Prospective Multi-Center, Single Arm Post-Market Study (PMS) of the Shockwave Medical, Inc. Coronary Lithoplasty® System in Coronary Arteries

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The objective of the study is to assess the safety and performance of the Shockwave Medical, Inc. Coronary Lithoplasty® System to treat calcified, stenotic, de novo coronary lesions prior to stenting in a real-world post-market study.

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

Summary

ID

NL-OMON46584

Source
ToetsingOnline

Brief title
Disrupt CAD II

Condition

- Coronary artery disorders
- Cardiac therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
coronary artery disease, coronary artery narrowing

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Coronary, Lithoplasty, System

Outcome measures

Primary outcome

Primary Safety Endoint:

In-hospital major adverse cardiac events (MACE)

Secondary outcome

Performance will be assessed by the ability of the Lithoplasty 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 subjects will be evaluated.

Angiographic success defined as success in facilitating stent delivery with <50% residual stenosis and without serious angiographic complications. Serious angiographic complications are defined as severe dissection (Type D to F), perforation, abrupt closure, and persistent slow flow or persistent no reflow.

Cardiac death at 30 days.

Study description

Background summary

Calcified coronary lesions are associated with age, diabetes and chronic kidney disease. Approximately 38% and 73% of all lesions display calcification as detected by angiography and intravascular ultrasound (IVUS), respectively. As IVUS is not routinely used as a diagnostic modality, coronary calcification is most likely underestimated.
Coronary artery calcification impacts interventional outcomes by adversely affecting device delivery, damaging the drug-eluting polymer and impairing stent expansion and apposition. Current therapies used to overcome these limitations include high-pressure balloon dilation and atherectomy. However, balloon angioplasty is limited in its ability to modify calcific plaque.
Dilatation in eccentric calcium may be biased by the guidewire towards the non-calcified segments of the artery, and in concentric calcium may be of insufficient pressure-generated force to lead to calcium fracture and vessel expansion.
Rotational and orbital atherectomy selectively ablate superficial calcium increasing stent deliverability but have limited impact on deep calcium that limits vessel expansion during stent implantation. In addition, peri-procedural complications including perforation, slow flow and peri-procedural myocardial infarction (MI) are still significantly higher with atherectomy than balloon based therapies.
Abdel-Waheb et al reported a 1.7% perforation rate following treatment with rotablator plus drug eluting stent (DES). At 9 months, rotational atherectomy (RA) had similar rates of binary restenosis, target lesion revascularization (TLR), stent thrombosis and MACE, despite a higher procedural acute gain over PTCA. Chambers et al reported the 30-day orbital atherectomy (OA) results from the ORBIT II Study. OA procedural success, defined as less than 50% residual stenosis after stenting and no in-hospital MACE, was 88.9%. In addition, percent residual stenosis following stenting was low at 5.8%. Angiographic complications included severe dissection and abrupt closure of 3.4% and 1.8%, and in-hospital non-Q wave MI*s occurred in 8.6% of the subjects.
Lithoplasty is a technique based on lithotripsy, an established treatment strategy for renal calculi, in which multiple lithotripsy emitters mounted on a traditional balloon catheter platform create diffusive pulsatile mechanical energy to disrupt calcium within the vessel wall at low inflation pressures.
The completed Disrupt CAD I Study reported the safety and performance of coronary Lithoplasty in vessel preparation for calcified, stenotic, de novo coronary lesions prior to stent implantation.
Successful delivery of the Lithoplasty balloon was achieved in 59 (98.5%) patients with reduction in residual stenosis to less than 50% in all 60 (100%) patients. The angiographic luminal acute gain following stent implantation was 1.7 mm and residual stenosis was 13.3%. Freedom from MACE was present in 57

(95%) patients due to 3 (5%) non-Q wave MI at 30 days. At 6 months, freedom from MACE was present in 54 of 59 (91.5%) patients due to 2 additional patients suffering cardiac death. Results of the optical coherence tomography (OCT) sub-study identified modification with fracture as a major mechanism of action of Lithoplasty in vivo and demonstrated efficacy in the achievement of significant acute area gain and favorable stent expansion.

Study objective

The objective of the study is to assess the safety and performance of the Shockwave Medical, Inc. Coronary Lithoplasty® System to treat calcified, stenotic, de novo coronary lesions prior to stenting in a real-world post-market study.

Study design

Prospective, multi-center, single arm post market study to evaluate the real-world safety and performance of the Coronary Lithoplasty® System for lithotripsy-enhanced, low-pressure balloon dilatation of calcified, stenotic de novo coronary arteries prior to stenting.

Intervention

The Coronary Lithoplasty System is a proprietary balloon catheter system designed to deliver a lithotripsy device through the coronary arterial system of the heart to the site of an otherwise difficult to treat calcified stenosis, including calcified stenosis that are anticipated to exhibit resistance to full balloon dilation or subsequent uniform coronary stent expansion. Energizing the lithotripsy device will generate intermittent sound waves within the target treatment site, disrupting calcium within the lesion and allowing subsequent dilation of a coronary artery stenosis using low balloon pressure. The Lithoplasty Catheter combines an angioplasty catheter design with integrated lithotripsy emitters to enable the localized delivery of intermittent sound wave therapy.

Study burden and risks

Refer to Section 7.0 of the Disrupt CAD II Post-Market Study Clinical Protocol and the IFU for the Shockwave Medical, Inc. Coronary Lithoplasty System for detailed information on the risks of the devices used in the study procedure, including a complete list of warnings, precautions and potential adverse events.

As with any endovascular procedure, appropriate safety precautions will be followed. Risks of observed or theoretical adverse events have been mitigated through the Instructions for Use, physician training, and patient selection in the study protocol.

All efforts will be made to minimize these risks by:
- Site selection
- Ensuring compliance to the protocol and IFU
- Study Monitoring
- Safety processes - protocol adverse event reporting requirements, CEC oversight, and safety reporting to regulatory authorities including Vigilance reporting
- Risk management process

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

Subjects are required to meet all of the following inclusion criteria in order to be included in this study.;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 24 hours prior to the procedure OR if troponin is elevated, concomitant CK must be normal
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, or 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 lesion in one 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;Angiographic Inclusion Criteria
1. Target lesion is located in a native LMCA, LAD, RCA or LCX artery. A single lesion may be treated per protocol
2. Target lesion reference vessel diameter is between 2.5 mm and 4.0 mm (visual estimate)
3. Target lesion is <= 32 mm in length
4. Stenosis of LMCA, LAD, RCA or LCX artery >=50%
5. Calcification within the lesion on both sides of the vessel
6. Ability to pass a 0.014* guidewire across the lesion

Exclusion criteria

Subjects who meet any of the following exclusion criteria will not be included in this 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, unless on chronic dialysis
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 signs of active

myocardial ischemia at the time of enrollment including elevated Troponin-I or T (with concomitant elevation of CK), ischemic ECG changes or chest pain
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 vessel < 2.4 mm in diameter
18. Target 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;Angiographic Exclusion Criteria
Patients that do not meet the final angiographic eligibility criteria will be documented as angiographic screen failures and will not be considered enrolled into the study and no data collection will be completed. Only patients that meet final angiographic eligibility criteria will be enrolled into the study and undergo treatment with the study device and followed per the clinical protocol with data collection.

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):	25-03-2019
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO Date:	15-11-2018
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL64556.075.18