A Prospective, Single Blind, Randomized Controlled Study to Evaluate the Safety and Effectiveness of the Tryton Side Branch Stent* used in Conjunction with a Drug-Eluting Stent Compared to Side Branch Balloon Angioplasty in Conjunction with a Drug-Eluting Stent in the Treatment of de novo Bifurcation Lesions Involving the Main Branch and Side Branch within the Native Coronary Circulation

Published: 22-04-2011
Last updated: 04-05-2024

To demonstrate the safety and effectiveness of the Tryton Side Branch Stent* with main branch approved DES compared to side branch balloon angioplasty and main branch approved DES in the treatment of de novo native coronary artery bifurcation...

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

Summary

ID

NL-OMON37935

Source
ToetsingOnline

Brief title
Tryton Side Branch Stent* Compared to Side Branch Balloon Angioplasty

Condition

- Coronary artery disorders

Synonym
Treatment of de novo Bifurcation Lesions Involving the Main Branch and Side Branch within the Native Coronary Circulation

Research involving
Human

Sponsors and support

Primary sponsor: Tryton Medical Corporate Headquarters
Source(s) of monetary or material Support: Tryton Medical

Intervention

Keyword: Bifurcation, Coronary, Stent, Tryton

Outcome measures

Primary outcome

Primary Endpoint:

Target Vessel Failure (TVF) defined as the composite of cardiac death, target vessel myocardial infarction (Q wave or non-Q wave) and target vessel revascularization (main branch or side branch) of the Tryton Side Branch Stent* with main branch DES compared to side branch balloon angioplasty and main branch DES at 9 months.

Secondary outcome

Secondary Endpoints:

Powered Secondary Angiographic Endpoint (Angiographic Cohort):

In-segment % diameter stenosis of the Tryton Side Branch Stent* compared to side branch balloon angioplasty at 9 months post-procedure.

Safety:

1. All-cause and cardiac mortality at 30 days, 6 and 9 months, and annually up to 5 years;

2. Myocardial infarction (MI): Q-wave and non-Q-wave, cumulative and individual at 30 days, 6 and 9 months, and annually up to 5 years;

3. Major Adverse Cardiac Event (MACE) defined as a composite of all cause death, MI (Q wave or non-Q wave), emergent coronary artery bypass surgery (CABG), or target lesion revascularization (TLR) by repeat PTCA or CABG at hospital discharge, 30 days, 6 and 9 months, and annually up to 5 years;

4. The composite of cardiac death, myocardial infarction (Q wave or non-Q wave) > 30 days post-procedure, stent thrombosis, and target vessel revascularization (main branch or side branch);

5. Rates of stent thrombosis using ARC definition of definite and probable stent thrombosis and categorized as early, late or very late, at 30 days, 6 and 9 months, and annually up to 5 years.

Effectiveness:

6. Device success, defined as attainment of <30% residual stenosis within the side branch;

7. Lesion success defined as attainment of <50% residual stenosis using any percutaneous method;

8. Procedure success defined as lesion success without the occurrence of in-hospital MACE;

9. Clinically or ischemia-driven target lesion revascularization at 30 days, 6 and 9 months, and annually up to 5 years;

10. Clinically or ischemia-driven target vessel revascularization at 30 days, 6 and 9 months, and annually up to 5 years;

11. Clinically or ischemia-driven target vessel failure (defined as cardiac death, target vessel MI (Q wave or non-Q wave) or target vessel revascularization TVR) at 30 days, 6 and 9 months, and annually up to 5 years;

12. Clinically or ischemia-driven target lesion failure (defined as cardiac death, target lesion MI (Q wave or non-Q wave) or target lesion revascularization TLR) at 30 days, 6 and 9 months, and annually up to 5 years;

13. Target lesion failure (TLF) defined as cardiac death, target lesion MI (Q wave or non-Q wave) and target lesion revascularization (TLR) at 30 days, 6 and 9 months, and annually up to 5 years.

Angiographic Cohort

14. In-stent and in-segment angiographic binary restenosis in the main branch and bifurcation lesion at 9 months;

15. In-stent and in-segment lesion minimal lumen diameter (MLD) in the side branch, main branch at 9 months;

16. In-stent, proximal and distal side branch, and main branch late lumen loss at 9 months.

IVUS Cohort

17. Percent of subjects free of stent fracture;

18. Minimum lumen cross-sectional area (CSA) within 5mm from the carina in the side branch;

19. Percent neointimal CSA at the site of the minimum lumen area;

20. Percent neointimal volume (equal to percent net volume obstruction or

neointimal volume/external elastic membrane volume) within 5mm distal to the

carina in the side branch;

21. Percent area stenosis (equal to minimum lumen area/reference area) in the

side branch;

22. Mean lumen CSA within 5mm distal to the carina in the side branch;

23. Stent apposition in the side branch and carina.

24. Stent apposition in the main branch

Study description

Background summary

This study is a post market, prospective multicenter, single blind and randomized controlled study to do research on the safety and effectiveness of the Tryton Side Branch Stent*. The Tryton Side Branch Stent* System is intended for improving coronary lumen diameter of the side branch of de novo bifurcation lesions in native coronary arteries in the side branch and in the main branch. The Tryton Side Branch Stent* is intended for use in conjunction with commercially available balloon expandable drug-eluting coronary stents (DES) in the main branch. The study will be executed in up to 704 patient in up to 50 research centers in Europe, Israel and North-America. All patients will be followed up on 30 days, 6 months, 9 months and yearly until 5 years post-procedure.

Study objective

To demonstrate the safety and effectiveness of the Tryton Side Branch Stent* with main branch approved DES compared to side branch balloon angioplasty and main branch approved DES in the treatment of de novo native coronary artery bifurcation lesions with side branch ranging in diameter from >=2.5 mm to <=3.5 mm and main branch ranging in diameter from >=2.5 mm to <=4.0 mm.

Study design

Prospective, multicenter, randomized, single blind controlled study.

Number of groups : 2

Group 1 :
treatment(s) : treatment with theTryton Side Branch StentTM plus approved main branch DES

Group 2 (control cohort) :
treatment(s) : treatment with Side branch balloon angioplasty plus approved main branch DES

Prospective, multicenter, randomized, single blind controlled study designed to enroll up to 704 subjects who will be randomized in a 1:1 fashion to the Tryton Side Branch Stent* with main branch approved DES (N=352) vs. side branch balloon angioplasty (POBA) and main branch approved DES (N=352) for treatment of native coronary artery bifurcation disease. The first 187 subjects enrolled in each arm will return for angiographic follow-up at 9 months. The first 64 subjects randomized to the Tryton cohort and the first 32 subjects randomized to the Control cohort will return for IVUS follow-up at 9 months at the same time as the angiographic follow-up at designated IVUS sites.

Total number of pts in the study: 704

Expected start date : Feb 2011
Expected end date : Nov 2017

Intervention

Prospective, multicenter, randomized, single blind controlled study.

Number of groups : 2

Group 1 :
treatment(s) : treatment with theTryton Side Branch StentTM plus approved main branch DES

Group 2 (control cohort) :
treatment(s) : treatment with Side branch balloon angioplasty plus approved main branch DES

Prospective, multicenter, randomized, single blind controlled study designed to enroll up to 704 subjects who will be randomized in a 1:1 fashion to the Tryton Side Branch Stent* with main branch approved DES (N=352) vs. side branch balloon angioplasty (POBA) and main branch approved DES (N=352) for treatment of native coronary artery bifurcation disease. The first 187 subjects enrolled in each arm will return for angiographic follow-up at 9 months. The first 64 subjects randomized to the Tryton cohort and the first 32 subjects randomized to the Control cohort will return for IVUS follow-up at 9 months at the same time as the angiographic follow-up at designated IVUS sites.

Study burden and risks

Known risks are associated with balloon inflation and stent implantation, including death (0.2 - 0.5%), heart attack (4 - 5%), or emergency surgery (0.5%). Other risks include (but are not limited to):
• Cardiac events such as inadequate or impaired blood flow to the heart causing chest pain or discomfort (angina or angina symptoms), impaired pumping ability of the heart, re-narrowing of a treated heart artery, collection of blood around the lining of the heart, injury or tear in a heart artery, tear or puncture in a heart wall, weakening and bulging in a heart artery, or an unexpected need for immediate heart surgery.
• Irregularities in the heart rhythm such as very fast or slow beating of the upper and/or the lower heart chambers, or disorganized beating of the lower heart chambers.
• Stent events such as failure to place it in the desired spot in the heart artery, clot or obstruction within the stent, unintended movement of the stent in the heart artery, losing the stent in the circulation as it is placed, inadequate expansion or fit of the stent in the heart artery.
• Respiratory events such as impaired ability of the lungs to provide oxygen for body tissues, fluid build-up in the lungs, or breathing difficulties.
• Blood vessel events such as bleeding or blood collection at catheter entry site/s in groin, high or low blood pressure, abnormal area or weakness in wall of artery, abnormal connection between an artery and vein in the groin, injury or tear in artery in groin leading to the heart, air, tissue debris, or blood clot that moves to smaller vessels away from the heart and may block flow, spasm in a vessel.
• Brain or nervous system events such as stroke, impaired brain function that improves over time, nerve injury in brain or in other body parts.
• Bleeding events such as bruising, bleeding from the catheter groin site/s, or bleeding in other body parts requiring a blood transfusion or other treatment.
• Kidney events such as impaired kidney function or kidney failure.
• Allergic or immune system events such as sensitivities or body reactions to medications given such as contrast dye, heparin, aspirin, Plavix, drug/polymer in the stent or other drugs the doctor prescribes for treating the heart artery; or fever or infection.

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 must meet ALL of the following criteria:
General Inclusion Criteria
1. The patient must be >=18 and <= 90 years of age;
2. Symptomatic ischemic heart disease (CCS class 1-4, Braunwald Class IB, IC, IIB, IIC, IIIB, IIIC, and/or have objective evidence of myocardial ischemia);
3. Acceptable candidate for CABG;
4. The intent to treat the side branch of the target bifurcation based on angiographic evaluation;
5. The patient is willing to comply with specified follow-up evaluations;
6. The patient or legally authorized representative has been informed of the nature of the study, agrees to its provisions and has been provided written informed consent, approved by the appropriate Medical Ethics Committee (MEC) or Institutional Review Board (IRB).
7. Planned use of one of the following approved and commercially available drug-eluting stents for subject*s index procedure: CYPHER®, RESOLUTE Family of products (ENDEAVOR® RESOLUTE or RESOLUTE INTEGRITY), PROMUS®, PROMUS ELEMENT Family of products (PROMUS® ELEMENT or PROMUS ELEMENT PLUS), XIENCE* V, or the XIENCE PRIME Family of products (XIENCE PRIME, XIENCE Xpedition or XIENCE PRO)

Angiographic Inclusion Criteria
8. a)Single de novo lesion in a bifurcation involving both the main branch and the side branch with

b) The bifurcation: main branch and side branch with a visual diameter stenosis >= 50% (Medina classification 1.1.1; 0.1.1; 1.0.1 by visual assessment);
9. Target lesion located in a native coronary artery;
10. a)Bifurcation lesion main branch reference vessel diameter must be >=2.5 mm to <= 4.0 mm
b) Side branch reference vessel diameter must be >=2.5 mm to <= 3.5 mm by visual estimate;
11. a) Bifurcation lesion main branch lesion length <= 28 mm
b) Side branch lesion length <= 5.0 mm (the ability to be treated with a single stent for both main and side branch);
12. Target lesion >=50% and <100% stenosed by visual estimate in both the main branch and side branch;
Refer to Protocol 1.9.5 for full list of Inclusion Criteria

Exclusion criteria

Patients will be excluded if ANY of the following conditions apply:
General Exclusion Criteria
1. Pregnant or nursing patients and those who plan pregnancy in the period up to 1 year following index procedure. Female patients of child-bearing potential must have a negative pregnancy test done within 7 days prior to the index procedure per site standard test;
2. Patient has had a known diagnosis of STEMI acute myocardial infarction (AMI) within 72 hours preceding the index procedure or >72 hours preceding the index procedure and CK and CK-MB have not returned to within normal limits at the time of procedure;
3. Patients with non-STEMI within 7 days prior to index procedure with continued CK-MB elevation;
4. Patients with non-target lesion PCI within 7 days prior to index procedure with continued CK-MB elevation;
Angiographic Exclusion Criteria
5. Left main coronary artery disease (protected and unprotected)
6. Trifurcation lesion;
7. Totally occluded target vessel (TIMI flow 0 or 1);
8. Severely calcified target lesion(s);
9. Highly calcified target lesion(s) requiring rotational atherectomy;
10. Target lesion has excessive tortuosity unsuitable for stent delivery and deployment;
11. Angiographic evidence of thrombus in the target lesion(s);
Refer to Protocol for full list of Exclusion Criteria.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-05-2011
Enrollment:	105
Type:	Actual

Medical products/devices used

Generic name:	Side Branch Stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-04-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-10-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-03-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	11-07-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-06-2013
Application type:	Amendment
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	NL34621.078.10

Study results

First publication
21-11-2016