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

Published: 20-07-2010
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To compare the effectiveness of PVI and VATS-PVI. Secondary objectives are to compare the duration of hospitalisation, quality of Life, cost and to compare the satisfaction of the patients.

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

Summary

ID

NL-OMON39516

Source
ToetsingOnline

Brief title
VATCAT

Condition

- Other condition
- Cardiac arrhythmias
- Cardiac therapeutic procedures

Synonym
atrial fibrillation

Health condition

minimaal invasieve interventie

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Stichting Hartcentrum Twente

Intervention

Keyword: Ablation, Atrialfibrillation, PVI, VATS

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

Recent studies demonstrated that radiofrequency isolation of the pulmonary veins (PVI) and surgically video assisted thorascopic pulmonary vein isolation (VATS-PVI) are acceptable or even superior alternatives to antiarrhythmic drug therapy in patients with symptomatically paroxysmal atrial fibrillation (AF). However, data comparing effectiveness in both interventions are limited.

Study objective

To compare the effectiveness of PVI and VATS-PVI. Secondary objectives are to compare the duration of hospitalisation, quality of Life, cost and to compare the satisfaction of the patients.

Study design

The Video Assisted Thoracoscopic pulmonary vein isolation versus percutaneous Catheter Ablation in atrial fibrillation Trial (VATCAT) is a prospective single center study.

Intervention

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

Study burden and risks

Using only routine non-pharmacological interventions will have no extra risk or burden for the patients. The two most important element of this study is the study design assign patients at random to either treatment and the intensive rhythm follow-up using a 7 day event recorder.

Contacts

Public
Medisch Spectrum Twente

Haaksbergerstraat 55
Enschede 7513ER
NL
Scientific
Medisch Spectrum Twente

Haaksbergerstraat 55
Enschede 7513ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Patients > 18 years of age
* Documented, symptomatic, episodes of paroxysmal or persistent AF
* 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.
* Able of providing informed consent

Exclusion criteria

* Pregnancy
* Unwillingness to use or contra-indications for vitamin K antagonists
* Severely enlarged left atrium (>50 mm) on echocardiography
* Prior AF ablation or AF surgery
* Intracardiac thrombus
* Prior heart surgery or pulmonary disease hampering thoracoscopic surgery

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-10-2010
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	20-07-2010
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	19-03-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28912
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL32865.044.10
OMON	NL-OMON28912