

# Concomitant epicardial pulmonary vein isolation in patients with atrial fibrillation undergoing elective cardiac surgery

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To establish the effectiveness of incorporating epicardial pulmonary vein isolation into elective cardiac surgery. Secondary objectives are comparison of the duration and hospitalization costs.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Cardiac arrhythmias
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON36466

### Source

ToetsingOnline

### Brief title

CONTROL-AF

### Condition

- Cardiac arrhythmias

### Synonym

atrial fibrillation

### 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, CABG, PVI

## 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.

The percentage of patients without post-operative atrial fibrillation during admission. An episode of AF is defined as an episode of at least 30 seconds duration.

### Secondary outcome

Secondary outcomes include comparison of cost and duration of hospitalization, post-procedural discomfort and experienced AF burden during follow-up.

## Study description

### Background summary

Recent studies demonstrated that radiofrequency isolation of the pulmonary veins (PVI) is a superior alternative to antiarrhythmic drug therapy in patients with symptomatic paroxysmal atrial fibrillation (AF). A substantial proportion of patients undergoing elective cardiac surgery also suffer from atrial fibrillation. No evidence exists if epicardial PVI is beneficial in patients with a history of AF undergoing coronary bypass surgery (CABG) for the concomitant treatment of AF.

## Study objective

To establish the effectiveness of incorporating epicardial pulmonary vein isolation into elective cardiac surgery. Secondary objectives are comparison of the duration and hospitalization costs.

## Study design

Concomitant epicardial PVI in patients with atrial fibrillation undergoing elective cardiac surgery is a prospective single center study.

## Intervention

Concomitant epicardial pulmonary vein isolation versus \*usual care\* based on a 1:1 randomization strategy.

## Study burden and risks

Using a strategy combining elective surgery with an extra intervention will introduce almost no extra discomfort or procedural risks. The application of a proven treatment of pulmonary vein isolation will most likely result into reduction of atrial fibrillation burden. Based on consensus statement regarding AF research, patients will undergo a seven day eventrecorder registration during follow-up adding some burden to study participation.

## Contacts

### Public

Medisch Spectrum Twente

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NL

### Scientific

Medisch Spectrum Twente

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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  $\geq 18$  years of age

EHRA class  $\leq 2$

Documented history of paroxysmal, persistent, longstanding persistent or newly-diagnosed AF prior to admittance for cardiac surgery

Patients will have elective coronary surgery planned

Able of providing informed consent

### Exclusion criteria

Patients  $\geq 70$  years of age

Pregnancy

Patients with contraindications for oral anticoagulant agents.

Patients undergoing emergency operation

Patients undergoing concomitant valve replacement

Severely enlarged LA ( $>50$  mm) on echocardiography

Prior AF ablation or AF surgery

## 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: Recruitment stopped  
Start date (anticipated): 01-08-2011  
Enrollment: 70  
Type: Actual

## Ethics review

Approved WMO  
Date: 29-03-2011  
Application type: First submission  
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

No registrations found.

## In other registers

Register	ID
CCMO	NL35192.044.11