Ablation as first line treatment of paroxysmal atrial fibrillation

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Primary objectives: To find out whether catheter ablation in the very early stages of AF (i.e. no structural nor electrical remodeling) compared to AADs leads to 1) more effective rhythm control after a blanking period of three months during an...

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

Summary

ID

NL-OMON39542

Source
ToetsingOnline

Brief title
AFLIT-PAF

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation, paroxysmal atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ablation, paroxysmal atrial fibrillation, treatment

Outcome measures

Primary outcome

Primary endpoint of this study is any recurrence of symptomatic AF or asymptomatic AF and atrial flutter/tachycardia during a follow-up period of 6 months after the blanking period.

Secondary outcome

1) any recurrence of symptomatic AF or asymptomatic AF and atrial flutter/tachycardia in the absence of AAD therapy after the initial six months follow-up, 2) comparison of the subjective findings of recurrence of AF by the patient through QoL and symptom questionnaires, 3) number of track complications, both acute (during the procedure) and chronic throughout the trial and 4) hospitalization rate during a two and a half year follow-up following the initial six months follow-up.

Study description

Background summary

Atrial fibrillation (AF) is leading to electrical and structural remodeling. In patients with paroxysmal AF there is minimal remodeling. In case of advanced remodeling restoration of sinus rhythm becomes more difficult and the results of catheter ablation of arrhythmogenic foci are disappointing. Catheter ablation in the very early stages of the disease could therefore be more effective than antiarrhythmic drug (AAD) therapy: it holds the potential to treat AF and reverse remodeling leading to better rhythm control.

Study objective

Primary objectives: To find out whether catheter ablation in the very early stages of AF (i.e. no structural nor electrical remodeling) compared to AADs leads to 1) more effective rhythm control after a blanking period of three months during an initial follow-up of six months, 2) less frequent progression of disease after at least two years follow-up. Secondary objectives are 1) describing the electrophysiologic behaviour of AF with continuous monitoring in the absence of important electrical or structural remodeling, 2) effectivity of catheter ablation for paroxysmal AF regarding AFburden and progression to persistent or permanent AF during a follow-up of three years, 3) the comparison of the quality of life (as assessed using Quality of Life (QoL) and symptom questionnaires), 4) number of acute or chronic complications and hospitalization rate during a three year follow-up, 5) definition of a well-described cohort of early-ablated paroxysmal AF patients for long term follow-up.

Study design

Single center, randomized, controlled trial

Intervention

Patients in the intervention group will undergo isolation of all pulmonary veins (PV) and nonPV foci. Patients in the control group will be treated with AADs except for amiodarone. Patients in both the intervention and control group will be continuously monitored with an implantable cardiac monitor (REVEAL*, Medtronic) during the whole follow-up period of the study (i.e. three years).

Study burden and risks

Patients assigned to the intervention group will undergo cryothermal pulmonary vein isolation. Cryothermal catheter ablation is a safe procedure with a risk of peri-operative complications of 6%, which is mostly due to a transient phrenic nerve palsy.30 However, it should be noted that many of the complications, although serious, typically result in only acute and not longterm morbidity. These complications include femoral pseudoaneurysm, arteriovenous fistula, pneumothorax, hemothorax, transient ischemic attack, and cardiac tamponade. The most serious complications resulting in permanent disability were uncommon (death in 0.05% and stroke in 0.28%). In our electrophysiology department we performed more than 200 AF ablation procedures over the last four years with an overall major complication rate comparable to other experienced centres.31 Implantation of the REVEAL device, is common clinical practice. The REVEAL device is placed under the skin in the upper chest area. The recommended implant zones are from the left parasternal area extending to the mid-clavicular line between the first intercostal space and the fourth rib. During the brief procedure, the area is numbed with local anesthesia, a small incision is made, and the monitor is inserted. The mean

complication of this procedure, is pocket infection with an occurrence rate of less than 1%.

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 will be eligible for inclusion in the study if they meet all of the following inclusion criteria:
* Age between 18 and 65
* At least three episodes of paroxysmal atrial fibrillation documented on an electrocardiogram or event recording during the last three years
* Never taken antiarrhythmic drugs or at most a pill in the pocket approach
* Willingness, ability and commitment to participate in baseline and follow-up evaluations

Exclusion criteria

Subjects are excluded from the study if any of the following conditions are present (for all procedures):
* Paroxysmal AF for more than three years
* An episode of atrial fibrillation that lasted more than seven days within the past six months
* Persistent/permanent atrial fibrillation
* Atrial fibrillation from reversible cause (i.e. surgery, hyperthyroidism, pericarditis)
* Documented atrial flutter
* Structural heart disease of clinical significance including:
o Cardiac surgery within six months of screening
o Unstable symptoms of congestive heart failure (CHF) including NYHA Class III or IV CHF at screening and/or ejection fraction <30% as measured by echocardiography or catheterization
o Unstable angina
o Myocardial infarction within six months of screening
o Surgically corrected atrial septal defect with a patch or closure device
o LA size > 40mm
* Any prior ablation of the pulmonary veins
* Enrollment in any other ongoing protocol
* Untreatable allergy to contrast media
* Pregnancy
* Any contraindication to cardiac catheterization
* Prosthetic mitral heart valve
* Poor general health that, in the opinion of the Investigator, will not allow the patient to be a good study candidate (i.e. other disease processes, mental capacity, etc.)
* Contraindication to coumadin or heparin
* History of pulmonary embolus or stroke within one year of screening
* Acute pulmonary edema
* Atrial clot on TEE regardless of the patient*s anticoagulation medication status

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2013
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	24-09-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-12-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	31-03-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NCT01466842
CCMO	NL37863.068.11

Study results

Date completed: 01-07-2016

Actual enrolment: 5

Summary results
Trial ended prematurely