Place of Reveal® In the peri-operative aSsessment of patients undergoing Major vascular surgery (PRISM2).

Published: 14-07-2008
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1. To capture (true) arrhythmic episodes in patients after a major vascular surgery procedure.

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

Summary

ID

NL-OMON33875

Source
ToetsingOnline

Brief title
PRISM2

Condition

- Cardiac arrhythmias

Synonym
management of post-operative patients, perioperative diagnosis of arrhythmias

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic Bakken Research Center B.V.
Source(s) of monetary or material Support: Medtronic BRC B.V.;onderdeel van Medtronic Minneapolis MN USA

Intervention

Keyword: arrhythmia monitoring, insertable cardiac monitor, non cardiac major vascular surgery

Outcome measures

Primary outcome

The detection of arrhythmic episodes by Reveal XT will be compared to the

standard 12-lead surface ECG.

Secondary outcome

not applicable

Study description

Background summary

The Reveal XT insertable cardiac monitor is indicated for patients at increased risk of cardiac arrhythmias, and for patients that experience transient symptoms indicative of cardiac arrhythmias.
Currently, patients scheduled for major vascular surgery are being assessed for clinical predictors of increased cardiovascular risk, including unstable coronary syndromes, decompensated heart failure, significant arrhythmias, and valvular disease. In the ACC/AHA 2007 Guidelines on Peri-operative Cardiovascular Evaluation and Care for Noncardiac Surgery the clinical practice concerning the identification and management of patients with post-operative arrhythmias and conducting disorders is being addressed.
According to these guidelines patients should be actively monitored post-operatively for cardiac arrhythmia*s (until discharge from the hospital) to allow physicians to manage their patients for example by prescribing anti-arrhythmic agents.
Currently, patient monitoring in the peri-operative setting can be achieved by Holter monitoring. However, this is being done in a discontinuous fashion and is only possible for a limited amount of time.
The use of the Reveal XT for post-operative risk assessment could improve the identification of patients at increased cardiovascular risk by increasing the time window of monitoring for arrhythmia and ischemia.

Study objective

1. To capture (true) arrhythmic episodes in patients after a major vascular surgery procedure.

Study design

The PRISM2 study is a research, non-randomized, open-label, single-center study.
The study will be conducted at the department of Vascular Surgery, Erasmus Medical Center, Rotterdam, The Netherlands.

Intervention

Participation in the PRISM2 study will require patients to undergo the following additional clinical procedures:
Implantation of Reveal XT
Holtermonitoring for 72 hrs during and after vascular surgery
Explant of Reveal XT
The study duration will amount to 8 weeks with a possilbe extension of 2 weeks

Study burden and risks

The potential risks to a subject participating in this study are expected to be similar to those encountered during standard Reveal XT implantation, use, explantation, ECG testing and Holter recording.

Reveal XT implantation will lead to scar formation. Other related events including pocket inflammation, and erosion through the skin have been estimated to occur in less than 1% of the cases.

Contacts

Public
Medtronic Bakken Research Center B.V.

Endepolsdomein 5
6229 GW Maastricht
Nederland
Scientific
Medtronic Bakken Research Center B.V.

Endepolsdomein 5
6229 GW Maastricht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patient is scheduled for non-cardiac vascular surgery of the for elective aortic abdominal aneurysm repair or lower extremity bypass surgery;
Patients eligible for the study are 18 years or older;
Patient is willing to receive a Reveal XT insertion and can be implanted with Reveal XT;
Patient is willing to wear external Holter devices for a 72 hour period;
Patient is willing to give his/her informed consent;

Exclusion criteria

Patient has an implanted pacemaker or ICD;
Patient has an allergy against adhesive surface ECG electrode;
The study will interfere with a therapeutic or diagnostic procedure which is planned or expected within the study period;
Patient is a minor, legally incompetent, or does not meet other local requirements for participation in a clinical study.
Patients has electrocardiographic abnormalities that preclude assessment of cardiac arrhythmias or myocardial ischemia will be excluded.
Patient has a changing ST-segment, i.e. a Bundle Branch Block and further ST-segment changes cannot be assessed.
Patient is pregnant

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-08-2008
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	14-07-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-09-2009
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	NL22719.078.08