escalating costs of healthcare.3 Treatment strategies consist of medical therapy alone or, frequently in combination with surgical or percutaneous revascularization.
Percutaneous coronary intervention (PCI) is a well-established treatment for obstructive coronary artery disease both in emergency and elective settings. The outcome of percutaneous revascularization is divers and depends on several known and unknown factors. After percutaneous revascularization of a coronary artery, a restenosis may occur due to intimal hyperplasia, leading to late lumen loss, ultimately leading to angina pectoris, or even a (repeat) myocardial infarction.
The initial treatment with balloon angioplasty alone was associated with extremely high restenosis rates of up to 50%, in addition to high procedural complications. The use of bare metal stent as scaffold to maintain coronary patency dramatically improved the short term result of coronary interventions. However, the medium and long term restenosis rates remained relatively high. The endeavour to further increase the procedural and long term success rates led to improvements in stent platform, the delivery system, and in early 2000*s the emergence of drug eluting stents. The latter being mainly responsible for considerable reduction in the rate of in-stent restenosis4, 5 To assess the stent functionality, frequently a repeat angiography and intravascular ultrasound (IVUS) analysis is performed to evaluate the result of PCI or medical therapy and to assess progression of the coronary lesions. This is due to the fact that up until now non-invasive testing, does not enable physician to make sufficient reliable assumptions of the lumen patency.

Study objective

To test the non-inferiority of the Synergy* abluminal coated everolimus eluting stent with bio-absorbable polymer from Boston Scientific compared to the Nobori* abluminal coated biolimus eluting stent with bio-absorbable polymer from Terumo in the treatment of de novo coronary artery lesions.
The secondary objective of the study is to validate the accuracy of the non-invasive angiography using a dual source 2x128 slice Computerized Tomography versus Intra Vascular Ultra Sound techniques in evaluating coronary stent patency of two new generation drug eluting stents with different platforms and drugs at 6 months post implantation.

Study design

Single center, prospective open 1:1 randomized controlled trial.

Intervention

Coronary intervention with stenting.

Study burden and risks

Participating patients will be asked to return to the hospital for one day at 6 months after the initial treatment, where they will receive a repeat coronary angiography and a subsequent repeat coronary CT scan. Therefore the radiation burden for the individual patient wille be somewhat higher than in patients not participating in this study.

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

1. age at least 18 years;
2. undergoing a planned elective PTCA procedure
3. signed written informed consent.

Exclusion criteria

1. Heavily calcified lesion detected at the time of angiography;
2. Vessels with a reference lumen smaller than 2.5 mm;
3. In-Stent restenosis.
4. Bifurcation lesions requiring stenting of both main branch and side branch.
5. Patients with renal function impairment, defined as a GFR <45 mL/min.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2012
Enrollment:	128
Type:	Actual

Medical products/devices used

Generic name:	Coronary stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	05-11-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL41959.028.12