Self-exPAndable Coronary stentIng in subacute and chrOnic total occlusions; a pilot study

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The objective for the study is to establish a proof of concept for the use of self-expandable stenting in subacute to chronic total occlusions and evaluate the safety and effectiveness of the STENTYS Coronary Stent System in the treatment of these...

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

Summary

ID

NL-OMON40524

Source
ToetsingOnline

Brief title
SPACIOUS

Condition

- Coronary artery disorders

Synonym
Coronary artery Chronic Total Occlusion, Coronary chronic occlusion

Research involving
Human

Sponsors and support

Primary sponsor: Albert Schweitzer Ziekenhuis
Source(s) of monetary or material Support: Medische Hulpmiddelen industrie (STENTYS)

Intervention

Keyword: Chronic total occlusions, Pilot study, Self-expanding, Stent

Outcome measures

Primary outcome

The primary endpoint will be mean lumen area gain at 4-6 weeks follow-up, measured by OCT. We hypothesize that this gain will be similar to the average 11.5% gain found in Apposition II, evaluated the STENTYS BMS with OCT after implantation for a STEMI.

Secondary outcome

Secondary endpoints include assessment of both safety and effectiveness endpoints, specifically:

1. Major Adverse Cardiac Events (MACE): defined as cardiac death, MI, emergent bypass surgery (CABG), or clinically driven target lesion revascularization (TLR) by percutaneous or surgical methods at discharge, 4-6 weeks, 6 and 12 months post-procedure.

2. Target vessel failure (TVF), defined as cardiac death, target vessel myocardial infarction (MI) [Q or Non Q-Wave], or clinically driven target vessel revascularization (TVR) by percutaneous or surgical methods at discharge, 4-6 weeks, 6 and 12 months post-procedure.

3. Success Rates:

4. Device Success: Attainment of <30% final residual stenosis of the segment of the culprit lesion covered by the STENTYS Stent, by visual estimation.

5. Procedure Success: Device success and no-peri-procedural complications.

6. Clinical Success: Procedural success and no in-hospital MACE.

7. Reperfusion post-procedural measured by TIMI flow.

8. Stent thrombosis at discharge, 4-6 weeks, 6 and 12 months post-procedure.

9. Imaging parameters (MLD, ISA, % stenosis) at the end of the procedure and

4-6 weeks

10. Presence of coronary spasm.

11. Presence of slow flow, no reflow phenomena

12. Mean and minimum lumen and stent area as measured by OCT at the end of the

procedure and after 4-6 weeks

13. Stent malapposition at the end of the procedure and 4-6 weeks.

Malapposition is defined as more than 5% mallaposed stent struts under OCT

Study description

Background summary

The treatment of subacute or chronic total coronary occlusion, defined as those coronary occlusions which exist for more than three days or more than three months, remain a topic for hot debate. The first issue is selecting those patients who benefit from opening such an occlusion. Data from the OAT trial shows that routine treatment of these occlusions does not improve rates of clinical events in patients without severe inducible ischemia. Patients with a CTO who, despite maximal medical therapy, remain symptomatic appear to benefit from successful revascularization, improving symptoms and survival as well as left ventricular function. A recently published study showed a difference in 5-year mortality of 17,2% after unsuccessful and 4.5% after successful CTO recanalization.
Analysis of quantitative coronary angiography data has shown that, after successful coronary revascularization of a CTO, distal vessel diameter increases 12-18% over time. This increase is explained by endothelial and smooth muscle cell dysfunction which is present directly after recanalization and only partially recovers over time. This impaired vasomotion suggest difficulties in choosing the correct stent size while it is known that undersizing of a coronary stent leads to incomplete apposition and stent thrombosis. Stent thrombosis is recognized as a potential fatal complication of PCI, occurring after 1.7% of treated CTOs. It is our hypothesis that this

stent sizing dilemma can be alleviated by the use a self-expandable stent. The first case-report of a CTO treated with a STENTYS stent showed promising results with an 24% increase in mean lumen area after seven days when evaluated with Optical Coherence Tomography (OCT), combined with excellent stent apposition (A.J.J. Ijsselmuiden, EuroPCR 2013). This warrants the need for a study examining the treatment of CTOs with the STENTYS self-expanding stent evaluating stent apposition, stent growth in the treated segment and vessel growth distal of the treated segment.

Study objective

The objective for the study is to establish a proof of concept for the use of self-expandable stenting in subacute to chronic total occlusions and evaluate the safety and effectiveness of the STENTYS Coronary Stent System in the treatment of these subacute to chronic total occlusions in coronary arteries.

Study design

This is a prospective, mono-centre, observational study consisting of one arm of 20 patients. Patients will be treated with the self expanding STENTYS DES(P).

Intervention

Patients meeting all selection criteria will receive a STENTYS DES stent

Study burden and risks

The physical examination procedure takes place and some questions about the history of the patients are asked. Then
the (index) procedure will be performed during which an angiography will be made (=standard).
During the 4-6 week follow-up an angiogram will be made and OCT imaging is performed. At this time questions regarding medication, and adverse events en overall physical wellbeing will be asked.
Six months after the procedure questions will be asked regarding medication, and adverse events en overall physical wellbeing. This will be
repeated 1 year after the procedure.

Contacts

Public
Albert Schweitzer Ziekenhuis

albert schweitzerplaats 25
Dordrecht 3318 AT
NL
Scientific
Albert Schweitzer Ziekenhuis

albert schweitzerplaats 25
Dordrecht 3318 AT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Patient with a total or subtotal occlusion as evidenced by angiography and under optimal drug regimen amenable for revascularization.
2. Subject >=18 years.
3. Reference vessel diameter >=2.5mm and <=6mm preferably measured by QCA, or if QCA not possible by visual estimate.
4. Subject understands the nature of the procedure and provides written informed consent prior to the procedure.
5. Subject is willing to comply with specified follow-up evaluation and can be contacted by telephone

Exclusion criteria

1. Acute coronary syndromes, but not post-infarction AP
2. Cardiogenic shock.
3. Any vasculature lesions or characteristics preventing PCI, introduction of the STENTYS delivery system or placement of the STENTYS Stent.
4. Allergies or contraindications to antiplatelet medication, contrast or to stent components

which cannot be adequately treated.
5. Female patient with child bearing potential not taking adequate contraceptives.
6. Participation in another investigational drug or device study in which the primary endpoint has not been reached yet and that interferes with this study.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-04-2014
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	29-01-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL47306.101.13