Combined Endoscopic Epicardial and Percutaneous Endocardial Ablation versus Repeated Catheter Ablation in Persistent and Longstanding Persistent Atrial Fibrillation [CEASE AF - Trial]

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

Summary

ID

NL-OMON42344

Source
ToetsingOnline

Brief title
CEASE-AF

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation, fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: AtriCure Europe B.V.
Source(s) of monetary or material Support: Industrie

Intervention

Keyword: Catheter abalation, Persistent AF, Radio-frequency ablation, Surgical ablation

Outcome measures

Primary outcome

The Primary Effectiveness Endpoint is freedom from documented AF/AFL/AT episodes > 30 seconds through 12 months follow-up, in the absence of Class I or III AADs (with the exception of previously failed AADs at doses not exceeding those previously failed).

Secondary outcome

The Secondary Effectiveness Endpoint is freedom from documented AF/AFL/AT) >30 seconds through 24 and 36 months follow-up, in the absence of Class I or III AADs (with the exception of previously failed AADs at doses not exceeding those previously failed).

The rhythm status used for evaluation of the Primary and Secondary Endpoint will be derived from regularly scheduled 48-hour Holter monitoring and any symptom driven monitoring performed.

Study description

Background summary

Atrial fibrillation (AF) is the most common cardiac arrhythmia with a lifetime risk of developing AF of 1 in 4 people aged over 40. Besides hemodynamic compromises, AF increases the risk of stroke by 5-fold, and is associated with

increases the odds ratio of death to 1.5 in males and 1.9 in females.
Anti-arrhythmic drug (AAD) therapy remains the first line treatment for AF;however, it does not represent a cure for AF. All AAD therapies used for AF treatment have significant side effects and they are of marginal effectiveness in
nearly all patient populations. Atrial pacing and defibrillators do not cure the arrhythmia and may not result in better quality of life.

Catheter ablation has evolved as a standardized treatment option in paroxysmal AF supported by the current guidelines. Although pulmonary vein isolation (PVI) is the cornerstone of all interventional approaches for AF-treatment, no uniform concept in the setting of the non-paroxysmal forms currently exists. Especially in the setting of long-standing persistent AF, additional strategies apart from sole pulmonary vein isolation are required to achieve reasonable results regarding rhythm control. Due to the advanced electrical and structural remodeling of the atria, the results of a single catheter ablation for persistent and longstanding persistent AF are disappointing, and repeated endocardial procedures are required in most patients. Due to these shortcomings, minimally invasive endoscopic surgical techniques applied epicardially have gained attention with good results in this difficult to treat patient population. The combination of initial epicardial (surgical) ablation followed by endocardial (catheter) ablation (staged hybrid ablation) is expected to be most efficacious in avoiding lesion gaps and providing the most complete lesion set for effective treatment of the arrhythmia.

Hybrid ablation procedures are currently being performed as standard practice by teams of surgeons and electrophysiologists to improve on the efficacy in the treatment of Persistent and Longstanding Persistent AF patients which currently represent a group of patients with less effective treatment alternatives.

Study objective

Currently, no robust clinical data are available comparing interventional ablation strategies in the setting of persistent AF with enlarged Atrium > 4 cm and longstanding persistent AF, which reflects a difficult to treat patient-subgroup.
Thus, it is the aim of the present randomized study to compare the effects of combined epicardial endoscopic surgical and endocardial catheter techniques vs standard endocardial catheter ablation strategies with regard to safety, efficacy and quality of life. Also, effects on health economics of the two treatment strategies will be evaluated

Study design

A total of 210 eligible patients will be randomized (2:1 ratio).
140 patients in the hybrid ablation arm, 70 in the catheter ablation arm.

For each patient, the study duration will be 3.5 years (42 months).
Subjects will be followed at discharge and at 3 and 6 months from the index procedure: during this interval, the study ablation treatment will be completed. The 6 month visit is the starting point of the follow-up period that lasts for additional 3 years and is defined as T0. During the follow-up period, patients will be evaluated at 6 and 12 months, and yearly thereafter, until 3 years after completion of the treatment phase.
At follow-up visits after hospital discharge, patients will undergo noninvasive routine diagnostic tests including 48 hour holter monitoring at several timepoints. To ensure consistent data an independent ECG/holter core laboratory will be used to provide the holter monitoring devices and perform ECG analysis and symptom driven analysis.

Intervention

hybrid ablation versus standard catheterablation.

For the endoscopic epicardial surgery of patients in the hybrid arm CE marked AtriCure devices will be used for the ablation procedure.
Endoscopic surgery will include a minimum lesion set including a PV isolation by the means of a box lesion (right and left epicardial isolation of the PVs, superior and inferior connecting lines) and exclusion of the left atrial appendage if considered safe by the surgeon under general anesthesia. Additional lesions may be performed, based on standard practice at the interventional sites.

Catheter ablation will be performed using standard endocardial transvenous technique of PV isolation and possibly additional ablations on physician*s discretion / center's strategy which are in accordance with current guidelines.

For details refer to section 7 of the Protocol.

Study burden and risks

Burden for the patient is limited to the completion of the SF12 questionnaire at 6 visits.
Other assessments and treatments are in line with current treatment for the patients condition.

At this moment both catheter and hybrid ablation are used but no robust data is available that compares both techniques in the difficult to treat patient group in this study.

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

Patients with Persistent and Longstanding Persistent Atrial Fibrillation
Patient is refractory to or intolerant of at least one antiarrhythmic drug (class I or III)

Exclusion criteria

1. Patient has longstanding persistent AF > 10 years
2. Patient presenting with paroxysmal AF
3. Patient with persistent AF and a LA-diameter <= 4cm
4. AF is secondary to electrolyte imbalance, thyroid disease, or other reversible or non-cardiovascular cause

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:	Recruiting
Start date (anticipated):	23-03-2016
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	AtriCure devices for the surgical ablation procedure (patients in the hybrid group)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-12-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	16-08-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	17-04-2020
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	NL54331.100.15