Catheter ablation versus video assisted thoracoscopic surgery for the treatment of (longstanding) persistent atrial fibrillation

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The aim of this study is to determine which treatment, SA or CA, is superior as a primary treatment option in patients suffering from symptomatic, drug refractory (longstanding) persistent AF.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON41871

Source
ToetsingOnline

Brief title
The CAVIAR-trial

Condition

- Cardiac arrhythmias

Synonym
Atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Atrial fibrillation, Catheter ablation, Minimal invasive surgery, Video assisted thoracoscopic surgery

Outcome measures

Primary outcome

-Success after 1 procedure with a follow-up duration of 12 months.

Success is defined as: freedom of atrial fibrillation/atrial flutter/atrial

tachycardia >30 seconds following the 3 months blanking period in the absence

of Class I and III AAD therapy.

Secondary outcome

-The incidence of periprocedural complications.

-Clinical success (75% or greater reduction in the number of AF episodes, the

duration of AF episodes, or the % time a patient is in AF in the presence or

absence of previously ineffective AAD therapy) after the first procedure.

-Procedural duration.

-Success and clinical success after 2 procedures with a follow-up duration of

12 months. A second procedure will be performed through catheter ablation in

both groups.

-Quality of life measurements before and 6 months after the first procedure.

Study description

Background summary

Atrial fibrillation (AF) is the world*s most common cardiac arrhythmia. It is

responsible for significant morbidity and mortality in the general population mainly caused by congestive heart failure and ischemic stroke. It may also lead to an impaired quality of life with the requirement for chronic use of medication. In case of symptomatic AF, refractory or intolerant to antiarrhythmic medication, ablation treatment may be performed. There are two treatment options using radiofrequency (RF) ablation, a transvenous approach (catheter ablation) and a surgical approach.
Catheter ablation (CA) is a well-established treatment option in patients with symptomatic, drug refractory atrial fibrillation. CA has proven to be a curative treatment option in patients suffering from paroxysmal atrial fibrillation. In patients with persistent and longstanding persistent AF the outcomes of catheter abaltion are less satisfactory.
Surgical ablation (SA) is considered minimally invasive when performed through Video Assisted Thoracoscopic Surgery (VATS). The results of minimally invasive surgical ablation through VATS are promising.
No randomized controlled trial directly comparing CA and SA for the primary treatment of (longstanding) persistent AF has been performed yet.

Study objective

The aim of this study is to determine which treatment, SA or CA, is superior as a primary treatment option in patients suffering from symptomatic, drug refractory (longstanding) persistent AF.

Study design

Single center randomised controlled intervention trial

Intervention

Minimally invasive surgical ablation through video assisted thoracoscopic surgery

Study burden and risks

The first results of SA through VATS are promising. A systematic literature overview and analysis of the first results and progress made SA showed 67% success after one procedure in patients suffering from persistent AF after one year. In studies applying the same additional left atrial linear lesions success even increased to 79%.
Catheter ablation seems, especially after one procedure, less successful. Experiences from the UMCU from 2009-2012 showed 38% success in patients with persistent and longstanding persistent atrial fibrillation 1 year after the primary ablation. This increased to 58% success one year after the second procedure.

Hospitalization in the SA group is prolonged with 2-3 days compared with CA. There*s conflicting evidence regarding the complication rates in SA compared with CA. Two recent systematic reviews focussing separately on CA or SA, concluded that the incidence of peri-procedural complications is approximately 6.3% for CA and 13.2% for SA, although the number of procedures studied in SA is much lower compared with CA. Mortality rates are comparable. A review which included all currently available comparative data of SA and CA only showed significantly more pacemaker implantations in the SA group but no differences in other major complications.

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 age is * 18 years

- Patients with persistent or longstanding persistent atrial fibrillation.
- Patients undergoing a first time invasive treatment procedure for persistent atrial fibrillation
- AF must be recorded at least once by ECG, holter, telemetry, loop recorder or internal device.
- Patients must give informed consent to participate

Exclusion criteria

- Patients suffering from paroxysmal atrial fibrillation
- Patients with any exclusion criteria or contra-indications for electrophysiologic study and ablation in the left atrium, such as pregnancy or presence of a left atrial thrombus
- Patients with any contra-indications for VATS such as pleural adhesions, elevated hemidiaphragm or prior lung/cardiac surgery
- Active infection or sepsis
- Body mass index> 40
- mitral or aortic valve regurgitation above grade 2
- moderate to severe mitral or aortic stenosis

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:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO Date:	09-09-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL51954.041.15
Other	volgt