POLARx Cardiac Cryoablation System Post Market Clinical Follow-up study

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Primary objective: This is a Post Market Clinical Follow-up (PMCF) study designed to establish the continued safety and effectiveness profile of the Boston Scientific Cardiac Cryoablation System after receiving CE mark.Secondary objective: The study…

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

Summary

ID

NL-OMON54978

Source
ToetsingOnline

Brief title
POLAR-ICE

Condition

- Cardiac arrhythmias

Synonym
Atrial Fibrilation

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific
Source(s) of monetary or material Support: Boston Scientific Corporation

Intervention

Keyword: Cardiac Cryoablation, Paroxysmal Atrial Fibrilation, PVI (Pulmonar Vein Isolation)

Outcome measures

Primary outcome

Primary Saferty Endpoint:

Safety event free rate at 12 months post-index procedure.

Primary safety events will consist of a composite of the following

procedure-related and device-related adverse events.

Acute primary safety endpoint events, events occurring up to 7 days postindex

procedure or hospital discharge, whichever is later, include:

• Death

• Myocardial infarction (MI)

• Persistent gastroparesis/injury to vagus nerve

• Transient ischemic attack (TIA)

• Stroke/Cerebrovascular accident (CVA)

• Thromboembolism/Air embolism*

• Cardiac tamponade/perforation

• Pneumothorax

• Serious vascular access complications**

• Pulmonary edema/heart failure

• AV block not attributable to medication effect or vasovagal reaction.

* Thromboembolic or /air embolic events collected in the study refer to any

occlusion of

blood vessel(s) that results in clinical symptoms

** Defined as prolongation of hospitalization, requirement of surgical

intervention or

blood transfusion

Chronic primary safety endpoint events, events occurring through 12

months post-index procedure, include:

• Atrial esophageal fistula

• Pulmonary vein stenosis (>= 70% reduction of diameter)

• Symptomatic pericardial effusion

• Persistent Phrenic nerve injury***

***A non-recovered phrenic nerve injury at 12 months post-index procedure will

count

as a chronic primary endpoint. The study will collect information on phrenic

nerve palsy

observed before the end of the index procedure and, in case it occurred, will

track

information for potential recovery during the study visits.

Primary Effectiveness Endpoint:

Failure free rate at 12 months post-index procedure.

Failure defined as:

• Failure to achieve acute procedural success* in the index procedure;

• More than one repeat procedure during the blanking period (within 90 days

post-index procedure);

• Documented atrial fibrillation, or new onset of atrial flutter or atrial

tachycardia event (>= 30 seconds in duration or from a 10 second 12-lead ECG) between days 91 and days 365 post-index procedure **;

• Any of the following interventions for atrial fibrillation, or new onset of atrial flutter or atrial tachycardia between days 91 and days 365 post-index procedure:

• Repeat procedure;

• Electrical and/or pharmacological cardioversion for AF/AFL/AT;

• Prescribed a higher dose of any AAD*** documented at baseline or a new AAD*** not documented at baseline.

* Acute procedural success is defined as isolation of the all pulmonary veins or anatomical equivalents achieved with the Cryoablation Catheter at the end of the index procedure and as demonstrated at minimum by entrance block using the Cryo Mapping Catheter (Other techniques of assessment are per investigator*s discretion).

** Subjects will be monitored for recurrences of the arrhythmias by means of clinical visits, ECG and 24-hour Holter monitoring.

*** AADs for endpoint will consist of all Class I/III and any Class II/IV medications taken for control of AF/AT/AFL recurrence

Secondary outcome

Documentation and rate of acute procedural success, defined as pulmonary vein isolation achieved with the Cryoablation System. Electrical isolation of a PV is demonstrated at minimum by entrance block using the Cryo Mapping Catheter (Other techniques of assessment are per investigator*sdiscretion).

Information on isolation method used per site standard of care will be

collected with a minimum by entrance block in all PVs or anatomical equivalents. Additional data, if available, will be collected on Exit Block or Conduction Block verification using 3D mapping.

Additional endpoints:

Additional endpoints and analyses include, but are not limited to:

• Procedure times: LA dwell time*, total ablation time, number of cryo applications per vein, time to thaw, total fluoroscopy time and total procedure time;

• Time-To-Isolation per ablation application, if available;

• Freedom from recurrence of individual types of atrial arrhythmias (AF, AFL, AT) between days 91 and days 365 post-index procedure;

• Analysis of ablation techniques (i.e. segmental approach to left common trunk, additional linear ablations, etc.);

• Analysis of different anaesthesia techniques (General anaesthesia with or without intubation versus sedation);

• Freedom from recurrence in subjects with non-common anatomical configurations of PV (e.g. left common trunk);

• Freedom from primary effectiveness failure evaluated in subgroups of subjects (termination of AAD versus continuation of AAD after blanking period);

• For the subgroup of subjects undergoing 3D mapping with the Boston Scientific mapping Rhythmia system and performing a post-procedural map, map information will be collected to determine lesion locations;

• For subjects that will undergo repeat ablation during the course of the

clinical follow-up, anatomical location of ablations gaps will be assessed.

* LA dwell time is defined as time from the Cryoablation Catheter introduced in

the left atrium (LA) to the last time of Cryoablation Catheter exiting the LA.

Additional ancillary analyses on specific subgroup of subjects, may be

presented.

These analyses will include but not limited to the following:

• Age (<60 versus >= 60 years);

• Gender (Male versus Female).

Study description

Background summary

Atrial fibrillation (AF) is the most commonly encountered sustained cardiac arrhythmia in
clinical practice. AF causes symptoms that impair quality of life, increases the risk of stroke fivefold, and increases mortality. There are multiple therapies in current use for the treatment of AF like ablation.
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.
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.

Study objective

Primary objective: This is a Post Market Clinical Follow-up (PMCF) study designed to establish the continued safety and effectiveness profile of the Boston Scientific Cardiac Cryoablation System after receiving CE mark.

Secondary objective: The study will provide information on real-world usage of the Boston Scientific Cardiac Cryoablation System when used to perform pulmonary vein isolation (PVI) for the ablation treatment of atrial fibrillation (AF), according to the current and future guidelines and system indications for use. This may include but not limited to: repeated ablations to treat AF, concomitant or delayed adjunctive ablation strategies with other products and use of different diagnostic products to validate the results such as 3D mapping systems. Collected information and analyses will include, but not limited to, the following:
• Arrhythmia characterisation at the time of enrollment: time since first AF diagnosis, number and duration of reported episodes, prior electrical cardioversions (if any);
• History of prior ablations and repeated ablations during follow-up period;
• Use of anti-arrhythmic drugs (AAD);
• Methods used for verification of procedure success (pulmonary vein isolation): entrance/exit block, provocative agents, use of three-dimensional (3D) mapping.

Study design

Prospective, non-randomized, multicenter (international), single arm study. All subjects signing the consent, undergoing the index procedure and reated with the study devices will be followed up for one year. Men and women with the age of 18 years or above and plannend for a de novo ablation for atrial fibrillation.

Study burden and risks

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

Contacts

Public
Boston Scientific

Lambroekstraat (Green Square) 5D
Diegem 1831
BE
Scientific
Boston Scientific

Lambroekstraat (Green Square) 5D
Diegem 1831

BE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Subjects indicated for the treatment of AF with the cryoablation system according to current and future Guidelines and system indications for use;
2. Subjects who are willing and capable of providing informed consent;
3. Subjects who are willing and capable of participating in all testing associated with this clinical study at an approved clinical investigational center;
4. Subjects whose age is 18 years or above, or who are of legal age to give informed consent specific to state and national law.

Exclusion criteria

1. Any known contraindication to an AF ablation or anticoagulation, including those listed in the instructions for use;
2. Subjects with indication for treatment of AF that is not according to current and future Guidelines and system indications for use;
3. Atrial fibrillation secondary to electrolyte imbalance, thyroid disease, or any other reversible or non-cardiac cause;
4. Known or pre-existing severe Pulmonary Vein Stenosis;

5. Evidence of myxoma, LA thrombus or intracardiac mural thrombus;
6. Previous cardiac surgery (e.g. ventriculotomy or atriotomy, CABG, PTCA, stent procedure) within 90 days prior to enrollment;
7. Implantable cardiac device procedures (e.g. PM, ICD, CRT) within 30 days prior to enrollment;
8. Implanted Left Atrial Appendage Closure device prior to the index procedure;

9. Interatrial baffle, closure device, patch, or patent foramen ovale (PFO) occluder;

10. Subjects with severe valvular disease OR with a prosthetic - mechanical or biological - heart valve (not including valve repair and annular rings);

11. Presence of any pulmonary vein stents;
12. Active systemic infection;
13. Vena cava embolic protection filter devices and/ or known femoral thrombus;
14. Any previous history of cryoglobulinemia;
15. History of blood clotting or bleeding disease;
16. Any prior history of documented cerebral infarct, TIA or systemic embolism (excluding a post-operative deep vein thrombosis (DVT)) <= 180 days prior to enrollment;
17. Subjects who are hemodynamically unstable;
18. The subject is unable or not willing to complete follow-up visits and examination for the duration of the study;

19. Life expectancy <= 1 year per investigator*s opinion;

20. Women of childbearing potential who are, or plan to become, pregnant during the time of the study (method of assessment upon investigator*s discretion);

21. Unrecovered/unresolved Adverse Events from any previous invasive Procedure;

22. Subjects who are currently enrolled in another investigational study or registry that would directly interfere with the current study, except when the subject is participating in a mandatory governmental registry, or a purely observational registry with no associated treatments; each instance must be brought to the attention of the sponsor to determine eligibility.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-11-2020
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	POLARx cryoablation system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	31-08-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-10-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-02-2021
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
CCMO	NL73440.100.20