Calcium Reduction by Orbital Atherectomy in Western Europe: the CROWN study

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To understand the mechanism of action of OA for the treatment of de novo, severely calcified coronary lesions prior to stent placement using optical coherence tomography (OCT) and to assess stent expansion, based on OCT derived minimal stent area (...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON51361

Source
ToetsingOnline

Brief title
CROWN

Condition

- Coronary artery disorders

Synonym
Calcified coronary lesions

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Cardiovascular Systems Inc., St. Paul,MN,USA,Cardiovascular Systems Inc.;St. Paul;MN;USA

Intervention

Keyword: Calcium, OCT, Orbital Atherectomy

Outcome measures

Primary outcome

The primary endpoint of this study is proportion of patients with stent expansion defined by OCT derived minimal stent area (MSA) >= 5.5mm^2.

Secondary outcome

Secondary endpoint

Divided into three subgroups, clinical, intracoronary imaging and angiographic endpoints.

Clinical endpoints (measured at discharge, 30 days and 12 months):

• Procedural success, defined as successful stent delivery with:

o Final Core Lab defined Thrombolysis in Myocardial Infarction (TIMI) flow of III.

o Angiographic in-stent diameter stenosis (DS) <=20%.

o Absence of in-hospital major adverse cardiac and cerebrovascular events (MACCE, consisting of all-cause death, spontaneous myocardial infarction (MI), target vessel revascularization (TVR), stroke).

• Target vessel failure (TVF, consisting of cardiac death, target vessel spontaneous MI, and TVR).

• Major adverse cardiac events (MACE, consisting of all-cause death, spontaneous MI, and repeat revascularization).

• Individual components of MACE and TVF.

• Incidence of periprocedural MI:

o Type 4a (4th universal def).

• Major intraprocedural complications including type C-F dissections, perforations, slow flow or no reflow, thrombus and major side branch occlusion (>2mm).

• Probable and definite stent thrombosis

Intracoronary imaging endpoints (OCT)

• Final MSA

• Percentage of stent expansion

• Percentage of lumen area gain post OA and post stenting

• Minimal lumen area (MLA) post OA and post stenting

• Number of calcium fractures

• Number of calcium fractures based on calcium thickness post OA

• Incidence of OCT defined hematomas post OA

• Incidence and quantification of dissections post OA

• Number of calcified nodules modified post OA

Angiographic endpoints (Core Lab Assessed):

• Lesion length, diameter percentage of stenosis, reference vessel diameter

• In-stent and in-segment DS

• In-stent and in-segment minimal lumen diameter (MLD)

• In-stent and in-segment acute gain

Study description

Background summary

The Diamondback 360° Coronary Orbital Atherectomy System (OAS) (Cardiovascular Systems Inc., St. Paul,MN,USA) is a percutaneous device indicated to modify calcified lesion in order to facilitate stent delivery in patients with severely calcified coronary artery disease (CAD). As of to date, detailed sequential intravascular imaging data unraveling the exact calcium modifying effect of orbital atherectomy (OA) prior to stent placement in vivo, are lacking.

Study objective

To understand the mechanism of action of OA for the treatment of de novo, severely calcified coronary lesions prior to stent placement using optical coherence tomography (OCT) and to assess stent expansion, based on OCT derived minimal stent area (MSA).

Study design

International, multicenter, prospective and observational single arm registry

Study burden and risks

Patients with severely calcified significant coronary lesions are at high risk of myocardial infarction and sudden death if left untreated. Treating such lesions have small procedural risks from the use of specified devices. Efficacy and safety of OAS was proved in the ORBIT I and II trials. Both OAS and OCT devices are already widely used, OAS facilitates stent delivery in severely calcified lesions and OCT facilitates procedure overall to optimize stenting result
Patients will be asked for a telephone contact at 30 days and clinic visit and 12 months.
Participation contributes to expand the knowledge base for the mechanism of action of the OAS which may assist physicians in their choice of treating any future patients, enhance the ability of use of the operator and by extension improve patient outcomes.

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. De novo significant native coronary artery lesion.
2. The target lesion must have evidence of severe calcification:
a. Presence of radiopacities noted without cardiac motion prior to contrast injection involving both sides of the arterial wall with calcification length of at least 15 mm and extend partially into the target lesion.
b. Presence of >=270° of calcium or lumen protruding calcified nodule(s) at >1 cross section assessed by OCT.
3. The target vessel reference diameter >= 2.5 mm and <= 4.0 mm and lesion must not exceed 40 mm in length.
4. Age > 18 years or minimum age as required by local regulations

Exclusion criteria

1. Left main disease
2. Prior stenting of the target vessel.
3. Target lesion has thrombus or dissection.
4. Known LVEF <=25%.

5. Diagnosed with chronic renal failure (GFR<30ml/min)
6. Confirmed pregnancy.
7. Life expectancy <12months.
8. Age<18y.
9. Coronary anatomy that prevent delivery of OCT catheter
10. Known allergy to soybean oil, egg yolk phospholipids, glycerin or sodium hydroxide

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-03-2024
Enrollment:	35
Type:	Actual

Medical products/devices used

Generic name:	Diamondback 360° Coronary Orbital Atherectomy System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	16-11-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	11-06-2024
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	NL81318.078.22