Elektrode studie.

Gepubliceerd: 29-09-2010 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26202

Bron
Nationaal Trial Register

Verkorte titel
Elektrode studie

Aandoening

Epicardial, Mapping, Atrial Fibrillation, Cardiac Surgery

Ondersteuning

Primaire sponsor: Erasmus MC Rotterdam The Netherlands
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Epicardial mapping.

Contactpersonen

Publiek

's Gravendijkwal 230

N.M.S. Groot, de
Erasmus MC, afdeling Cardiologie, Kamer BA-579
Rotterdam 3015 CE
The Netherlands
+31 (0)10 7034479

Wetenschappelijk

's Gravendijkwal 230

N.M.S. Groot, de
Erasmus MC, afdeling Cardiologie, Kamer BA-579
Rotterdam 3015 CE
The Netherlands
+31 (0)10 7034479

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2010
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-09-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2431
NTR-old	NTR2540
Ander register	MEC Erasmus MC / THCHOZ : 2010-054 / 2009-013 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A