Five year outcome of minimally invasive surgical ablation of paroxysmal and persistent atrial fibrillation

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The aim of this study is to investigate the efficacy and safety of minimally invasive surgery after five year follow up in a cohort of patients with symptomatic, drug refractory, paroxysmal or persistent AF. The patients will have an additional...

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

Summary

ID

NL-OMON42532

Source
ToetsingOnline

Brief title
5-year outcome Minimaze

Condition

- Cardiac arrhythmias
- Cardiac therapeutic procedures

Synonym
atrial fibrillation, fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: atrial fibrillation, follow up, minimal invasive surgical ablation

Outcome measures

Primary outcome

-Freedom of any recurrence of atrial fibrillation, atrial flutter or atrial tachycardia, documented on ECG or 24-hour Holter within five years after the procedure without the use of antiarrhythmic drugs.

-Sinus rhythm on electrocardiogram at follow up visit five years or more ofter the procedure.

-Use of antiarrhythmic drugs at follow up visit.

Secondary outcome

-Functional status measured by the SF-36 Quality of Life questionnaire at 60 months follow up.

-The occurrence of any procedure related complications and the occurrence of other clinical events during 60 months follow up.

-Major adverse cardiac events (MACE) during 60 months or more follow up.

Study description

Background summary

Atrial Fibrillation (AF) is the most common cardiac arrhythmia. Treatment of AF is challenging, despite increasing pharmacological and technological treatment options. Patients with symptomatic AF, who are refractory to antiarrhythmic drugs (AAD), have an indication for invasive treatment, either with catheter ablation or with surgical ablation. Catheter based interventions have a lower single procedure success rate of 57% off AAD after a mean follow up of 14 months1, but are less invasive than minimally invasive surgery for AF. A systematic literature overview by Krul et al. showed that the single procedure

success rate for minimally invasive surgery is 69% (95% CI, range 58%-78%) without AAD and 79% (95% CI, range 71%-85%) at one year follow up with AAD2. Long term follow up data on invasive treatment options for AF is limited. Studies show that success rates after a single catheter ablation procedure decrease significantly to 16.8%- 29% at five year follow up3 4. In previous studies on minimally invasive surgery with a maximum follow up of 30 months, the success rates does not seem to decrease further after one year follow up5. However, these studies have high numbers of patients, who are lost to follow up. Therefore, clinical data on long term outcome of minimally invasive surgical ablation is sparse. This study is aimed to investigate the efficacy and safety of minimally invasive surgery after five year follow up in a cohort of patients with paroxysmal and persistent AF.

Study objective

The aim of this study is to investigate the efficacy and safety of minimally invasive surgery after five year follow up in a cohort of patients with symptomatic, drug refractory, paroxysmal or persistent AF. The patients will have an additional follow up visit at the outpatient clinic of the department of Cardiology more than five years after the surgical procedure .

Study design

This study is a retrospective, single center, cohort study.

Study burden and risks

This study poses no significant risk for the participants.

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 who have undergone minimal invasive surgical ablation for paroxysmal or persistent atrial fibrillation between 2008 and 2010 in the Academic Medical Center.

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-07-2015
Enrollment:	66

Type:	Actual

Ethics review

Approved WMO Date:	29-06-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL53839.018.15