Epicardial and Endocardial mapping of Atrial Fibrillation

Published: 29-10-2015
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to demonstrate persistent atrial fibrillation is associated with endocardial and epicardial dissociation of the heart.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON53005

Source
ToetsingOnline

Brief title
Epic End

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: Europese Unie

Intervention

Keyword: atrial fibrillation, endocardial, epicardial, mapping

Outcome measures

Primary outcome

parameter obtained from the mapping procedure: percentage of discontinuous

conduction.

Secondary outcome

Differences between the endo- and epicardium in electrophysiological parameters.

Development of (persistent) atrial fibrillation during the 5-year follow-up

period is an endpoint

Study description

Background summary

Atrial fibrillation (AF) is a common arrhythmia en incidence is expected to further increase over the next years. AF is associated with an increased risk of cerbrovascular accidents (CVA) and transient ischemic attacks (TIA). Consequently, the number of hospital admissions due to AF will also increase. Therapies often are unsuccesfull or give temporary results and are even less succesfull if patients have persisent forms of AF.

The cause for development or progression of AF is still unclear. In the past, studies have shown that dissociation and conduction delay occurs between following atrial cells during atrial fibrillation. More recently studies have also demonstrated in an atrial model of the goat that dissociation occurs between endo- and epicardial layers of the atrium during persistent AF. Our hypotheses is that also in humans with persistent AF dissociation occurs between de endo-and epicardial layers of the heart.

Study objective

to demonstrate persistent atrial fibrillation is associated with endocardial and epicardial dissociation of the heart.

Study design

This is an interventional study. During cardiac surgery endo-epicardial mapping will be performed during sinus rhythm and atrial fibrillation and biopsy of the heart appendage is performed. The only intervention exist of inducement of atrial fibrillation, if neccessary, via pacing with standard pacemaker leads. This is frequently done in other (i.e. elektrophysiological) procedures. There is a follow-up period of five years, which consists of two visits to our out-patient clinic with collection of a blood sample and four telephone calls.

Intervention

Pacing: Atrial Fibrillation will be induced by a standard pacemaker during the procedure

Study burden and risks

Extension of max. 15 minutes of the surgical procedure and 6 telephone calls within 5 years. On admission an extra blood sample will be taken (if possible) during routine blood sampling. Pacing and Epicardial mapping has been performed extensively in the Erasmus MC (QUASAR, MEC 2010-054) without any complications related to the electrode so far. Possible complications are those similar to standard complications of the cardiothoracic surgical procedure.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

patients > 18 years scheduled for standard cardiac surgery

Exclusion criteria

emergency cardiac surgery
prior left-sided radiation of the chest for malignancies
Severe kidney or liver failure

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2016
Enrollment:	300
Type:	Actual

Medical products/devices used

Generic name:	Multi-electrode array (MEA) type 192p-TUD-V1.3
Registration:	No

Ethics review

Approved WMO Date:	29-10-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-03-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-02-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-07-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-08-2022
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

ID: 26625
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50711.078.15
OMON	NL-OMON26625