**Add-on value of Bi-Atrial Pacing in combination with standardised Sotalol treatment for the prevention of postoperative Atrial Fibrillation after Cardiovascular Surgery."

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To determine the add-on value of bi-atrial pacing in combination with standardised Sotalol treatment for the prevention of postoperative atrial fibrillation (POAF).

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

Summary

ID

NL-OMON41441

Source
ToetsingOnline

Brief title
Bi-atrial Pacing in combination with Sotalol to prevent Postoperative AF

Condition

- Cardiac arrhythmias
- Cardiac therapeutic procedures

Synonym
atrial fibrillation, fibrillation of the muscles of the 2 upper chambers of the heart

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: NWO VIDI Research Grant 91786379 to US

Intervention

Keyword: Atrial Fibrillation, Atrial pacing, electrophysiology, substrate

Outcome measures

Primary outcome

To determine the difference in incidence, frequency and duration of POAF after

cardiac surgery.

To study the development of the electropathological atrial substrate.

Secondary outcome

Clinical characteristics (age, echographic measurements, AF history, mediacion,

'AF burden', etc)

Histological and biochemical study of tissue (degree of fibrosis, hypertrophy,

etc).

Study of biomarkers in blood.

Study description

Background summary

Postoperative atrial fibrillation (POAF) is an important complication of cardiothoracic surgery. Pharmacological strategies can diminish, but not prevent POAF, therefore other than pharmacological treatments need to be developed in order to reduce the incidence of POAF.
Atrial fibrillation (AF) is the most frequent cardiac arrhythmia in adults with growing socio-economic burden. Although a significant progress has been made in understanding the pathophysiology of this arrhythmia, treatment of AF patients is still far from satisfactory. The success rate of electric cardioversion is still limited and anti-arrhythmic drugs are unable to prevent recurrences of

AF. Prevention of thromboembolic events still requires anticoagulation therapy with all the associated risks. Ablation techniques vary in their efficacy to cure persistent AF. Only a better understanding of this disease can lead to a better treatment.

Study objective

To determine the add-on value of bi-atrial pacing in combination with standardised Sotalol treatment for the prevention of postoperative atrial fibrillation (POAF).

Study design

: This is an open prospective randomised trial, comparing two treatment strategies (with or without bi-atrial pacing) for postoperative AF on a long-term basis, using trans-telephonic electrocardiographic monitoring until 6 weeks after surgery. Epicardial mapping will be conducted in patients in the non-pacing group and in patients with concomitant AF.

Intervention

Bi-atrial pacing for 72 hours postoperatively.

Study burden and risks

Their will be no risk of thromboembolic event during induction of acute AF as the patients will be heparinised. Mapping will take place before cardiopulmonary bypass and will not affect the aortic clamp time. There will be a 6 weeks postoperative follow-up.

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 with and without preoperative AF history who undergo isolated CABG or valve surgery.
Patients have given written consent.

Exclusion criteria

Patients who are scheduled for reoperation
Patients who do not speak/understand Dutch
Patients with sick sinus syndrome, AV-block or internal pacemaker
Patients who are not will-competent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-04-2009
Enrollment:	216
Type:	Actual

Ethics review

Approved WMO Date:	23-06-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-05-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-04-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-06-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-07-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL21417.068.08