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Excitation-contraction and excitation-transcription coupling in atrial fibrillation

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

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 Ca2+-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 Ca2+ 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)
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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