A 9 months follow-up study of the Tryton Side branch Stent, a dedicated bifurcation stent, with optical coherence tomography and 3D quantitative coronary angiography

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This study has the following objectives:1. To investigate whether stent (mall)apposition is predictive for strut uncoverage. 2. To investigate the *distribution* of mallapposed struts in both Tryton as conventional stent. 3. To investigate the...

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

Summary

ID

NL-OMON35834

Source
ToetsingOnline

Brief title
A 9 months OCT and 3D QCA follow up study of Tryton stent.

Condition

- Coronary artery disorders

Synonym
bifurcation stenosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 3D QCA, Bifurcation, OCT, Tryton stent

Outcome measures

Primary outcome

• Strut apposition as predictor strut uncoverage.

Secondary outcome

• Correlation of strut apposition in different segments.

• Maximum neointimal hyperplasia [NIH] thickness (µm) as predictor for Minimal

lumen area (MLA, in mm2).

Study description

Background summary

The treatment of bifurcation lesions is one of the unsolved challenges for interventional cardiologists. Fifteen to twenty percent of the percutaneous coronary interventions (PCI) are performed to treat bifurcation lesions. Patients with bifurcation lesions tend to have more advanced disease and multiple co-morbidities. Furthermore, bifurcation lesions have been associated with lower procedural success and a poorer clinical outcome than non-bifurcation lesions. Therefore new dedicated bifurcation stents are designed. Some are already on the market, like the Tryton Side Branch stent. The idea behind its specific design is that it will provide optimal scaffolding at the carina, with well-apposed struts and also the number of the struts limited.

Study objective

This study has the following objectives:
1. To investigate whether stent (mall)apposition is predictive for strut uncoverage.

2. To investigate the *distribution* of mallapposed struts in both Tryton as conventional stent.
3. To investigate the correlation between OCT-derived maximal neointimal hyperplasia thickness and 3D QCA-derived minimal lumen area.

Study design

This is a prospective observational study which evaluates stent apposition, neointimal strut coverage and in-stent restenosis in the new Tryton Side Branch StentTM after 9 months follow up using optical coherence tomography. All patients with a bifurcation lesion who are treated with a Tryton Side Branch Stent in our center are eligible for this study. All these patients are undergoing nine month follow-up angiography, according to standard clinical practice for patients with complex lesions. Before angiography, written informed consent is obtained. In addition to the angiography, OCT is performed of the stented bifurcation lesion to obtain information about stent apposition, strut coverage and restenosis. During the angiography we obtain angiographic views to reconstruct a 3D image of the treated bifurcation lesion.

Study burden and risks

2 guide wires are introduced: 1 in the side branch and 1 in the main vessel, which gives a small chance of dissection, like always when guide wires are introduced in the coronary arteries. The follow up coronary angiography is extended with 5 minutes. So, the extra radiation burden is limited, the fluroresence time is prolonged with only 1 minute. With the introduction of two guidewires, there is always a minimal change for dissection or other complications which are related to coronary catheterization. For the OCT, 16ml of extra contrast is used for each vessel.

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 a bifurcation lesion which are treated with the Tryton Side Branch Stent.

Exclusion criteria

general exclusion criteria:
1. Patients participating in the Tryton IDE trial.
2. Any intercurrent revascularization involving of the Tryton-treated bifurcation lesion
Exclusion criteria related to the optical coherence tomography:
1. Impaired renal function (eGFR <60 ml/min/1,73m2)
2. Any other contra-indication for Optical Coherence Tomography, at discretion of the operator

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-02-2012
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	24-10-2011
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	NL35959.018.11