

Excitation-contraction and excitation-transcription coupling in atrial fibrillation

Submission date 28/05/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 10/02/2011	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 29/05/2020	Condition category Circulatory System	☐ Individual participant data ☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Interventional open study

Study type(s)

Treatment

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(s)

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 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)

Key secondary outcome(s)

Measured on day of biopsy:

1. To determine the type of intracellular 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration