

# Excitation-contraction and excitation-transcription coupling in atrial fibrillation

<b>Submission date</b> 28/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/02/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/05/2020	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
MEC 10-2-004

# Study information

## Scientific Title

Calcium role in the excitation-contraction and excitation-transcription coupling processes in human atrial fibrillation

## Study objectives

1. Reduction of the action potential duration in atrial fibrillation (AF) alters the intracellular calcium signaling which can be proarrhythmic
2. The alterations in intracellular calcium signaling affect the nuclear calcium signaling which induces the activation of specific calcium-dependent transcription pathways in AF

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Medical Ethics Committee of AZM, Maastricht Hospital, pending as of 28/05/2010

## Study design

Interventional open study

## Primary study design

Interventional

## Secondary study design

Non randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Cardiac atrial fibrillation

## Interventions

Biopsies of right atrial appendages in patients in SR, with paroxysmal and persistent AF and undergoing for open chest surgery.

## Intervention Type

Other

## Phase

Not Applicable

## Primary outcome measure

Measured on day of biopsy:

1. To study the intracellular calcium alterations in human paroxysmal and persistent AF and the proarrhythmic effects of these alterations in comparison to SR
2. To study the nuclear calcium signaling in human paroxysmal and persistent AF in comparison to SR
3. To determine the  $\text{Ca}^{2+}$ -dependent transcription pathways activated in AF and to study the consequences of the inactivation of these pathways on atrial cell electrical properties (i.e. AP, currents) and function (contraction)

### **Secondary outcome measures**

Measured on day of biopsy:

1. To determine the type of intracellular  $\text{Ca}^{2+}$  signals which can trigger cellular arrhythmias
2. To determine the key elements which play a major role in the activated calcium-dependent transcription pathways for drug targets
3. Long term goals: to restore contraction in AF and to prevent thrombosis

### **Overall study start date**

01/08/2010

### **Completion date**

31/01/2015

## **Eligibility**

### **Key inclusion criteria**

1. Patients applying to the predefined groups
2. Patients have given written consent
3. Both women and men between 18 years (included) and 70 years (included) old

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

570

### **Key exclusion criteria**

1. Patients who are scheduled for re-operation
2. Patients who do not speak/understand Dutch
3. Patients with sick sinus syndrome, atrioventricular (AV)-block or internal pacemaker
4. Patients who are not will-competent

**Date of first enrolment**

01/08/2010

**Date of final enrolment**

31/01/2015

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**Maastricht University**

Maastricht

Netherlands

6200 MD

## **Sponsor information**

**Organisation**

Maastricht University (Netherlands)

**Sponsor details**

Cardiovascular Research Institute Maastricht (CARIM)

Department of Physiology

Universiteitssingel 50, Room 3.112

PO Box 616

Maastricht

Netherlands

6200 MD

**Sponsor type**

University/education

**Website**

<http://www.maastrichtuniversity.nl>

**ROR**

<https://ror.org/02jz4aj89>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Fondation LEDUCQ (France)

**Alternative Name(s)**

Leducq Foundation

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

France

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration