Epicardial Mapping Studies in Patients undergoing Cardiac Surgery Roepnaam Quasar

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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	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
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NL
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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	ID
CCMO	NL31162.078.10

Study results

Date completed: 20-04-2020

Results posted: 19-04-2021

First publication
01-01-1900

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