

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

Published: 14-02-2013

Last updated: 24-04-2024

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 lipid-core content and the increase in cardiac biomarkers (...)

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Coronary artery disorders
<b>Study type</b>	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 lipid 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 expandable 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 lipid-core content and the increase in cardiac biomarkers (occurrence 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

### Public

Academisch Medisch Centrum

Meibergdreef 9  
Amsterdam 1105AZ  
NL

### Scientific

Academisch Medisch Centrum

Meibergdreef 9  
Amsterdam 1105AZ  
NL

## 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