

# Epicardial Mapping Studies in Patients undergoing Cardiac Surgery

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To investigate whether high resolution multi-site epicardial mapping of the atria in patients with structural heart disease undergoing cardiac surgery can identify patients at risk for developing early post-operative atrial fibrillation. The...

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

## Summary

### ID

NL-OMON39666

### Source

ToetsingOnline

### Brief title

Epicardial Mapping Studies in Patients undergoing Cardiac Surgery

### Condition

- Cardiac arrhythmias
- Cardiac therapeutic procedures

### Synonym

atrial fibrillation

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

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

## Intervention

**Keyword:** cardio-thoracic surgery, epicardial, mapping, post-op atrial fibrillation

## Outcome measures

### Primary outcome

The main endpoint of the study is reached when atrial fibrillation develops.

There is a follow-up period of 5 years after cardiac surgery. Each year, the participant will be called by the investigator in order to check whether atrial fibrillation has occurred.

### Secondary outcome

NA

## Study description

### Background summary

Rationale: Post-operative AF after cardiac surgery affects not only early but also late mortality. The exact mechanism of post-operative AF is still unknown. Subsequently, at present there are no diagnostic tools available to identify patients at risk pre-operatively.

Objective: To investigate whether high resolution multi-site epicardial mapping of the atria in patients with structural heart disease undergoing cardiac surgery can identify patients at risk for developing early post-operative atrial fibrillation.

### Study objective

To investigate whether high resolution multi-site epicardial mapping of the atria in patients with structural heart disease undergoing cardiac surgery can identify patients at risk for developing early post-operative atrial fibrillation. The acquired knowledge will be used in clinical practice to ensure an appropriate selection of patients for AF therapy and to improve existing AF treatment modalities

### Study design

This study is designed as an observational study. Patients will be recruited at the department of thoracic surgery. The investigator is responsible for patient selection and appropriate inclusion. Patients scheduled for routine cardiac surgery will be asked to participate in this study.

## **Intervention**

Epicardial mapping during CABG

## **Study burden and risks**

Max. extension of 10-15 minutes of the surgical procedure

Max. 15 minutes per Follow-Up visit (Outpatient Clinic) once per year and a total Follow-up of 5 years.

## **Contacts**

### **Public**

Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230  
ROTTERDAM 3015 CE  
NL

### **Scientific**

Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230  
ROTTERDAM 3015 CE  
NL

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

All patients > 18 years scheduled for standard cardiac surgery.

## Exclusion criteria

paced atrial rhythms  
usage of anti-arrhythmic drugs  
hemodynamic instability  
presence of assist devices  
usage of inotropic agents  
emergency cardiac surgery  
redo-cardiac surgery

## 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): 01-09-2010

Enrollment: 650

Type: Actual

### Medical products/devices used

Generic name: Finger electrode MI05-077

Registration: No

## Ethics review

Approved WMO

Date: 04-05-2010

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 11-04-2013

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 30-09-2013

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 29-04-2014

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 12-08-2014

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## 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

CCMO

### ID

NL31162.078.10

## Study results

Date completed: 20-04-2020

Results posted: 19-04-2021

### First publication

01-01-1900

### URL result

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