Catheter Cryoablation versus Antiarrhythmic Drug as First-Line Therapy of Paroxysmal Atrial Fibrillation

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The primary objective of this study is to evaluate if PVI performed with cryoballoon and other cryocatheters is superior to AAD as first-line therapy in preventing atrial arrhythmia recurrences

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

Summary

ID

NL-OMON42900

Source
ToetsingOnline

Brief title
CRYO-FIRST

Condition

- Cardiac arrhythmias

Synonym
Atrial Fibrillation, Cryo ablation

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic B.V.
Source(s) of monetary or material Support: Medtronic Bakken Research Centrum

Intervention

Keyword: Cryoablation, paroxysmal atrial fibrillation

Outcome measures

Primary outcome

The primary endpoint is freedom from any atrial arrhythmia recurrence at 12 months (at least one episode of AF, atrial flutter or atrial tachycardia with a duration > 30 seconds documented by 7 day Holter ECG or any other printed ECG recording following a blanking period or a dosing optimizing period of 3 months).

Secondary outcome

Secondary endpoint 1

The quality of life of the two arms measured by SF-36 Health Survey and Atrial Fibrillation Effect on QualiTy-of-Life (AFEQT) questionnaires will be compared at 12 months follow-up.

Secondary endpoint 2

Hospital or emergency services accesses due to symptoms caused by documented atrial arrhythmias will be compared in the two arms at 12 months follow-up.

Secondary endpoint 3

Freedom from occurrence of AF (after 3 months blanking period) will be compared between the two arms at 12 months follow-up.

Secondary endpoint 4

Freedom from occurrence of documented left atrial tachycardia and typical - or atypical left atrial flutter (after 3 months blanking period or AAD optimization period) will be compared between the two arms at 12 months

follow-up.

Secondary endpoint 5

Symptomatic palpitations burden will be evaluated by mean of Patient*s diary information and compared between the two arms at 12 months follow-up.

Secondary endpoint 6

Severe adverse events incidence will be compared between the two arms during the whole course of the study.

Secondary endpoint 7

Freedom from persistent AF (AF episode lasting longer than 7 days or interrupted by pharmacological or electrical cardioversion after 48h from the onset of the episode) will be compared between the two arms at 12 months follow-up.

Secondary endpoint 8

Echocardiographic left atrial parameters will be compared between the two arms at 6 and 12 months follow ups.

Secondary endpoint 9

Frequency, type and associated cost of health care utilization will be compared between the two arms at 12 months follow-up.

Study description

Background summary

see page 13-16 of the protocol

Study objective

The primary objective of this study is to evaluate if PVI performed with cryoballoon and other cryocatheters is superior to AAD as first-line therapy in preventing atrial arrhythmia recurrences

Study design

Prospective, multi center, open-label, randomized, interventional post market release study

Intervention

Cryo-ablation in the pulmonary vein

Study burden and risks

Standard risks associated with the medical devices used in this study, an analysis of Adverse Device Effects, residual risks associated with the investigational device, as identified in the risk analysis report and a history of modification or recall of device under investigation or equivalent devices are listed in the Investigator*s Brochure.

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

* Subject has been diagnosed with symptomatic paroxysmal atrial fibrillation as defined above and at least two symptomatic episodes in the last six months prior to inclusion.
* At least one episode of AF must be documented during the prior year by any kind of ECG recording.
* Subject has structural normal heart with an LVEF * 50%, thickness of the inter-ventricular septum *12 mm and left atrium diameters (short axis) < 46 mm obtained by transthoracic echocardiography.
* Subject has normal ECG parameters (QRS width in the 12 channel surface ECG *120 ms, QTc * interval < 440 ms, PQ * interval * 210 ms; all parameters should be measured at sinus rhythm).
* Subject is at least 18 and * 75years old.
* Subject is able and willing to give informed consent.

Exclusion criteria

* Subject developed persistent AF at least once in history (electrical or pharmacological cardioversion after 48h or episode duration >7 days).
* Subject has documented typical atrial flutter.
* Subject has any history of successful or unsuccessful treatment of AF with class I or III antiarrhythmic or sotalol with the intention to prevent an AF recurrence. Patients pretreated with above AAD at maximum 48 hours with the intention to convert an AF episode are allowed.
* Subject had any previous left atrial ablation.
* Subject had any previous cardiac surgery, e.g. prosthetic valves.
* Subject has permanent pacemaker or defibrillator implant.
* Subject has 2° type II, 3° degree AV-block or left/right bundle branch block pattern.
* Subject has unstable angina pectoris.
* Subject has history of previous myocardial infarction or percutaneous intervention during the last three months.
* Subject has symptomatic carotid stenosis.
* Subject has chronic obstructive pulmonary disease with detected pulmonary hypertension or any other evidence of significant lung disease.
* Subject has any contraindication for oral anticoagulation.
* Subject has any history of previous transient ischemic attack or stroke.
* Subject has known intra-cardiac thrombus formation.

* Subject has any significant congenital heart defect corrected or not (except for patent foramen ovale that is allowed).
* Subject has evidence of congestive heart failure (NYHA class II, III or IV) in sinus rhythm.
* Subject has hypertrophic cardiomyopathy.
* Subject has abnormal long or short QT interval, signs of Brugada syndrome, known inheriting ion channel disease on the family, arrhythmogenic right ventricular dysplasia.
* Subject has sarcoidosis.
* Subject has pulmonary vein stent.
* Subject has myxoma.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-10-2017
Enrollment:	26
Type:	Actual

Medical products/devices used

Generic name:	Arctic Front Advance Cardiac CryoAblation Catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-12-2016

Application type:	First submission
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
Other	Clinicaltrials.gov
CCMO	NL57677.078.16