READ-POAF pilot study. The use of the reveal XT as device for postoperative atrial fibrillation detection after cardiac surgery.

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To investigate the real incidence of POAF a Reveal device is implanted. Afterwards a risk stratification of POAF is made.Using modern mapping equipment and techniques, it is now possible to investigate the substrate for development of atrial...

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

Summary

ID

NL-OMON38044

Source
ToetsingOnline

Brief title
READ-POAF

Condition

- Cardiac arrhythmias

Synonym
AF, atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

Source(s) of monetary or material Support: Academisch Ziekenhuis Maastricht (cardiochirurgie) & Maatschap CTC Eindhoven

Intervention

Keyword: cardiac surgery, electrophysiology, POAF, RevealXT

Outcome measures

Primary outcome

Incidence of POAF untill 3 months after cardiac surgery.

determining an electrophysiological substrate for development of post operative

atrial fibrillation.

Secondary outcome

Incidence of POAF untill 3years after cardiac surgery.

Determine risk factors for early and late POAF.

Detect pre-operative (unnoticed) episodes of AF.

Determining an electrophysiological and histological substrate for the

incidence of paroxysmal AF in the first 3 years post cardiac surgery.

Study description

Background summary

Postoperative atrial fibrillation (POAF) after cardiac surgery is a common (1 in 3) complication and associated with morbidity and mortality. Not all episodes of AF are noticed and detected, especially after discharge.
There is evidence suggesting there is an electrophysiological and histological atrial substrate making patients susceptible for development of postoperative atrial fibrillation but also paroxysmal AF. This however has not yet been thoroughly investigated.

Study objective

To investigate the real incidence of POAF a Reveal device is implanted.

Afterwards a risk stratification of POAF is made.
Using modern mapping equipment and techniques, it is now possible to investigate the substrate for development of atrial fibrillation. This potentially has great consequences for prevention and treatment of this highly morbid arrhythmia.

Study design

130 patients will receive a Reveal device. Data will be substracted from the device at different moments from home.
Mapping during the operating will take place in 100 patients in AZM.

Study burden and risks

There is a small risk of minor complications (hemorrhage and infection of the pocket).The device can be explanted easyly if necessary. Ther is a burden of the im- and explantation of the device (local anesthesia, approx. 20 minutes). Patient will have to visit the out-hospital clinic twice.
The operation can be prolonged with 30 minutes for the purpose of mapping. Untill now there are no specific risks known to be associated with this 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

Undergoing elective cardiac surgery.

Exclusion criteria

AF in history.
Pacemaker.
Cardiac surgery before.
Participation in other study.
Patient not willing to co-operate.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2012
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Reveal XT

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-10-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-05-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-12-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL37204.060.11