Video-Assisted Thoracoscopic pulmonary vein isolation versus percutaneous Catheter Ablation in atrial fibrillation Trial.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28912

Source
NTR

Brief title
VATCAT

Health condition

atrial fibrillation Non pharmacological treatment

Sponsors and support

Primary sponsor: Medisch Spectrum Enschede, thoraxcenter
Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

The percentage of patients without a recurrence of AF, without AADs, within a follow-up

period of at least 12 months after a stabilisation period of 90 days after the initial procedure. An episode of AF is defined as an episode of at least 30 seconds duration.

Secondary outcome

Secondary objectives include the duration and cost of hospitalization, discomfort during admission, assessment and experienced AF burden during follow-up of procedural impact on the patient and time to recurrence after intervention. A complication register will also be kept.

Study description

Background summary

N/A

Study objective

The primary hypothesis of the VATCAT trial is that PVI is superior to VATS-PVI in patients with symptomatic AF in terms of cardiovascular mortality and morbidity, QoL and cost.

Study design

3, 6 and 12 months.

Intervention

Percutaneous catheter ablation (n=104) versus video-assisted epicardial ablation and left atrial appendage exclusion (n=52) in a 2:1 randomization.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients > 18 years of age;

2. Documented, symptomatic, episodes of paroxysmal or persistent AF;

3. During the last 6 months patients must have at least 2 documented episodes of AF, despite the use of at least 1 anti arrhythmic drug;

4. Able of providing informed consent.

Exclusion criteria

1. Pregnancy;

2. Unwillingness to use or contra-indications for vitamin K antagonists;

3. Severely enlarged left atrium (>50 mm) on echocardiography;

4. Prior AF ablation or AF surgery;

5. Intracardiac thrombus;

6. Prior heart surgery or pulmonary disease hampering thoracoscopic surgery.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	09-08-2010
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-08-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39516
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2349
NTR-old	NTR2455
CCMO	NL32865.044.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39516

Study results

Summary results
N/A