Cryterion Cardiac Cryoablation System CE Mark Study (Amendment 02)

Published: 09-09-2019
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The clinical study objective is to demonstrate the acute and 12 months safety and performance of the Cryterion Cardiac Cryoablation System when used as intended.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON48322

Source
ToetsingOnline

Brief title
CRYTERION

Condition

- Cardiac arrhythmias

Synonym
Atrial Fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Cryterion Medical Inc. supported by Boston Scientific Corporation
Source(s) of monetary or material Support: Boston Scientific Corporation

Intervention

Keyword: Atrial Fibrillation, Cryoablation, PVI

Outcome measures

Primary outcome

Safety endpoint is assessed by freedom from device or procedure related serious adverse events (referred to as Major Adverse Events, MAE) occurring up to 12 months post index procedure. MAEs include the following:

* Death

* Myocardial infarction

* Cardiac perforation/ pericardial tamponade

* Cerebral infarct or systemic embolism

* Major bleeding requiring transfusion of blood products

* Mitral or tricuspid valvular damage

* Phrenic nerve palsy causing persistent diaphragmatic paralysis

* Symptomatic pulmonary vein stenosis

* Atrio-esophageal fistula

* Air embolism leading to a life-threatening event such as a ventricular arrhythmia, stroke or myocardial infarction

* Any other serious or non-serious adverse device effects (SADEs or ADEs)

Secondary outcome

Secondary endpoints include:

* All Procedure and device related adverse events

* Documentation of all PVs that demonstrate isolation immediately post ablation and then show reconnection during entrance/exit block testing

* Operator*s assessment of handling characteristics (through a System

Performance Questionnaire) compared to commercially available sheaths circular

mapping catheters and balloon ablation technologies

Study description

Background summary

Cryoablation has gained significant popularity and utilization worldwide. With the understanding the pulmonary veins may be the *cornerstone* of ablation strategies, a cryo balloon has been developed to provide a *single shot* therapy for isolation of the pulmonary veins. By navigating the balloon to the ostium of the PV and occluding flow, a PV may be isolated with a single cryoablation of 3 - 4 minutes. The currently approved technology (Artic Front*/ Arctic Front Advance* Cryoablation Balloon, Medtronic®) has completed two landmark studies demonstrating efficacy for PAF management of approximately 70% and 65% respectively.22,23
Complications arising from cryoablation are consistent with those of heat-based therapies. Additionally, as the balloon is placed in the right-sided PVs and near the phrenic nerve, diaphragm paralysis, (both transient and permanent), has been reported. To mitigate this risk, pacing maneuvers and continuous analysis of diaphragmatic movement has been used. (Protocol page 20).

Study objective

The clinical study objective is to demonstrate the acute and 12 months safety and performance of the Cryterion Cardiac Cryoablation System when used as intended.

Study design

Multi-center, open label, prospective, open enrollment study to document the safety and performance of the Cryterion Cardiac Cryoablation System.

Intervention

A de novo ablation procedure followed by clinical follow up visits at 1M, 3M, 6M and 12M post procedure.

Study burden and risks

Risks associated with an ablation procedure. Risks associated with the cryo ablation procedure do not differ from the standard ablation procedure.

Contacts

Public
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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

IC 1 Male or female between the ages of 18 - 80 years old.
IC 2 Currently scheduled for a de novo ablation of atrial fibrillation (AF) defined as AF with self-terminating episodes lasting no longer than 7 continuous days (PAF).
IC 3 Willingness, ability, and commitment to participate in baseline and follow-up evaluations for the full duration of the clinical study.
IC 4 Willing and able to give informed consent.

Exclusion criteria

EC 1 In the opinion of the Investigator, any known contraindication to an AF

ablation, TEE, or anticoagulation
EC 2 Any duration of continuous AF lasting longer than 7 days
EC 3 History of previous left atrial ablation or surgical treatment for AF/AFL/AT
EC 4 Atrial fibrillation secondary to electrolyte imbalance, thyroid disease, or any other reversible or non-cardiac cause
EC 5 More than four (4) electrical cardioversions in the year prior to enrollment excluding cardioversions performed within 24 hours of arrhythmia onset.
EC 6 Structural heart disease or implanted devices as described below:
a. Left ventricular ejection fraction (LVEF) < 40% based on TTE based on most recent TTE (* 6 months)
b. Left atrial size > 50mm or left atrial volume index >50 ml/m2 based on most recent TTE (* 6 months, one measurement of the two being sufficient)
c. An implanted pacemaker or ICD
d. Previous cardiac surgery: ventriculotomy, or atriotomy (excluding atriotomy for CABG)
e. Previous cardiac valvular surgical or percutaneous procedure, or prosthetic valve
f. Interatrial baffle, closure device, patch, or PFO occluder
g. Presence of a left atrial appendage occlusion device
h. Presence of any pulmonary vein stents
i. Coronary artery bypass graft (CABG) or PTCA procedure within the last 30 days
j. Unstable angina or ongoing myocardial ischemia
k. Previous myocardial infarction (* 6 months)
l. Moderate or severe mitral insufficiency noted on baseline TTE (* 6 months)
EC 7 Any previous history of cryoglobulinemia
EC 8 History of blood clotting or bleeding disease
EC 9 ANY prior history of documented cerebral infarct, TIA or systemic embolism (excluding a post-operative DVT)
EC 10 Pregnant or lactating (current or anticipated during study follow up)
EC 11 Current enrollment in any other study protocol where testing or results from that study may interfere with the procedure or outcome measurements for this study
EC 12 Any other condition that, in the judgment of the investigator, makes the subject a poor candidate for this procedure, the study or compliance with the protocol (includes vulnerable subject population, mental illness, addictive disease, terminal illness with a life expectancy of less than two years, extensive travel away from the research center), Secondary Screening: subject or conducted per physician discretion according to institution*s SOC

EC 1 Any pulmonary vein diameter >30 mm as evidenced by CT scan, LA venogram or intracardiac echo (ICE)
EC 2 A common long left pulmonary vein ostium as evidenced by CT scan, LA venogram or ICE that in the judgment of the investigator makes the subject a poor candidate for this study

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):	17-10-2019
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Cryterion Cardiac Cryoablation System
Registration:	No

Ethics review

Approved WMO Date:	09-09-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	13-02-2020
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
ClinicalTrials.gov	NCT03723070
CCMO	NL70072.078.19