Tryton I, A first in man clinical evaluation of the TRYTON * Sidebranch stent.

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The primary objective of this registry trial is to assess the safety and effectiveness of the Tryton sidebranch stent in de novo native coronary bifurcated lesions.

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

Summary

ID

NL-OMON30192

Source
ToetsingOnline

Brief title
Tryton I

Condition

- Coronary artery disorders

Synonym
bifurcation

Research involving
Human

Sponsors and support

Primary sponsor: Tryton Medical, Inc.,
Source(s) of monetary or material Support: Tryton Medical Inc.

Intervention

Keyword: bifurcation lesion, sidebranch stent

Outcome measures

Primary outcome

Composite Endpoint- *Procedural Success*

- Successful deployment of the Tryton sidebranch

- Angiographic Success: <30% residual stenosis in main vessel and sidebranch

and TIMI 3 flow post-procedure

- Without in-hospital Major Adverse Cardiac Event (MACE)

Secondary outcome

Clinical Parameters:

- Non-MACE, Serious Adverse Events (SAE) at hospital discharge

- MACE and Anginal Status at post procedure and up to nine (9) months

Angiographic Parameters

- Acute IVUS Success

- Angiographic restenosis at six months

- Volumetric Late Loss by IVUS at six months

- In-stent and vessel segment percentage DS (diameter stenosis) post-procedure

Study description

Background summary

Bifurcation lesions, i.e., lesions involving a significant side branch diameter >= 2.2 mm occur in approximately 15% of all coronary lesions considered for

percutaneous intervention. Since a side branch (SB) of this diameter provides blood supply to a significant myocardial territory, failure to preserve SB vessel patency has been associated with significant complications Early interventional experience using balloon angioplasty (PTCA) for the treatment of bifurcation lesions were associated with higher rates of acute complications in the side branch, restenosis and target vessel revascularization due to complications with the SB The data that is available for DES placements in a SB suggest that the results for SB stenting were not as favorable. This study and others suggest that the outcomes are related to the way the stents sit within the vessel and fit together in the difficult bifurcation anatomy.
Therefore a stent designed specifically for bifurcation lesions will be needed to reduce restenosis rates and improve long term outcomes.

Study objective

The primary objective of this registry trial is to assess the safety and effectiveness of the Tryton sidebranch stent in de novo native coronary bifurcated lesions.

Study design

This is multi-center, prospective, non-randomized single arm study. This study will involve the collection of demographic, clinical, and angiographic data on the targeted patient population. Patients will be followed up clinically for 9 months post -procedure and receive a control angiography at 6 months post-procedure. Approximately 30, patients from maximum 3 centers will be included in the study.

Intervention

The Tryton sidebranch stent is developed to treat bifurcation lesions. The Tryton stent itself will be placed in the sidebranch. The Cypher stent will be placed in the main vessel.

Study burden and risks

The possible risks are not different from other stent implants as mentioned in the brochure of the Nederlandse Hartstichting
- Death 0.2%-0.5%
- MI during the intervention
- Haematoma at the access site
- Major bleedings due to anti coagulance medication given during or after the procedure

The possible risks related to the medication
The standard medication that you will receive (aspirin and clopidogrel,or

ticlopidine) is meant to minimize the likelihood of clot formation at the stent site. This medication is standard for patients who receive a stent.
- Aspirin mincrease the likelihood of gastrointestinal adverse effects and bleeding.
- A recent study with Clopidogrel showed that this medication shows less adverse events tnen Asperin
- Clopidogrel is uncommonly associated with rash, diarrhea, nausea, vomiting, stomach pain, and blood disorder

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

Patients from 18- 85 years of age.
Patients with symptomatic ischemic heart disease and/or objective evidence of myocardial

ischemia.
Treatment of a single de novo lesion involving a side branch.
Main vessel target lesion is located in a native coronary artery.

Exclusion criteria

Totally occluded vessel
Excessive tortuousity
Evidence of thrombus
A significant > 50% stenosis proximal or distal to the target lesion.
Females who are pregnant or nursing or females of childbearing potential

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):	11-10-2006
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	05-10-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL13681.078.06