# Identification of the Pathophysiological Substrate of Atrial Fibrillation in Patients Undergoing Cardiac Surgery

Published: 04-12-2008
Last updated: 06-05-2024

To study the underlying pathophysiological substrate of atrial fibrillation in the individual patient by intraoperative measurements and histological analysis of atrial tissue. With this method we may identify patients that do not favor from...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Cardiac arrhythmias |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON32366

**Source**
ToetsingOnline

**Brief title**
The pathophysiological substrate of atrial fibrillation

### Condition

- Cardiac arrhythmias

**Synonym**
atrial fibrillation, heart rhythm disturbances

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** ablation, atrial fibrillation, electrophysiology, surgery

## Outcome measures

### Primary outcome

Sinus rhythm 6 and 12 month after treatment.

Mortality (in hospital, 6 month and 12 month).

Degree of fibrosis from the left atrial appendage.

Atrial fibrillation cycle length from different atrial locations.

Degree of electrogram fragmentation during AF from different locations of the right and left atria and the pulmonary veins.

Conduction characteristics from different locations of the right and left atria and the pulmonary veins.

Electrophysiological exit and entrance block after pulmonary vein ablation.

### Secondary outcome

Morbidity including CVA, TIA

Hospital length of stay

Use of antiarrhythmic agents

Preoperative duration of AF.

Preoperative echocardiographic parameters such as atrial dimensions, left ventricular dimensions and ejection fraction, valvular characteristics.

# Study description

### Background summary

Atrial fibrillation (AF) is one of the most common arrhythmias in clinical practice. It is associated with an 2-3 fold increased mortality and significant morbidity. AF generally occurs in the presence of an atrial substrate in the context of different underlying pathologies. Despite the improvement in knowledge, current surgical treatment of AF comprises a standard approach for all patients without taking into account the variation in underlying pathology. This standard approach includes a minimized ablation pattern with isolation of the pulmonary veins and resection of the left atrial appendage. This treatment is offered to patients with AF undergoing cardiac surgery for other reasons and to a selective group with *lone* AF using minimally invasive surgery.

Success of treatment depends on the type of AF and the underlying pathology. Although several factors such as duration of AF, atrial size, left ventricular ejection fraction and valvular disease have been identified, it remains unclear which patients favor most from pulmonary vein isolation. The higher success percentages (80-90%) of pulmonary vein isolation in patients with paroxysmal AF points toward the involvement of the pulmonary veins, whereas in patients with chronic AF, structural heart disease and dilated atria, the success rate of pulmonary vein ablation remains poor (50-60%). This indicates that ectopic foci from the pulmonary veins may not be the mechanism for AF in all patients, and isolation of the pulmonary veins may thus be ineffective and even redundant in some. Also the atrial region responsible for initiation and maintenance of AF can differ from patient to patient and it is not known whether isolation of other regions than the pulmonary veins can increase the success percentage.

**Study objective**

To study the underlying pathophysiological substrate of atrial fibrillation in the individual patient by intraoperative measurements and histological analysis of atrial tissue. With this method we may identify patients that do not favor from pulmonary vein isolation alone and identify other arrhythmogenic areas that could be a target for ablation. These data can be a guide for future treatments of atrial fibrillation with substrate targeting, which may increase the success percentages of AF treatment significantly.

**Study design**

This is a prospective clinical study. Patients with AF admitted for surgical AF treatment alone or concomitant with valvular and/or coronary bypass surgery will be studied. During surgery, epicardial electrophysiological measurements will be performed on different locations of the atria. Epicardial electrophysiological measurements have shown to be safe. To gain more insight in the relation between structural changes en electrophysiological parameters, atrial biopsies of the left atrial appendage will histologically studied. The left aterial appendage is routinely removed during surgical treatment of AF.

The operation time will be lengthened with 10-15 minutes. A total of 125 patients will be studied. The study is expected to take 24-30 month for inclusion and another 12 month for follow-up.

**Study burden and risks**

There is no direct benefit for patients to participate. The benefit can be found in more insight in the pathophysiological mechanisms of atrial fibrillation with a better treatment in the future. The burden and risks include an lengthening of operating time due to intraoperative measurements with 10 minutes. The risks of epicardial measurements include theoretically damage to the epicardium with bleeding, but many studies have shown that intraoperative electrophysiological measurements are feasible and safe.

# Contacts

**Public**
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10, postbus 9101
6500 HB Nijmegen
NL
**Scientific**
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10, postbus 9101
6500 HB Nijmegen
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

### Inclusion criteria

Patients with atrial fibrillation selected to undergo surgical treatment of AF alone or in combination with valvular and/or coronairy surgery.
History of AF (both paroxysmal and chronic AF)
Age between 18 and 80 years
Patient did give informed consent in writing

### Exclusion criteria

Previous thoracic surgery (epicardial measurements not possible due to adhesions)

## Study design

### Design

**Study type:** Observational invasive

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-11-2009 |
| Enrollment: | 30 |
| Type: | Actual |

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 04-12-2008 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

# 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 | NL23434.091.08 |