Elektrode studie.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26202

Source
Nationaal Trial Register

Brief title
Elektrode studie

Health condition

Epicardial, Mapping, Atrial Fibrillation, Cardiac Surgery

Sponsors and support

Primary sponsor: Erasmus MC Rotterdam The Netherlands
Source(s) of monetary or material Support: N/A

Intervention

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

N/A

Study description

Background summary

Background of the study:

Post-operative AF after isolated coronary bypass graft 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 of the study:

To investigate whether high resolution multi-site epicardial mapping of the atria in patients with coronary artery 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 open chest surgery will be asked to participate in this study.

Study population:

Patients scheduled for standard coronary artery bypass grafting will be studied. Patients will be recruited at the
department of cardiology and cardiothoracic surgery. Routine surgical procedures are being performed daily. At least 2-4 patients will be included every week. Each patient, prior to enrolling in the study, will be provided with a written explanation of the study procedure together with an assessment of risks in participating in the study. Written informed consent will be obtained from all patients; no patient will be enrolled if the consent form is not signed. The informed consent form will also be signed by the investigator.

Primary study parameters/outcome of the study:

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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Max extension of 10 minutes of CABG surgery

Study objective

Post-operative AF after isolated coronary bypass graft 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 coronary artery 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

Pre-op, procedure, FU postop 1, 2, 3, 4 and 5 years.

Intervention

Epicardial mapping.

Contacts

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Eligibility criteria

Inclusion criteria

All patients > 18 years scheduled for standard coronary bypass grafting.

Exclusion criteria

1. Paced atrial rhythms;

2. Usage of anti-arrhythmic drugs;

3. Hemodynamic instability;

4. Presence of assist devices;

5. Usage of inotropic agents;

6. Emergency cardiac surgery;

7. Redo-cardiac surgery;

8. History of atrial fibrillation.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2010
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-09-2010
Application type:	First submission

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
NTR-new	NL2431

Register	ID
NTR-old	NTR2540
Other	MEC Erasmus MC / THCHOZ : 2010-054 / 2009-013 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A