Identification of a Risk Profile Associated with Failure of the Cryoballoon Ablation of Atrial Fibrillation; a Multicenter Explorative Registry.

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The primary aim of the present registry is to assess a risk profile including biomarkers and genetics, associated with failure of the cryoballoon AF ablation, so we can predict failure of the cryoballoon AF ablation. Failure will be assessed within…

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

Summary

ID

NL-OMON46840

Source
ToetsingOnline

Brief title
Cryoballoon AF Ablation.

Condition

- Cardiac arrhythmias

Synonym
Atrial Fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Gelden vanuit de Van Buchem Stichting (afdeling Cardiologie;UMCG),Medtronic B.V.

Intervention

Keyword: Ablation, Atrial Fibrillation, Cryoballoon, Risk profile

Outcome measures

Primary outcome

The primary objective is to assess a risk profile, including circulating biomarkers and genetic background, associated with failure of the cryoballoon AF ablation, i.e. any (a)symptomatic AF/AFL/AT >30 sec without anti-arrhythmic drugs determined within 1 year of follow-up by ECG recording and 1-day Holter monitoring.

Secondary outcome

Secondary outcomes concern the identification of a risk profile associated with (long term) failure or success of the procedure; the number of patients requiring repeat baltaion following cryoballoon AF ablation; the electrophysiological findings during the (redo) procedure; procedural predictors of succes of the cryoballoon AF ablation; the incidence and type of supraventricular tachyarrhythmia*s following the procedure; the occurence of major cardiac and cardiovascular events; safety of the cryoballoon AF ablation; changes in left atrial size and function following ablation; the degree of epicardial adipose tissue; the use of anti-arrhythmic drugs; the frequency of repeated ablations; quality of life and physical activity.

Study description

Background summary

Outcome of rhythm control therapy depends on the severity of atrial fibrillation (AF), i.e. atrial (electrical/mechanical/structural) remodeling. Beside echocardiographic markers of atrial structural remodeling, atrial remodeling also seems to be represented by circulating biomarkers. Catheter ablation of atrial fibrillation by pulmonary vein isolation (PVI) is an established therapy for patients with symptomatic atrial fibrillation. Currently, different catheters are available for ablation of the pulmonary veins. The cryoballoon catheter is an established ablation technique with good documented efficacy and safety rates in patients with atrial fibrillation. In patients where the cryoballoon ablation has not been successful, this is probably due to the underlying substrate of the arrhythmia, including fibrosis of the atria. We hypothesize that the severity of atrial remodeling in patients with AF can be measured by clinical factors, echocardiographic parameters, circulating biomarkers and genetic background, and that these factors can be used to identify a risk profile to predict failure of the cryoballoon AF ablation therapy.

Study objective

The primary aim of the present registry is to assess a risk profile including biomarkers and genetics, associated with failure of the cryoballoon AF ablation, so we can predict failure of the cryoballoon AF ablation. Failure will be assessed within one year of follow-up using ECG and 1-day Holter monitoring. In addition patients eligible for the cryoballoon AF ablation procedure will be asked to undergo extra blood analysis for determining biomarkers and genetics.

Study design

A prospective multicenter registry.

Study burden and risks

Extra (study-related) investigations consist of blood sampling for biomarker and genetic analysis at baseline, questionnaires for quality of life and physical activity at baseline, and at 1 and 5 year of follow-up, and telephone consultation to collect data at 3 and 5 year of (long-term) follow-up. Extra visits to the outpatient clinic will not be necessary. At baseline blood samples for biomarkers are collected together with blood sample collection for routine clinical care, so no additional venipuncture will be necessary. Risks

of the (study related) investigations are negligible.

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

1. Patients who have agreed to undergo the cryoballoon ablation procedure for atrial fibrillation.
2. Age >18 years.
3. Written informed consent.

Exclusion criteria

1. Patients who had a prior ablation treatment because of atrial fibrillation.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-10-2018
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO Date:	30-09-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-10-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-03-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL53511.042.15