A FACT (Atrial Fibrillation ablation and AutonomiC modulation via Thoracoscopic Surgery). A randomized single center study to prospectively investigate the effect of ablation of the autonomic ganglia in addition to minimally invasive surgical isolation of the pulmonary veins in patients with atrial fibrillation.

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Ethical review	-
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON34819

Source
ToetsingOnline

Brief title
A FACT

Condition

- Cardiac arrhythmias

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, Autonomic ganglia, Minimally invasive surgery, Pulmonary vein isolation

Outcome measures

Primary outcome

The primary endpoint of the study is freedom of AF after one and two years

after the procedure with or without the use of antiarrhythmic drugs. Freedom of

AF is defined as the absence of documentation of AF on serial Holter recordings

during follow up and on ECGs recorded outside the scope of the study. One

single episode of <30 minutes is allowed. Patients complaints about

palpitations without the documentation of AF is allowed.

Secondary outcome

The secondary endpoints include:

1) Freedom of AF after one and two years after the procedure without the use of

any antiarrhythmic drug. Definition of freedom of AF as above.

2) Improvement of functional status as measured by the RAND 36 quality of life

questionnaires

Study description

Background summary

Atrial fibrillation (AF) is the most common chronic arrhythmia in man. Its treatment consists of control of ventricular rate or attempts to restore sinus rhythm. For symptomatic patients who fail on antiarrhythmic drugs, isolation of the pulmonary veins (PV), with additional linear left atrial lesions when appropriate, can cure AF. At least in some, but probably in many patients, the autonomous nervous system plays a pivotal role in the initiation and perpetuation of AF. The autonomic ganglia, or ganglionated plexi (GP) are located within the epicardial fat pads of the left atrium. This study aims at investigating the additional value of ablation of those GPs in addition to totally thoracoscopic PV isolation.

Study objective

This study aims at investigating the role of autonomic modulation of AF. Therefore, totally thoracoscopic PV isolation with additional ablation of ganglionated plexi (GP) will be studied against PV isolation alone. Two groups of patients (paroxysmal AF with or without structural heart disease and persistent AF with or without heart disease) of 130 patients each will be studied.

Study design

This is a single center, randomized single blinded study

Intervention

In patients randomized to additional GP ablation, the following procedures will be carried out during the totally thoracoscopic procedure in addition to the PV isolation (and extended lesion set when appropriate): The left atrial autonomic GPs are localized within the epicardial fat pads and subsequently ablated with radiofrequency current delivered through an ablation probe (AtriCure Isolator* Transpolar* pen).

Study burden and risks

The intervention carries no risks other than the risks associated with the minimally invasive surgery (the standard treatment).

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 with paroxysmal or persistent atrial fibrillation, refractory to at least one antiarrhythmic drug, between 18 and 80 years of age and willing to participate in the study and the follow-up

Exclusion criteria

Catheter treatment for atrial fibrillation within 4 months before inclusion, myocardial infarction within the previous 2 months, heart failure, stroke in the previous 6 months, refuse to take medication, severely enlarged left atrium.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-03-2010
Enrollment:	275
Type:	Actual

Ethics review

Not available

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	NL30199.018.10