The CAVIAR-trial

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20520

Source
NTR

Brief title
CAVIAR

Health condition

Persistent and longstanding persistent atrial fibrillation

Sponsors and support

Primary sponsor: University Medical Center Utrecht (UMCU)
Source(s) of monetary or material Support: University Medical Center Utrecht (UMCU)

Intervention

Outcome measures

Primary outcome

The primary objective of the study is to evaluate which treatment- surgical ablation or catheter ablation- is most effective in treating persistent and longstanding persistent atrial fibrillation measured by success at 12 months after 1 procedures.

Secondary outcome

The incidence of periprocedural complications, clinical success after 12 months, procedural

duration, number of repeat procedures, success and clinical success after 2 procedure after 12 months, quality of life measurements before and 6 months after the first procedure.

Study description

Background summary

Introduction

Catheter ablation (CA) is a successful treatment option in patients suffering from paroxysmal atrial fibrillation (AF). In patients with (longstanding) persistent AF the results are substantially lower. Over the last years, minimal invasive surgical ablation (SA) through video assisted thoracoscopic surgery (VATS) has been developed. Compared with CA, SA may be more effective, especially after one procedure. No randomized controlled trials directly comparing CA and SA for the primary treatment of (longstanding) persistent AF have been performed yet.

Purpose

The aim of this study is to determine which treatment, SA or CA, is superior as a primary treatment in patients suffering from (longstanding) persistent atrial fibrillation (AF) measured by success at 12 months after 1 procedure

Methods

The CAVIAR-trial is a single center, randomized intervention study with a follow up of 12 months. 60 Patients will be randomized in either:

o Transvenous catheter ablation

o Minimal invasive surgical ablation through video assisted thoracoscopic surgey

The follow-up protocol is the same as standard care. Patients will visit the outpatient clinic at 3, 6, and 12 months post-ablation.

Study objective

The hypothesis is that minimal invasive surgical ablation through video assisted thoracoscopic surgey as a primary treatment in patients suffering from (longstanding) persistent atrial fibrillation is superior to transvenous catheter ablation

Study design

Follow up will take place at 3,6 and 12 months

Intervention

-Catheter ablation

-Surgical ablation

Contacts

Public
Heidelberglaan 100
C. Teunissen
Utrecht 3584CX
The Netherlands
+3188-7550398
Scientific
Heidelberglaan 100
C. Teunissen
Utrecht 3584CX
The Netherlands
+3188-7550398

Eligibility criteria

Inclusion criteria

- Patients age is > 18 years

- Patients with persistent or longstanding persistent atrial fibrillation. Persistent AF is defined as sustained episodes of atrial fibrillation lasting >7 days. Longstanding persistent AF is defined as sustained episode lasting >1 year.

- 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. Paroxysmal AF is defined as episodes of AF that terminates spontaneously within 7 days.

- Patients suffering from AF secondary to a reversible cause as electrolyte imbalance or hyperthyroidism.

- Body mass index >40

- Active infection or sepsis

- Unstable angina, myocardial infarction within the previous 6 months

- Patients with any contra-indications for electrophysiologic study and ablation in the left atrium:

-pregnancy

-presence of a left atrial thrombus

- Patients with any contra-indications for video assisted thoracoscopic surgery:

- prior lung/cardiac surgery

- pleural adhesions

- elevated hemidiaphragm

- 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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2015
Enrollment:	60
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL4809
NTR-old	NTR5081
Other	ABR : 51954

Study results