OMEGA: A Prospective, Multicenter Single-Arm Trial to Assess the OMEGA* Coronary Stent System for the Treatment of a Single De Novo Coronary Artery Lesion

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To evaluate the safety and effectiveness of the OMGEA Coronary Stent System for the treatment of subjects with a de novo atherosclerotic coronary artery lesion * 28 mm in length (by visual estimate) in a native coronary artery *2.25 mm to *4.50 mm...

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

Summary

ID

NL-OMON38308

Source
ToetsingOnline

Brief title
The OMEGA Clinical Trial

Condition

- Coronary artery disorders

Synonym
Angina, Coronary artery plaque

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific Europe
Source(s) of monetary or material Support: Industrie

Intervention

Keyword: Coronary artery lesion, Stent

Outcome measures

Primary outcome

The primary endpoint is nine-month target lesion failure (TLF) rate, defined as any ischemia-driven revascularization of the target lesion (TLR), myocardial infarction (MI, Q-wave and non*Q-wave) related to the target vessel, or cardiac death.

Secondary outcome

Clinical endpoints measured in hospital and at 30 days, 9 months and 12 months:

* TLR rate

* TLF rate (primary endpoint at 9 months)

* Target vessel revascularization (TVR) rate

* Target vessel failure (TVF) rate

* MI (Q-wave and non*Q-wave) rate

* Cardiac death rate

* Non-cardiac death rate

* All death rate

* Cardiac death or MI rate

* All death or MI rate

* All death/MI/TVR rate

* Stent thrombosis rate (definite or probable by Academic Research Consortium

[ARC] definitions)

Periprocedural endpoints:

* Technical success rate

* Clinical procedural success rate

Study description

Background summary

The OMEGA CSS is the next generation BSC bare coronary stent system. The new design has reduced strut thickness with addition of PtCr alloy for improved deliverability and optimal radiopacity without compromising the radial strength. The OMEGA stent is the same as the stent used in the CE Mark approved PROMUS Element and TAXUS Element CSSs, which are currently under investigation in PLATINUM and PERSEUS clinical trials, respectively. Clinical outcomes from the PERSEUS and PLATINUM trials have demonstrated the safety and effectiveness of the TAXUS Element CSS and PROMUS Element CSS respectively.
Drug-eluting stents have proven to be highly effective in the treatment of CAD by reducing clinical and angiographic restenosis. However, while DES have shown lower revascularization rates compared with BMS, the benefit of DES appears to be confined to lowering the rate of repeat intervention; death and MI rates are equivalent in patients receiving either treatment. The introduction of DES has also potentially introduced new risks. Higher rates of late ST, likely due to delayed and incomplete endothelialization, emerged as a major concern with DES. Accordingly, the required duration of dual anti-platelet therapy is considerably longer with DES than with BMS. Furthermore, it has been postulated that polymers used in DES may cause localized hypersensitivity. Bare metal stents remain a safe and effective alternative in PCI for patients with hypersensitivity to the drug or polymer of DES and for those patients who are unable to tolerate or unlikely to comply with prolonged DAPT

Study objective

To evaluate the safety and effectiveness of the OMGEA Coronary Stent System for the treatment of subjects with a de novo atherosclerotic coronary artery lesion
* 28 mm in length (by visual estimate) in a native coronary artery *2.25 mm to

*4.50 mm in diameter (by visual estimate).

Study design

A prospective, single-arm, multicenter trial to enroll 328 subjects with a de novo atherosclerotic coronary artery lesion *28 mm in length (by visual estimate) in a native coronary artery *2.25 mm to *4.50 mm in diameter (by visual estimate).The study will be considered complete (with regard to the primary endpoint) after all subjects have completed the 9-month follow-up.

Intervention

All patients will undergo a coronography and an Omega study stent will be implanted.

Study burden and risks

The risks associated to this procedure are similar to the risks related with the implantation of any other (commercial) study stent.
The burden voor de patient is minimal. The patient only has to return to the hospital for a visit once after 9 months, the other 2 visits are telephone follow-up visits.
The main difference with the regular procedure is the second blood draw after the insertion proceudre and an ECG at the 9 month FU office visit.

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

CI1.Subject must be at least 18 years of age.
CI2.Subject indicates understanding of the trial requirements and the treatment procedures and provides written informed consent before any trial-specific tests or procedures are performed.
CI3.Subject is eligible for percutaneous coronary intervention (PCI)
CI4.Subject has symptomatic coronary artery disease or documented silent ischemia.
CI5.Subject is an acceptable candidate for coronary artery bypass grafting (CABG).
CI6.Subject has a left ventricular ejection fraction (LVEF) *30% as measured within 60 days prior to enrollment.
CI7.Subject is willing to comply with all protocol-required follow-up evaluations.
AI1.Target lesion must be a de novo lesion located in a native coronary artery with a visually estimated reference vessel diameter (RVD) * 2.25 mm and *4.5 mm.
AI2.Target lesion length must measure (by visual estimate) as follows:
o 28 mm for stent diameter lengths of 2.75 mm, 3.00 mm, 3.50 mm, 4.00 mm and 4.50 mm.
o 24 mm for stent diameter lengths of 2.25 mm and 2.50 mm.
AI3.Target lesion must be in a major coronary artery or branch with visually estimated stenosis *50% and <100% with Thrombolysis in Myocardial Infarction (TIMI) flow >1.
AI4.Target lesion must be successfully pre-dilated.

Exclusion criteria

CE1. Subject has clinical symptoms and/or electrocardiogram (ECG) changes consistent with acute MI.
CE2. Subject with unstable angina or recent MI (clinically diagnosed within 3 days) must have CK/CK-MB or troponin documented prior to the procedure and are excluded if any of the following criteria are met at the time of the index procedure:
1. If CK MB >2× upper limit of normal (ULN), the subject is excluded regardless of the CK Total.
2. If CK Total >2× ULN, CK-MB must be drawn and the subject is excluded if CK-MB is abnormal.
3. If CK/CK MB results are not available at the time of the procedure, the subject is excluded

if troponin >1× ULN and the subject has at least one of the following:
* Subject has ischemic symptoms and ECG changes indicative of ongoing ischemia (e.g., >1 mm ST segment elevation or depression in consecutive leads or new left bundle branch block [LBBB])
* Development of pathological Q waves in the ECG or;
* Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality
Note: Subjects who do not have unstable angina or recent MI must still have CK/CK-MB drawn prior to the index procedure. However, the results for these subjects do not need to be available prior to the index procedure and there are no exclusion criteria based on these studies.
CE3. Subject is receiving chronic (*72 hours) anticoagulation therapy (e.g., heparin, coumadin) for indications other than acute coronary syndrome.
CE4. Subject has a platelet count <100,000 cells/mm3 or >700,000 cells/mm3.
CE5. Subject has a white blood cell (WBC) count <3,000 cells/mm3.
CE6. Subject has documented or suspected liver disease, including laboratory evidence of hepatitis.
CE7. Subject is on dialysis or has known renal insufficiency (e.g. serum creatinine level >2.0 mg/dL).
CE8. Subject has active peptic ulcer disease, an active gastrointestinal (GI) bleed, other bleeding diathesis or coagulopathy or will refuse transfusions.
CE9. Subject has had a cerebrovascular accident (CVA) or transient ischemic attack (TIA) within the past 6 months, or has any permanent neurologic defect that may cause non-compliance with the protocol.
CE10. Target vessel (including side branches) has been treated with any type of PCI (e.g., balloon angioplasty, stent, cutting balloon, atherectomy) within 12 months prior to the index procedure.
CE11. Target vessel has been treated within 10 mm proximal or distal to the target lesion (by visual estimate) with any type of PCI (e.g., balloon angioplasty, stent, cutting balloon, or atherectomy) at any time prior to the index procedure.
CE12. Non-target vessel or side branch has been treated with any type of PCI (e.g., balloon angioplasty, stent, cutting balloon, atherectomy) within 1 day prior to the index procedure.
Note: One lesion in a non-target vessel may be treated during the index procedure prior to the treatment of the target (study) lesion.
CE13. Planned or actual target vessel treatment with an unapproved device, directional or rotational coronary atherectomy, laser, cutting balloon, or transluminal extraction catheter immediately prior to stent placement.
CE14. Planned PCI or CABG after the index procedure.
CE15. Subject previously treated at any time with coronary intravascular brachytherapy.
CE16. Subject has known allergy to the study stent system or protocol-required concomitant medications (e.g., stainless steel, platinum, chromium, nickel, iron, thienopyridines and ASA) and contrast (that cannot be adequately premedicated).
CE17. Subject has any other serious medical illness (e.g., cancer, congestive heart failure) that may reduce life expectancy to less than 12 months
CE18. Subject has current problems with substance abuse (e.g., alcohol, cocaine, heroin, etc.)
CE19. Subject has a planned procedure that may cause non-compliance with the protocol or confound data interpretation.

CE20. Subject is participating in another investigational drug or device clinical trial that has not reached its primary endpoint or intends to participate in another investigational drug or device clinical trial within 12 months after the index procedure.
CE21. Subject is female of childbearing potential with a positive pregnancy test within 14 days before the index procedure, is lactating, or intends to become pregnant during the study.
CE22. Subject has more than 1 target lesion, or more than 1 target lesion and 1 non-target lesion, which will be treated during the index procedure.
AE1. Target lesion meets any of the following criteria:
o Aorto-ostial location (i.e., lesion located within 5 mm of the ostium by visual estimate)
o Left main location
o Located within 5 mm of the origin of the left anterior descending (LAD) coronary artery or left circumflex (LCX) coronary artery or RCA by visual estimate
o Located within a saphenous vein graft or an arterial graft
o Will be accessed via a saphenous vein graft or an arterial graft
o Involves a side branch *2.0 mm in diameter by visual estimate
o Involves a side branch <2.0 mm in diameter by visual estimate that has a clinically significant stenosis at the ostium
o TIMI flow 0 (total occlusion) or TIMI flow 1 prior to guide wire crossing
o Excessive tortuosity proximal to or within the lesion
o Extreme angulation proximal to or within the lesion
o Target lesion and/or target vessel proximal to the target lesion is moderately to severely calcified by visual estimate
o Restenotic from previous intervention
o Thrombus, or possible thrombus, present in the target vessel
o Target lesion cannot be covered by a single study stent (unplanned bailout stenting is allowed)
AE2. Non-target lesion to be treated during the index procedure meets any of the following criteria:
o Located within the target vessel
o Located within a bypass graft (venous or arterial)
o Left main location
o Chronic total occlusion
o Involves a complex bifurcation (e.g., bifurcations requiring treatment with more than 1 stent)
o Requires additional unplanned stents (treatment of the non-target lesion with more than one stent is permitted as long as the stents are initially planned)
o Treatment not deemed a clinical angiographic success
o Treatment not completed prior to treatment of target lesion
AE3. Subject has unprotected left main coronary artery disease (>50% diameter stenosis).
AE4. Subject has protected left main coronary artery disease and a target lesion in the LAD or LCX.
AE5. Subject has an additional clinically significant lesion(s) in the target vessel for which an intervention within 12 months after the index procedure may be required.

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):	23-02-2012
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	OMEGA Monorail Coronary Stent System (CSS)
Registration:	No

Ethics review

Approved WMO

Date:	21-12-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	26-03-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	11-06-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	14-06-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
Other	Clinical Trials.gov ID# NCT01419171
CCMO	NL37411.098.11