Prospective Multi-Center, Single Arm Study of the Shockwave Coronary Rx Lithoplasty® System in Coronary Arteries

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To assess the safety and performance of the Shockwave Coronary Rx Lithoplasty® System to treat calcified, stenotic, de novo coronary lesions prior to stenting.

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

Summary

ID

NL-OMON43455

Source
ToetsingOnline

Brief title
Shockwave heart study

Condition

- Coronary artery disorders

Synonym
arterial stenosis, stenotic coronary arteries

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Arterial stenosis, Lithoplasty system, Trans catheter

Outcome measures

Primary outcome

Safety

Safety will be assessed by the frequency of major adverse cardiac events (MACE)

within 30 days of the procedure. MACE is defined as:

* Cardiac death

* MI - defined as a CK-MB level > 3 times the upper limit of lab normal (ULN)

value with or without new pathologic Q wave

* TVR - defined as revascularization at the target vessel (inclusive of the

target lesion) after the completion of the index procedure

Performance

Performance will be assessed by the ability of the Shockwave System to produce

acceptable residual stenosis (* 50%) after stenting with no evidence of

in-hospital MACE.

Each patient that achieves both of these requirements will be considered a

clinical success, and the rate of clinical success among patients will be

evaluated.

Secondary outcome

* Quantitative assessment of the residual stenosis in treated lesions

o Angiographic success defined as success in facilitating stent delivery with

<50% residual stenosis and without serious angiographic complications

o Serious angiographic complications defined as severe dissection (Type D to F), perforation, abrupt closure, and persistent slow flow or persistent no reflow.

* 180 Day MACE (Post-Market Clinical Follow-up)

The ability of the Shockwave device to achieve a post-Lithoplasty residual diameter stenosis of *30% (without adjunctive vessel preparation prior to stenting) as assessed by the operator via visual inspection

Study description

Background summary

It concerns a study regarding coronary arteries stenosis.
The standard treatment for the condition is *balloon angioplasty* followed by placement of a coronary stent (a small mesh tube).

The study device that will be used in this study is called the Shockwave Coronary Lithoplasty System. It is similar to other balloon devices that are routinely used during angioplasty procedures; however, it has electrodes inside the balloon which are designed to deliver energy to crack the calcified blockage. The Lithoplasty Catheter will be moved over a wire, fed through a catheter, and placed inside the narrowed part of the vessel. The balloon will then be inflated to low pressure and pushed against the wall of the artery. Then the energy source will be activated, delivering sound waves to the vessel wall. The energy delivered via a generator and the calcium within the vessel wall responsible for the narrowing within the artery will crack. This allows the artery to widen with only a small amount of pressure in the balloon. The energy used in Shockwave Coronary Lithoplasty is the same as what is used to treat kidney stones. No part of the device will be left behind in your blood vessel after your angioplasty. A stent will be placed after the lithoplasty to support the treated area.

Study objective

To assess the safety and performance of the Shockwave Coronary Rx Lithoplasty® System to treat calcified, stenotic, de novo coronary lesions prior to

stenting.

Study design

Prospective, multi-center, single arm study designed to evaluate the safety and performance of the Shockwave Coronary Rx Lithoplasty® System to treat calcified lesions in the coronary arteries for the purpose of enhancing the placement of stents and reducing the ultimate residual stenosis. Patients will be followed through discharge and at 30 and 180 days.

Intervention

Percutaneous insertion of the Shockwave Coronary Rx Lithoplasty® System for lithotripsy-enhanced, low-pressure balloon dilation of calcified, stenotic de novo coronary arteries.

Study burden and risks

The risks relating to balloon angioplasty will have been explained by the doctor, and those risks exist whether or not the subject takes part in this study. The risks associated with the study procedure are consistent with any heart vessel procedure, a minimally invasive procedure to open blocked arteries, and include the following.
VERY COMMON (* 10%, 10 people in 100)
* Chest pain or discomfort.
COMMON OR FREQUENT (* 1.0% to < 10%, 1 to less than 10 people out of 100)
* Access site pain, hematoma or haemorrhage.
* Vascular complications at access site that might need vessel repair.
* Death.
* Heart attack (myocardial infarction).
* Increased/decreased blood pressure (Hypertension/hypotension).
* Irregular heart rhythm Nausea and vomiting.
* Tearing of the coronary artery (Dissection of the coronary artery).
* Repeat closure of the coronary artery over time (Restenosis of the treated artery).

UNCOMMON OR INFREQUENT (* 0.1% to < 1.0%, less than 1 person in a 100)
* Allergic reaction to blood-thinning agents (antiplatelet/anticoagulant) or contrast agent.
* Bleeding complications which may require transfusion.
* Blockage of the coronary artery (total occlusion).
* Contraction causing the coronary artery to narrow slowing or stopping the blood flow (arterial spasm).
* Decreased blood supply to the limbs (arms and/or legs) possibly causing cramping, pain (Peripheral ischemia due to vascular injury).
* Dilation of an artery with an actual break in one or more layers of its walls

(Pseudoaneurysm).
* Emergency or non-emergency bypass surgery.
* Fever.
* Fluid development in the lungs (Pulmonary edema).
* Infection/sepsis.
* Movement of air, tissue, or thrombus resulting in blockage in blood flow (emboli).
* Puncture of the heart artery (arterial perforation) and injury to the coronary artery.
* Stroke.

RARE (* 0.01% to < 0.1%, less than 1 person in a 1,000)
* Abnormal connection between an artery and a vein next to it (Arterio-venous fistula).
* Fracture of the guide wire or any component of the device that may or may not lead to device embolism, serious injury or surgical intervention
* Pericardial effusion (Fluid around the heart).
* Shock.
* Squeezing of the heart due to accumulation of blood in the sac around the heart (Cardiac tamponade).
* Renal failure/insufficiency.

VERY RARE (< 0.01%, less than 1 person in 10,000)
* Rupture of the heart artery (Arterial rupture).
* Sudden blockage of the artery (Abrupt closure).

In addition, the subject may be exposed to other risks associated with coronary angioplasty procedures, including risks from conscious sedation and local anaesthetic, the radiographic contrast agents used during angiography, and the drugs given to manage the participant during the procedure. These risks are present in any angioplasty procedure in which the subject would participate because of his/ her disease. The doctor will explain to the subject the risks related to balloon angioplasty. These risks exist whether or not the subject takes part in the study.

There are risks related to the Shockwave Coronary Lithoplasty System. These risks are uncommon and it is not expected that they will occur. The risks are listed here below.
* There is a low risk the angioplasty balloon might burst exposing the coronary artery to the electrode materials. Should this occur the doctor may replace the device with another device to continue treatment. There are no known problems related to short term exposure to the probe materials.
* Allergic reaction to the catheter material or coating
* There is a low risk the system may not function properly. Should this occur the doctor will treat the subject with standard of care.
* There is a low risk that not enough or too many shocks are delivered during treatment. The doctor can treat the subject with standard of care in the event

that the Shockwave treatment did not help the subject.
* There is a low risk of excess heat at target site due to the system not functioning properly
* There is a moderate risk that the subject will experience irregular heartbeats during the procedure. The doctor will monitor the heartbeats throughout the treatment and it is expected that any irregular heartbeats, should they occur, will return to normal once treatment is complete.
The type of material used in the trial Coronary Lithoplasty Catheter is also used in other balloon catheters. The risk of reaction to these materials is thought to be minimal.

The potential risks of using OCT are similar to balloon angioplasty. Due to the extended procedure time, (10 minutes) OCT may increase the exposure to radiation, though the dose would be extremely low. The subject will also require extra X-ray dye (contrast media) to take the OCT images. In high doses, the X-ray dye is harmful to the kidneys. However, high doses rarely occur in these types of procedures, and if so, can be treated effectively with high fluid (water/saline) volumes that *flush* the X-ray dye out of the kidneys. Serious complications are rare with OCT.

Pregnant or nursing women are excluded from this study.

At the time of the study, some risks may be unknown.

Benefits
Currently available angioplasty balloons are designed to be blown-up to high pressures. There are times when the force of the balloon pushing on the blood vessel wall at this pressure causes damage. The Shockwave balloon is designed to allow the expansion of vessels at much lower pressure by using sound energy to break down the calcium in the narrowing. It is believed that the application of this energy to the blood vessel with this unique balloon will result in less damage to the blood vessel due to the lower pressure. This could potentially reduce the risk of some of the common complications seen in angioplasty procedures with currently available balloons.
It is possible that the subject may have no personal benefit from being in this study; however, the knowledge gained in this study may be used to help others in the future with coronary artery disease.

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

1. Patient is > 18 years of age
2. Troponin must be less than or equal to the upper limit of lab normal value within 12 hours prior to the procedure
3. The target vessel must have a TIMI flow 3 at baseline
4. Patients with significant (> 50% diameter stenosis) native coronary artery disease including stable or unstable angina and silent ischemia, suitable for PCI
5. Ability to tolerate dual antiplatelet agent (i.e. aspirin, clopidogrel, prasugrel, or ticagrelor for 1 year and single antiplatelet therapy for life
6. Single lesion stenosis of protected LMCA, LAD, RCA or LCX artery *50% in a reference vessel of 2.5 mm - 4.0 mm diameter and * 32 mm length
7. Presence of calcification within the lesion on both sides of the vessel as assessed by angiography
8. Planned treatment of single lesions per vessel
9. Ability to pass a 0.014* guide wire across the lesion
10. Patient, or authorized representative, signs a written Informed Consent form to participate in the study, prior to any study-mandated procedures
11. Patient is able and willing to comply with all assessments in the study

Exclusion criteria

1. Concomitant use of Atherectomy, Specialty balloon, or investigational coronary devices
2. Prior PCI procedure within the last 30 days of the index procedure
3. Patient has planned cardiovascular interventions within 30 days post index procedure
4. Second lesion with >50% stenosis in the same target vessel
5. Left ventricular ejection fraction < 40%
6. Patient refusing or not a candidate for emergency coronary artery bypass grafting (CABG) surgery
7. Uncontrolled severe hypertension (systolic BP >180 mm Hg or diastolic BP >110 mm Hg)
8. Severe renal failure with serum creatinine >2.5 mg/dL
9. Untreated pre-procedural hemoglobin <10 g/dL
10. Coagulopathy manifested by platelet count <100,000 or International Normalized ratio (INR) >1.7 (INR is only required in patients who have taken warfarin within 2 weeks of enrollment)
11. Patients in cardiogenic shock
12. Acute myocardial infarction (MI) within the past one (1) month, and/or elevated Troponin-I or T (with concomitant elevation of CK) at the time of enrollment
13. History of a stroke or transient ischemic attack (TIA) within 3 months
14. NYHA class III or IV heart failure
15. Active peptic ulcer or upper gastrointestinal (GI) bleeding within 6 months
16. Patients with a life expectancy of less than 1 year
17. Target main branch vessel < 2.4 mm in diameter
18. Target main branch lesion > 32 mm in length
19. Chronic Total Occlusion (CTO)
20. Previous stent procedure within 5 mm of target lesion
21. Angiographic evidence of a target lesion severe dissection prior to Coronary Lithoplasty treatment
22. Unprotected Left Main diameter stenosis * 50%
23. Visible thrombus (by angiography) at target lesion site
24. Target lesion is located in a native vessel distal to anastomosis with a saphenous vein graft or LIMA/RIMA bypass
25. Patient has active systemic infection
26. Patient has connective tissue disease (e.g., Marfan*s syndrome)
27. Patient has a hypercoagulable disorder

28. Uncontrolled insulin dependent diabetes
29. Patient has allergy to imaging contrast media for which they cannot be pre-medicated
30. Evidence of aneurysm in target vessel
31. Patient is pregnant or nursing

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):	22-07-2016
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Shockwave Coronary Rx Lithoplasty® System
Registration:	No

Ethics review

Approved WMO Date:	17-06-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-08-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-10-2016
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	NL56014.078.15