The influence of Stentys self-apposing stent on the lipid-core burden index assessed with near-infrared spectroscopy: could Stentys potentially prevent periprocedural MIs?

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1) To investigate the differences in lipid content of the plaques after placement of a Stentys self-apposing stent. 2) To investigate whether there is a correlation between the decrease lpid-core content and the increase in cardiac biomarkers (...

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

Summary

ID

NL-OMON39928

Source
ToetsingOnline

Brief title
Influence of Stentys on the lipid-core burden index

Condition

- Coronary artery disorders

Synonym
atherosclerosis of the coronary arteries, coronary artery disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: lipid-core burden, Near-InfraRed Spectroscopy, Peri-procedural myocardial infarction, Stentys Stent

Outcome measures

Primary outcome

* Differences the maximum value of LCBI for any of the 4-mm segments in the

treated segment (max 4mm LCBI) pre- and post Stentys placement:

Secondary outcome

* Differences the maximum value of LCBI for any of the 4-mm segments in the

treated segment (max 4mm LCBI) pre- and post PCI.

* Differences in max 4mm LCBI pre- and post PCI in large lpid core plaques

(LCPs)

* Correlation between differences in max 4mm LCBI and peri-procedural MI:

Study description

Background summary

Previous studies have shown that there are large differences in lipid core content pre- and post-PCI. This difference is associated with distal embolization and periprocedural MIs. The presumed mechanism of MI after PCI of large LCPs is distal embolization of lipid contents released during PCI. Another mechanism has also been hypothesized; manipulation of lesions with large LCPs liberates atheromatous material which can stimulate thrombus formation which subsequently embolizes distally. The hypothesis of the current observational study is that the use of a self-expanding stents such as the Stentys stent is associated with less decrease of lipid-content of the plaque, when compared with balloon expendable stent, due to less outward force.

Study objective

1) To investigate the differences in lipid content of the plaques after placement of a Stentys self-apposing stent.
2) To investigate whether there is a correlation between the decrease lpid-core content and the increase in cardiac biomarkers (occurence of peri-procedural MIs) after PCI.

Study design

This is a prospective single center observational study, which evaluates the differences of lipid content of a coronary atherosclerotic plaque after PCI with a Stentys stent. Patients are eligible if they have a clinical diagnosis of stable angina in whom a percutaneous coronary intervention is clinically indicated. After coronary angiography, NIRS measurements of the culprit lesion(s) are performed prior to PCI. After PCI and post-dilation, second and third NIRS measurements are done of the stented lesions to evaluate the decrease in lipid-core content.

Study burden and risks

Because a NIRS measurement is performed three times during the procedure, the procedural time is prolonged with approximately 5 minutes (fluoroscopy time with 1 minute). Although introducing an image catheter such as the NIRS potentially increase the risk of dissections, we consider the additional risk of NIRS imaging in the current protocol as being marginal, since the guidewires are already introduced to treat the lesion. Furthermore, we would like to emphasize the NIRS to be CE-marked and fully FDA-proved. The extra radiation burden due to prolongment of the procedure will be calculated separately.

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. Patients with stable angina due to coronary artery stenosis.
2. Indication for PCI to treat this stenosis is set by the local heart team.
3. The lesion could be treated with a single Stentys stent

Exclusion criteria

1. Impaired renal function (eGFR <60 mls/min/1,73 m2)
2. Known allergies to aspirin, all thienopyridines (Plavix ®, Effient ®), heparin, stainless steel, copper or a sensitivity to contrast media which cannot be adequately pre-medicated
3. Disabling stroke within the past year
4. History of significant gastro-intestinal bleeding, bleeding diathesis or coagulopathy
5. Any prior bypass graft surgery
6. Prior or planned heart transplant or any other organ transplant
7. Planned major non-cardiac (for example oncological) surgery
8. Women who are pregnant or women of childbearing potential who do not use adequate contraception
9. Severe calcified lesions in which aggressive pre-dilatation with balloons is necessary.
10. Restenosis of a (previously treated) culprit lesion
11. Untreated left main disease with * 50% stenosis
12. Known tendency for coronary vasospasm

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-04-2013
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	13-03-2013
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	NL42654.018.12