COBRA II Study (Use of the Cobra Cobalt Super Alloy Coronary Stent System in the Treatment of Coronary Artery Disease)

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In an effort to collect safety and effectiveness information on the stent, Medlogics is conducting the Cobra II study.

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

Summary

ID

NL-OMON32730

Source
ToetsingOnline

Brief title
COBRA II Study

Condition

- Coronary artery disorders

Synonym
ischemic heart disease; stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Medlogics Device Corporation
Source(s) of monetary or material Support: Medlogics Device Corporation

Intervention

Keyword: Coronary Stent System, PCI, symptomatic ischemic heart disease

Outcome measures

Primary outcome

The primary safety and effectiveness endpoint for this study is target vessel failure (TVF), defined as cardiac death, target vessel myocardial infarction (MI), or clinically driven target vessel revascularization (TVR) by percutaneous or surgical methods within 270 days post-procedure.

Secondary outcome

1. Major Adverse Cardiac Events (MACE): defined as cardiac death, MI, emergent bypass surgery, or clinically driven target lesion revascularization (TLR) at 30, 180 and 270 days

2. TVF at 30 and 180 days

3. Acute Success Rates:

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

b. Lesion Success: Attainment of < 30% final residual stenosis of the target lesion using any percutaneous method

c. Procedure Success: Attainment of < 30% residual stenosis of the target lesion and no in-hospital MACE

4. Bleeding or vascular complications at discharge

5. Late stent thrombosis at 180 and 270 days

6. Angiographic Endpoints (on 63 subjects) at 6 months post-procedure

a. In-segment percent diameter stenosis (within the 5 mm margins proximal

and distal to stent)

b. In-stent percent diameter stenosis

c. In-segment late lumen loss

d. In-stent late lumen loss

e. In-segment binary restenosis (stenosis of >50% of the reference vessel

diameter)

f. In-stent binary restenosis

g. In-stent minimum lumen diameter (MLD)

Study description

Background summary

When a heart (coronary) artery has a narrowing that would be suitable for a non-surgical treatment, a balloon can open up the artery or a specially-designed metallic mesh tube can be used to keep the narrowing open (stent implantation). Over a period of approximately 1 to 3 months, the inner lining of the artery will grow over the stent surface and the stent will become a permanent part of the artery. Many clinical studies have been completed that show stent placement may lead to a wider channel in the artery than only using a balloon to open the artery (balloon angioplasty).

Medlogics Device Corporation received CE Mark approval for the Cobra Coronary Stent System, made of Cobalt Chromium, in February 2008. To date, there has been no clinical study of the Cobra.

Study objective

In an effort to collect safety and effectiveness information on the stent, Medlogics is conducting the Cobra II study.

Study design

The Medlogics Cobra II Study is a prospective, multi-center, non-randomized, single-arm study. 258 patients will be included and followed-up during 9 months.

Intervention

Before the procedure, the patient will have some blood drawn for tests and an electrocardiogram (ECG).

As part of the stent placement procedure, the investigator will take pictures of the coronary arteries using X-rays (coronary angiogram). If the physician determines that the narrowing in the coronary artery is suitable for stent implantation and the patient meets the entrance criteria for this study, a Cobra stent will be used to treat the narrowing.

Following the procedure the patient will be given standard medication that helps to prevent blood clots from forming inside the stent. The patient will also have blood tests 3 times and another ECG done before being discharged from the hospital.

30 days after the procedure, the patient will return for a clinic visit and will have an ECG and blood taken to check the cardiac enzymes.

6 months after the procedure, the patient will be contacted by phone and will be asked questions about any heart symptoms that the patient may have had. Of 63 study subjects, a new coronary angiogram will be taken to evaluate the stent efficiency.

9 months after the procedure, the patient will return for a clinic visit and will have an ECG and blood taken to check the cardiac enzymes.

Study burden and risks

The risks associated with using this device may be associated with the use of a coronary artery stent device or PCI procedure but are estimated no different than other coronary artery stent devices or PCI procedures, except for the 63 subjects undergoing an angiographic follow-up at 6-months post-procedure, who will be exposed to additional radiation, but of whom the results will provide extra information regarding the Cobra Stent.

Contacts

Public
Medlogics Device Corporation

3589 Westwind Boulevard
Santa Rosa, California 95403
USA

Scientific
Medlogics Device Corporation

3589 Westwind Boulevard
Santa Rosa, California 95403
USA

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

General Inclusion Criteria:
1. The subject is >= 18 years old;
2. Subject is eligible for percutaneous coronary intervention (PCI), stent placement, and emergent coronary artery bypass graft (CABG) surgery;
3. Subject has clinical evidence of ischemic heart disease, stable or unstable angina or silent ischemia;
4. The subject has a documented left ventricular ejection fraction (LVEF) >= 30%;
5. The subject or legal representative has been informed of the clinical study and the required follow-up procedures and must provide written informed consent using a form that is reviewed and approved by the Institutional Review Board/Ethics Committee (IRB/EC) for the clinical site;
6. Female subjects of childbearing potential must have a negative pregnancy test within 7 days before treatment;
7. Subject must agree to comply with the required follow-up procedures (including antiplatelet regimen) to the best of their ability, be geographically available for all study follow-up procedures and visits and not have a known medical condition that precludes completion of the required follow-up visits.;Angiographic Inclusion Criteria:
8. The lesion is either de novo or restenotic (previously unstented) in nature, located in a native coronary artery AND is >= 50% and < 100% stenosed by visual estimate or on-line QCA;
9. The target vessel reference diameter >= 2.5mm and <= 4mm by visual estimate and is

appropriate for treatment with available stent diameters of 2.5 mm, to 4.0 mm;
10. The lesion length is able to accommodate placement of a single stent;
11. The target lesion is a minimum of 15 mm from any previously placed stent;
12. The target vessel must have a Thrombolysis In Myocardial Infarction (TIMI) flow >= 2.

Exclusion criteria

General Exclusion Criteria:
1. The subject has a known hypersensitivity or contraindication to aspirin, heparin and bivalirudin, ticlopidine and clopidogrel, cobalt, nickel, chromium, molybdenum, or a sensitivity to contrast media, which cannot be adequately pre-medicated;
2. A platelet count < 100,000 cells/mm³ or > 700,000 cells/mm³, or a WBC < 3,000 cells/mm³;
3. A creatinine level > 2.5 mg/dL within 7 days prior to the index procedure;
4. Evidence of an acute myocardial infarction (MI) within 72 hours of the intended treatment (defined as: Q wave (QWMI) or any elevation of creatine kinase myocardial-band (CKMB) isoenzyme elevated above the Institution's upper limit of normal;
5. Any previous PCI (with or without stent) of the target vessel within 30 days prior to the index procedure;
6. Previous stent placement anywhere in the target lesion;
7. Previous drug eluting stent (DES) deployment anywhere in the target vessel;
8. The subject requires staged procedure of any non-target vessel within 30 days postprocedure;
9. The subject requires staged procedure of the target vessel within 9 months postprocedure;
10. The target lesion requires treatment with a device other than PTCA prior to stent placement (including, but not limited to, cutting balloon, directional coronary atherectomy, excimer laser, rotational atherectomy, thrombectomy, etc.);
11. History of a stroke or transient ischemic attack (TIA) within the previous 6 months;
12. Active peptic ulcer or upper gastrointestinal (GI) bleeding within the previous 6 months;
13. History of bleeding diathesis or coagulopathy or will refuse blood transfusions;
14. A known concurrent medical condition resulting in a life expectancy of less than 12 months;
15. Any previous or planned treatment of the target vessel with anti-restenotic therapies including, but not limited to brachytherapy;
16. The subject is currently participating in another investigational device or drug study and has not completed the primary endpoint(s) follow-up phase of that study at least 30 days prior to enrollment in this trial; or interferes with the current trial endpoints; or the subject has previously been enrolled in the study;
17. The subject has a known medical condition that will cause them to be non-compliant with the study protocol or confound the data interpretation.;Angiographic Exclusion Criteria:
18. The target vessel has evidence of thrombus or other lesions having a > 60% stenosis by visual estimate or on-line QCA;
19. Target vessel exhibiting multiple lesions with greater than 60% diameter stenosis outside of a range of 5 mm proximal and distal to the target lesion based on visual estimate or on-line QCA;

20. The target vessel has evidence (visual or QCA) of excessive tortuosity (two or more 90° bends prior to the target lesion) or is severely calcified;
21. The target lesion is in an unprotected left main, involves a side branch vessel having a diameter of > 2.0 mm or is at the aorto-ostial location.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	05-11-2008
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Cobra Cobalt Super Alloy Balloon-Expandable Coronary Stent System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	18-09-2008
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	NL24120.060.08