REDUCER-I: An Observational Study of the Neovasc Reducer* System

Published: 01-06-2016
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To collect long term outcomes on the use of the Neovasc Reducer

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

Summary

ID

NL-OMON54544

Source
ToetsingOnline

Brief title
Reducer I

Condition

- Coronary artery disorders

Synonym
Chronic refractory angina pectoris, untreatable chest pain

Research involving
Human

Sponsors and support

Primary sponsor: Neovasc Medical, Inc
Source(s) of monetary or material Support: Neovasc Medical

Intervention

Keyword: Chronic refractory angina pectoris, stent

Outcome measures

Primary outcome

The percentage of subjects who experience improvement in their angina symptoms defined as a reduction in CCS grade, at 6 months as compared to baseline

The rate of occurrence of device and / or procedure related periprocedural Serious Adverse Events (SAEs) defined as a composite of death, myocardial infarction (MI), cardiac tamponade, clinically-driven re-dilation of a Reducer, lifethreatening arrhythmias (ventricular tachycardia [VT] or ventricular fibrillation [VF]), and respiratory failure through 30 days post-implant

Major Adverse Cardiac Events (MACE): a composite of cardiac death, major stroke, and MI through 30 days post implant

Secondary outcome

The percentage of subjects who experience improvement in their angina symptoms defined as a reduction in CCS grade at 12 months and annually through 5 years post implant as compared to baseline

Major Adverse Cardiac Events (MACE): a composite of cardiac death, major stroke, and MI at 6 months, 12 months and annually through 5 years post implant

Study description

Background summary

The Reducer is intended for patients with refractory angina pectoris despite medical therapy, who are either not amenable or are at high risk for revascularization by coronary artery bypass grafting (CABG) or by percutaneous coronary intervention (PCI). The Reducer is designed to create a narrowing in

the coronary sinus (CS) after implantation. CS narrowing improves perfusion to ischemic myocardium in the presence of reversible ischemic heart disease to alleviate the symptoms of refractory angina pectoris.

Study objective

To collect long term outcomes on the use of the Neovasc Reducer

Study design

A multi-center, multi-country, three-arm observational study.
Arm 1: Subjects are enrolled prior to receiving the Reducer.
Subjects will be followed at baseline, implant procedure, 30 day (phone visit), 6 and 12 months post implant and annually through 5 years.

Arm 2: Subjects who were previously enrolled and treated with the Reducer, during the COSIRA study will be invited to participate in this long term follow up study. This arm will collect both retrospective and prospective data.
* Data previously collected from the treatment arm of the COSIRA study (baseline, procedure, 30 days and 6 month post implant) will be included in this arm
* Retrospective data (prior to consent) and/or prospective data (after consent) will be collected at 12 months post implant and annually through 5 years post implant

Arm 3: Subjects who received a Reducer under CE Mark (unrelated to the COSIRA study), will be invited to participate. This arm will collect both retrospective and prospective data.
* Available baseline and procedure data will be collected retrospectively
* Retrospective and/or prospective data will be collected at 30 days, 6 months, 12 months post implant and annually through 5 years post implant

Study burden and risks

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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

Arm 1:
• Symptomatic CAD with chronic refractory angina pectoris classified as CCS grade II, III or IV despite attempted optimal medical therapy
• Subject has limited treatment options for revascularization by CABG or by PCI
• Evidence of reversible myocardial ischemia in at least one of the following objective clinical tests performed up to 6 months prior to consent: Thallium/Methoxyisobutyl Isonitrile (MIBI) Single Photon Emission Computed Tomography (SPECT), Dobutamine Stress Echo (DSE), Perfusion magnetic resonance imaging (MRI), Exercise Tolerance Testing (ETT)
• Left ventricular ejection fraction (LVEF) greater than or equal to 30%
• Male or non-pregnant female (If required by institutional procedures, females of childbearing
potential must have a negative pregnancy test)Arm 2:
• Subjects previously implanted in the Reducer (treatment) arm of the COSIRA studyArm 3:
• Subjects in whom the Reducer was implanted under CE Mark (unrelated to the COSIRA study), prior to enrollment in the REDUCER-I studyAll Arms:
• Subject has been informed about the study and provides written informed consent prior to

enrollment
• Subject is willing to comply with specified follow-up evaluations and can be contacted by telephone

Exclusion criteria

Arm 1:
• Recent (within three months) acute coronary syndrome
• Recent (within six months) PCI or CABG
• Unstable angina (recent onset angina, crescendo angina, or rest angina with electrocardiogram
[ECG] changes) during the 30 days prior to baseline
• Decompensated congestive heart failure (CHF) or hospitalization due to CHF during the three
months prior to baseline
• Life threatening rhythm disorders or any rhythm disorders that would require placement of an
internal defibrillator and / or pacemaker
• Severe chronic obstructive pulmonary disease (COPD) as indicated by a forced expiratory volume in one second that is less than 55% of the predicted value
• Subject cannot undergo exercise tolerance test or 6-minute walk test for reasons other than
refractory angina
• Severe valvular heart disease
• Subject with pacemaker or defibrillator electrode in the right atrium (RA), right ventricle
(RV), or CS
• Subject having undergone tricuspid valve replacement or repair
• Chronic renal failure (serum creatinine >2 mg/dL), including subjects on chronic hemodialysis
• Moribund subjects, or subjects with comorbidities limiting life expectancy to less than one year
• Contraindication to required medications that cannot be adequately controlled with
pre-medication
• Known allergy to stainless steel or nickel
• Currently enrolled in another device or drug trial that has not completed the primary
endpoint or that clinically interferes with the current study endpointsAngiographic Exclusion
• Mean right atrial pressure greater than or equal to 15 mmHg
• ubject with anomalous or abnormal CS as demonstrated by angiogram. Abnormality defined as:
• Abnormal CS anatomy (e.g., tortuosity, aberrant branch, persistent left superior vena cava [SVC])

and/or;
• CS diameter at the site of planned Reducer implantation less than 9.5 mm or greater than 13
mm• Mean right atrial pressure greater than or equal to 15 mmHg
• Subject with anomalous or abnormal CS as demonstrated by angiogram. Abnormality defined as:
• Abnormal CS anatomy (e.g., tortuosity, aberrant branch, persistent left superior vena cava [SVC])
and/or;
• CS diameter at the site of planned Reducer implantation less than 9.5 mm or greater than
13 mm

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-05-2017
Enrollment:	78
Type:	Actual

Medical products/devices used

Generic name:	Neovasc Reducer
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	01-06-2016
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	14-02-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	31-10-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-11-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	08-01-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-01-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	16-09-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-04-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-03-2023
Application type:	Amendment
Review commission:	METC NedMec

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	NL55679.041.16