Svelte SOAW Coronary Stent Clinical Observational Study

Published: 03-11-2009
Last updated: 04-05-2024

To evaluate the 30-day Safety and Performance of the SOAW Coronary Stent System in the treatment of de novo coronary lesions.

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

Summary

ID

NL-OMON33323

Source
ToetsingOnline

Brief title
Svelte SOAW

Condition

- Coronary artery disorders

Synonym
angina, coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Svelte Medical Systems, Inc
Source(s) of monetary or material Support: Medische hulpmiddelen industrie

Intervention

Keyword: Ischemic heart disease, PCI, Stent

Outcome measures

Primary outcome

Major Adverse Cardiac Events (MACE): defined as cardiac death, MI [Q or Non Q-wave], emergent bypass surgery, or clinically driven target lesion revascularization (TLR) by percutaneous or surgical methods at 30 days.

Secondary outcome

1. 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 6 months

2. Angiographic Restenosis rate at 6 months (for 50 patients)

3. Composite endpoint of cardiac death and MI at 30 days and 6 months post procedure

4. TLR at 30 and 180 days

5. Rates for each component of the MACE composite endpoint (cardiac death, MI, emergent coronary artery bypass graft (CABG)), and TLR at 30 days and 6 months post-procedure

6. Rates for each component of target vessel failure (TVF) composite endpoint (cardiac death, target vessel MI, TVR) reported at 30 days and 6 months post-procedure

7. Acute success rates:

a. Device Success: Attainment of < 30% final residual stenosis of the target lesion using only the Svelte Stent.

b. Lesion Success: Attainment of < 30% final residual stenosis of the target

lesion using any percutaneous method.

c. Procedure Success: Attainment of < 30% final residual stenosis of the target

lesion and no in-hospital MACE.

d. Direct Stenting Success: Attainment of < 30% final residual stenosis of the

target lesion using the Svelte Stent without predilation.

8. Bleeding or vascular complications at discharge

9. Late stent thrombosis at 6 months

10. Procedural resource utilization

11. SOAW performance evaluation at implant

Study description

Background summary

Conventional practice in PCI with stenting is to perform predilatation of the target lesion prior to stent placement. This convention was dictated by the first generation stent characteristics. The initial stent designs were large profile, stiff devices making deliverability an issue. Additionally, these stents were hand-crimped onto the balloon catheter, resulting in tenuous securement of the device onto the delivery system. 5, 6 These features made predilatation of the target lesion mandatory to permit stent placement. Current stent delivery systems allow for stent placement without predilatation, a strategy known as direct stenting.
The Svelte Medical Systems Stent-On-A-Wire (SOAW) system is a coronary stent delivery system using a fixed-wire catheter platform. The system consists of a wire, balloon, and cobalt chromium stent. The Svelte SOAW system represents the next generation iteration of fixed wire technology and is unique in that it has a direct stenting indication by design. The introduction of SOAW technology to the practice of PCI would represent a significant advance in the field.

Study objective

To evaluate the 30-day Safety and Performance of the SOAW Coronary Stent System in the treatment of de novo coronary lesions.

Study design

This is a prospective, nonrandomized, single-arm study to be conducted at a single European site.

Intervention

Studystent implantation, followed by OCT during initial procedure and 6 month follow-up angio with OCT.

Study burden and risks

It is to be expected that the risks are identitical to those of a conservative PCI with stenting, with the acception that an extra catheter is introduced (OCT). It should also be noted that a 6 month angio with OCT will be performed.

Contacts

Public
Svelte Medical Systems, Inc

127 Main Street
Chatham, NJ 07928
USA
Scientific
Svelte Medical Systems, Inc

127 Main Street
Chatham, NJ 07928
USA

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patient >18 years old.
- Eligible for percutaneous coronary intervention (PCI).
- Patient understands the nature of the procedure and provides written informed consent prior to the catheterization procedure.
- Patient is willing to comply with specified follow-up evaluation.
- Acceptable candidate for coronary artery bypass graft (CABG) surgery.
- (un)stable angina pectoris or a positive functional ischemia study.
- Male or non-pregnant female patient of non child-bearing potential.
- A number of specific Angiographic Inclusion Criteria (see protocol).

Exclusion criteria

- Currently enrolled in another trial that has not completed the primary endpoint.
- A previous coronary interventional procedure < 30 days prior to the procedure.
- The patient requires a staged procedure within 30 days post-procedure.
- The target lesion requires treatment with a device other than PTCA prior to stent placement (such as, but not limited to, directional coronary atherectomy, excimer laser, rotational atherectomy, etc.).
- Previous bare metal stent (BMS) deployment anywhere in the target vessel within the past 6 months.
- Any DES deployment anywhere in the target vessel within the past 9 months.
- Co-morbid condition(s) that could limit the patient*s ability to participate in the trial or to comply with follow-up requirements, or impact the scientific integrity of the trial.
- Concurrent medical condition with a life expectancy of <12 months.
- Documented LVEF < 30% at the most recent evaluation.
- Evidence of an AMI within 72 hours of the intended trial procedure.
- History of cerebrovascular accident or TIA <6 months.
- Specific Angiographic Exclusion Criteria, incl left main lesion (see protocol)

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):	10-11-2009
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	SOAW Coronary Stent System
Registration:	No

Ethics review

Approved WMO

Date:	03-11-2009
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	NL28452.078.09