PINNACLE I Clinical Study: A clinical trial to assess the Elixir Medical LithiX Coronary Hertzian Contact Intravascular Lithotripsy Catheter for treatment of moderately to severely calcified, stenotic de novo coronary artery lesions

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To assess safety and performance of the LithiX Coronary HCIVLC to treat moderately to severely calcified coronary artery lesions by calcium fragmentation utilizing Hertzian contact stress from LithiX HCIVLC.

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

Summary

ID

NL-OMON56130

Source
ToetsingOnline

Brief title
PINNACLE I

Condition

- Coronary artery disorders

Synonym
Calcified, stenotic de novo coronary artery lesions

Research involving

Human

Sponsors and support

Primary sponsor: Elixir Medical LtD
Source(s) of monetary or material Support: Elixir Medical Corporation

Intervention

Keyword: calcified lesions, coronary artery lesions, Coronary Hertzian Contact intravascular Lithotripsy Catheter

Outcome measures

Primary outcome

Primary effectiveness and safety endpoint:

• Clinical Success defined as residual stenosis <50% after final treatment

(with or without stenting) with no evidence of in-hospital major adverse

cardiovascular events (MACE).

MACE is defined as a per-subject composite endpoint of cardiovascular death,

myocardial infarction, and target vessel revascularization.

Primary safety endpoint:

• Major adverse cardiovascular events (MACE) through 30 days.r

Secondary outcome

Angiographic Imaging Endpoints

Baseline (just before pre-dilation), post-LithiX treatment, and at the end of

procedure following stent deployment:

• Reference Vessel Diameter (RVD), mm

• Minimum Lumen Diameter (MLD), mm

• % Diameter Stenosis (pre-procedure), %

• Lesion Length, mm

• Calcified Length, mm

• Calcium classification (moderate or severe)

• Lesion Assessment (concentric, eccentric, nodular), and involvement of side-branch

• Acute Gain (post-LithiX treatment and final)

• Residual Diameter Stenosis % (post-LithiX treatment and final),

* Residual diameter stenosis < 50%

* Residual diameter stenosis < 30%

OCT Imaging Endpoints

Baseline (just before pre-dilation), post-LithiX treatment, and at the end of procedure following stent deployment:

• Lumen area, mm2

• Calcium Angle, *

• Maximum calcium thickness, mm

• Presence of calcium fracture

• Stent area, mm2

• Stent expansion, %

• Acute gain, mm2

Additional Endpoints

Clinical endpoints, tabulated at Discharge, 30 days and 6 months:

• Clinical Success - the ability of LithiX Coronary HCIVLC to produce a residual diameter stenosis of <50% after stenting with no evidence of in-hospital MACE.

• Angiographic Success - defined as success in facilitating stent delivery with <50% residual stenosis and without serious angiographic complications (severe dissection impairing flow [type D-F], perforation, abrupt closure, persistent slow flow, or no reflow)

• Stent Delivery Success

• Procedural Characteristics:

* Procedural Time

* Pre-dilatation

* Post-dilatation

* Number of LithiX devices used

* Number of LithiX inflations

* Mean LithiX inflation pressure

* Mean LithiX inflation time

* Number of stents used

* Device crossing success

• All MI (peri-procedural and spontaneous)

• Target Lesion Failure (TLF)

• Target Lesion Revascularization (TLR)

• Target Vessel Revascularization (TVR)

• All Revascularization

• Stent Thrombosis

• All mortality

• Usability (Physician feedback will be obtained for the device usability

characteristics)

Study description

Background summary

Patients with moderately or severely calcified coronary artery lesions are on average older and have a greater incidence of baseline comorbidities. Long-term outcomes for these patients commonly associated with a higher incidence of patient-oriented composite endpoints (POCE) (any death, any revascularization, or any myocardial infarction (MI)) and target lesion failure (TLF) (cardiovascular death, target vessel-MI, or ischemia-driven target lesion revascularization (ID-TLR)) as compared to patients with no or mild coronary artery calcification.

Vessel preparation of moderately to severely calcified coronary artery lesions prior to stenting allows for full stent expansion and apposition to the vessel wall.

The LithiX Coronary Hertzian Contact intravascular Lithotripsy Catheter (LithiX Coronary HCIVLC; LithiX Catheter; LithiX) combines the balloon approach with the enhanced calcium fragmentation abilities and visualization for treatment of moderately to severely calcified, stenotic de novo coronary artery lesions.

Study objective

To assess safety and performance of the LithiX Coronary HCIVLC to treat moderately to severely calcified coronary artery lesions by calcium fragmentation utilizing Hertzian contact stress from LithiX HCIVLC.

Study design

This is a prospective, multicenter, single-arm clinical study. Enrollment of up to 60 patients requiring percutaneous coronary intervention (PCI) on up to two de novo coronary artery lesions with reference vessel diameters >= 2.25 mm and <= 3.5 mm, and lesion lengths of <= 34 mm, with moderate to severe calcification. Up to 3 roll-in patients per operator are allowed to be enrolled. All roll-in patients that meet the study eligibility criteria will be included in the main

cohort analyses.
Up to two de novo moderately to severely calcified coronary artery lesions located in separate epicardial vessels (RCA, LCX or LAD) which meet the inclusion/exclusion criteria may be treated with the LithiX Coronary HCIVLC to prepare the lesion prior to stenting.
All patients will undergo coronary angiography to assess the final residual stenosis immediately post-LithiX treatment and post stenting.
In the Optical Coherence Tomography (OCT) imaging subgroup, approximately 30 patients will undergo OCT imaging just before pre-dilation (baseline), post-LithiX treatment, and the end of procedure following stent deployment.
All angiographic and OCT images will be analyzed by the independent core laboratory.
Stent implantation is performed per standard practice.
Subjects will be followed through hospital discharge and will have clinical follow-up conducted by phone at 30 days and 6 months post-index procedure.

Intervention

Primary safety endpoint:
• Major adverse cardiovascular events (MACE) through 30 days. MACE is defined as a per-subject composite endpoint of cardiovascular death, myocardial infarction, and target vessel revascularization
Primary performance endpoint:
• Clinical Success defined as residual stenosis <50% after final treatment (with or

Study burden and risks

The patient has calcified arteries which carry a higher risk during treatment. This risk is not greater than those risks associated with other percutaneous calcified lesion treatment such as cutting balloon, rotablation, or lithoplasty. Benefit is that patients do not have to undergo invasion follow-up.

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

General Inclusion Criteria

1. Subject is >= 18 years of age.
2. Subject or a legally authorized representative must provide written informed consent prior to any study related procedures.
3. Subject must agree not to participate in any other clinical study during the course of the study that would interfere with the endpoints of this study.
4. Subjects must have a single or double vessel coronary artery disease (CAD) and clinical evidence of ischemic heart disease, such as CAD, silent ischemia, stable / unstable angina, and NSTEMI if biomarkers are stable or falling at time of inclusion

Angiographic Inclusion Criteria

1. Subject must have de novo lesion(s) in native coronary arteries suitable for percutaneous coronary intervention.
2. Up to 2 de novo coronary artery lesions in separate epicardial vessels, which are moderately to severely calcified*, meeting all of the following criteria visually assessed by angiography:
• >=70% diameter stenosis by visual estimation
• reference vessel diameters of 2.25 mm - 3.5 mm
• lesion length of <= 34 mm
• TIMI flow >= 1 at baseline
3. Any non-target lesion must be located in different coronary artery from a

target lesion. Treatment of non-target lesion, if any, must be completed prior to treatment of target lesion and must be deemed a clinical angiographic success as visually assessed by the physician.
*Calcium Classification Definitions:
Moderate calcification: radiopacities noted only during the cardiac cycle before contrast dye injection.
Severe calcification: radiopacities seen without cardiac motion before contrast dye injection.

Exclusion criteria

General Exclusion Criteria

1. Subject with a known hypersensitivity or contraindication to aspirin, heparin, bivalirudin, anti-platelet medications, or sensitivity to contrast media which cannot be adequately pre-medicated.
2. Subject with known diagnosis of STEMI at index presentation or within 7 days of study screening.
3. Patient refusing or not a candidate for emergency coronary artery bypass grafting (CABG) surgery.
4. Subject with known pregnancy or is nursing. Women of child-bearing potential should have a documented negative pregnancy test within 7 days before index procedure.
5. Planned use of atherectomy, laser, lithoplasty, thrombectomy, scoring or cutting balloon, or any investigational device other than LithiX in the target lesion during the index procedure.
6. Patients on renal dialysis or with known eGFR < 30 ml/min.
7. NYHA class III or IV heart failure.
8. Patient has active systemic infection.
9. Cerebrovascular accident (CVA) or transient ischemic attack (TIA) within the past 6 months.
10. Active peptic ulcer or active gastrointestinal (GI) bleeding within the past 6 months.
11. Subject has a known left ventricular ejection fraction (LVEF) <30% (LVEF may be obtained at the time of the index procedure if the value is unknown, if necessary).
12. Subject is a member of a vulnerable population as defined GCP E6, including individuals with mental disability, persons in nursing homes, children, impoverished persons, persons in emergency situations, homeless persons, nomads, refugees, and those incapable of giving informed consent. Vulnerable populations also may include members of a group with a hierarchical structure such as university students, subordinate hospital and laboratory personnel, employees of the Sponsor, members of the armed forces, and persons kept in detention.

Angiographic Exclusion Criteria

1. More than two target lesions or more than 1 target and 1 non-target lesion requiring treatment.
2. Extreme angulation (90º or greater) proximal to or within the target lesion.
3. Previous percutaneous intervention of lesions in a target vessel (including side branches) conducted within 6 months before the study procedure, or any prior lesion treated within 10 mm (proximal or distal) from the current target lesion.
4. Previous percutaneous intervention of lesions in a non-target vessel (including side branches) conducted within 30 days before the study procedure.
5. Angiographic evidence of a target lesion dissection prior to LithiX Hertzian Contact Lithotripsy.
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Protocol Summary ELX-CL-2202, Version 2.0, 8 February 2023
6. Visible thrombus (by angiography) at target lesion site.
7. Unprotected left main coronary artery disease (Greater than 50% diameter stenosis).
8. Target lesion is located in a native vessel distal to anastomosis with a saphenous vein graft or LIMA/RIMA bypass.
9. Evidence of aneurysm in target vessel.
10. Coronary artery spasm of the target vessel in the absence of a significant stenosis.
11. Target lesion involves a bifurcation requiring treatment with more than one stent or pre-dilatation of a side branch >2.0 mm in diameter.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	31-10-2023
Enrollment:	25

Type:	Actual

Medical products/devices used

Generic name:	Coronary Hertzian Contact intravascular Lithotripsy Catheter
Registration:	No

Ethics review

Approved WMO Date:	25-09-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-01-2024
Application type:	Amendment
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
ClinicalTrials.gov	NCT05828173
CCMO	NL84378.000.23