

# PVAI alone vs. PVAI plus ablation of complex fractionated atrial electrograms in a specific area of the left atrium in patients suffering from (longstanding) persistent atrial fibrillation.

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The aim of this study is to determine if adding ablation restricted to specific areas of the left atrium to PVAI is superior to the standard care PVAI alone.

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

## Summary

### ID

NL-OMON41115

### Source

ToetsingOnline

### Brief title

The PVAI+ trial

### Condition

- Cardiac arrhythmias

### Synonym

atrial fibrillation

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** atrial fibrillation, catheter ablation, fractionation, pulmonary vein antrum isolation

## Outcome measures

### Primary outcome

The primary objective of the study is to evaluate which ablation strategy- PVAI

alone or PVAI plus limited ablation of CFAE\*s in a specific region of the left

atrium- is most effective in treating persistent and longstanding persistent

atrial fibrillation measured by success at 12 months after 1 or 2 procedures.

Success is defined as freedom from recurrences following the 3-month blanking

period in the absence of Class I and III AAD therapy.

Recurrence is defined as recurrence of atrial fibrillation, atrial flutter or

atrial tachycardia of at least 30 seconds\* duration that is documented by an

ECG or device recording system more than 3 months following AF-ablation.

### Secondary outcome

-procedural duration

-fluoroscopy time

-number of repeat procedures

-number of patients showing CFAE in the particular region of the left atrium

-incidence of periprocedural complications

-quality of life measurements before and after ablation

# Study description

## Background summary

Atrial fibrillation (AF) is the world's most common cardiac arrhythmia. It is responsible for a significant morbidity and mortality in the general population primarily caused by congestive heart failure and ischemic stroke. Catheter ablation is a well-established treatment option in patients with symptomatically, drug refractory atrial fibrillation. During the past decade it transformed from a experimental approach to a commonly worldwide performed procedure. The cornerstone of catheter ablation is pulmonary vein antrum isolation (PVAI). Over the last years catheter ablation is being applied increasingly in patients with persistent and longstanding persistent AF. In these patients the outcome of PVAI is more disappointing than in patients with paroxysmal AF.

Different ablation strategies have developed over the years, with special focus on the ablation of complex fractionated atrial electrograms (CFAE) and additional linear ablation lesions. CFAE's are very rapid electrograms or electrograms with multiple, continuous split components. They may represent areas in the atrium that contribute to re-entry and maintain AF. On the other hand they also may indicate sites of non-pulmonary vein triggers for AF. Incomplete linear lesions and irregular ablation lesions after (extensive) ablation of CFAE's may act pro-arrhythmic and lead to (macro) re-entry tachycardia's.

To this day, the optimal primary approach for catheter ablation of (longstanding) persistent AF remains unclear. Recently, our focus shifted to fractionated electrograms in the area under the right inferior pulmonary vein, the inferior left atrial septum and the ostium and roof of the coronary sinus. Several patients who underwent a repeat procedure, showed CFAE in these particular regions of the left atrium. Ablation of these CFAE led to good results (unpublished data)

## Study objective

The aim of this study is to determine if adding ablation restricted to specific areas of the left atrium to PVAI is superior to the standard care PVAI alone.

## Study design

A single center, randomized controlled single-blind intervention study

## Intervention

pulmonary vein antrum isolation plus limited ablation of CFAE's in a specific

region of the left atrium (the area under the right inferior pulmonary vein, the inferior left atrial septum and the ostium and roof of the coronary sinus)

### **Study burden and risks**

A recent systematic review concluded that ablations of CFAE showed no significant difference in complication rate compared with PVAI.

## **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 age is  $\geq 18$  years
- Patients with persistent or longstanding persistent atrial fibrillation.

- Patients undergoing a first time ablation 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.
- Patients with any exclusion criteria or contra-indications for electrophysiologic study and ablation in the left atrium, such as pregnancy or presence of a left atrial thrombus
- Prior PVAI with RF or cry ablation

## 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:	Recruiting
Start date (anticipated):	09-09-2014
Enrollment:	90
Type:	Actual

## Ethics review

Approved WMO	
Date:	09-07-2014
Application type:	First submission

## 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	NL48677.041.14