Spinal Cord Stimulation to treat post-operative AF

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See protocol page 19The primary objective is to determine the occurrence of post-operative AT/AF between the start of anesthesia and the first 5 days after CABG surgery in randomized groups, defined as patients in the SCS group and patient in the...

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

Summary

ID

NL-OMON41184

Source
ToetsingOnline

Brief title
SCS-PAF

Condition

- Cardiac arrhythmias

Synonym
post-operative atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic Trading NL BV
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: CABG, post-operative AF, Prevention of arrhythmias, Spinal Cord Stimulation

Outcome measures

Primary outcome

See protocol page 19.

The primary objective is to determine the occurrence of post-operative AT/AF between the start of anesthesia and 5 days after CABG surgery in randomized groups, defined as patients in the control group and patient receiving SCS.

Secondary outcome

See protocol page 19, 20.

- Description of integral medication related to AT/AF and pain
- Description of number of cardioversion
- Description of hospitalizations longer than 5 days
- Description of blood pressure and heart rate
- Description of the total number of AT/AF episodes
- Description of the burden of AT/AF episodes
- Description of the amount of premature atrial beats
- Description of the total number of VT/VF episodes
- Description of the burden of VT/VF episodes
- Improvement LF/HF ratio of Heart Rate Variability
- Description of pain-score

- Description of blader function

Study description

Background summary

See protocol page 13,14.

CABG surgery, could lead to Post-Operative Atrial Fibrillation (POAF) in about a third of the patients.
During AF, the heart will maintain most of its function since the ventricles will still work effectively. However, the rate will be slightly less regular, leading to symptoms such as a racing heart, tiredness or fainting and a reduced quality of life. Moreover, patients with AF also have a higher risk of having a stroke than patients without AF. Post-operative AF (POAF) is AF developed within the first 5 days after the CABG operation. Symptoms could lead to prolonged hospitalization, of prolonged bladder catheterization and of medication assumption.

Recent experimental studies have shown that the delivery of low electric stimuli, to the spinal cord might have a role in protecting the heart from the occurrence of AF. For this reason we would like to investigate if these electric stimuli generated by the Spinal Cord Stimulation (SCS) device System are able to reduce the percentage of AF in the five days after surgery.

Study objective

See protocol page 19
The primary objective is to determine the occurrence of post-operative AT/AF between the start of anesthesia and the first 5 days after CABG surgery in randomized groups, defined as patients in the SCS group and patient in the control group.

Study design

See protocol page 22

This is a prospective pre-market single center clinical research feasibility study. The study is a non-blinded randomized controlled study with 50 subjects. Patients in the treatment group will be implanted with a spinal cord lead (n = 25) before surgery. This lead will be connected to an external spinal cord stimulator (SCS). Patients will be stimulated continuously at the highest amplitude which is still comfortable for the patient until hospital discharge, which will be 5 days after surgery. Control patients (n = 25) will be treated

according to clinical practice. End-points will be evaluated at various times before, during and after surgery up to 5 days after surgery.
Patient will come for a final visit one week after dischage for a final check (extra visit compared to standard of care).

Intervention

Half (n=25) of the patients will receive a temporary lead into the spinal cord and will receive spinal carod stimulation(SCS) for 5 days after the CABG procedure. Conform the standard procedures for a lead implantation an Xray will be made to check the lead position.

All patients (n=50) will receive a holter from day 0 to day 5.

Study burden and risks

See protocol page 65-68.

* Implanting a neurostimulation lead has small risks similar to spinal procedures, including spinal fluid leak, headaches, swelling, bruising, bleeding, infection, or paralysis, hematoma on your back where the lead is inserted.
* If you are on anticoagulation therapy you might be at a greater risk for postoperative complications such as hematomas that could result in paralysis in rare cases.
* Adverse effects of stimulation are usually mild and go away when stimulation is reduced or turned off. These adverse effects could include radicular chest wall stimulation, uncomfortable stimulation, a jolting or shocking sensation, or persistent pain at the incision site.
* The lead or extension could migrate within the body or erode through the skin. There could be undesirable changes in stimulation, possibly related to cellular changes around the electrode(s), changes in the position of the electrode(s), loose electrical connections, or lead or extension fractures. It is also possible that the implanted materials could cause an allergic or immune system response.
* Your neurostimulation system might unexpectedly cease to function due to electrical shorts or open circuits, conductor (wire) fractures, and insulation breaches. These events cannot be predicted.
* In rare cases, excessive tissue growth around the electrode(s) may result in spinal cord compression and paralysis. Additional surgery is required to treat these complications, which can occur weeks to years after lead implantation.

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 which will be subjected to an OFF-pump CABG procedure

Exclusion criteria

1) Patients with known history of atrial arrhythmias.
2) Patients which are not treated with *-blockers unless heart rate is too low for B-blockers assumption.

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-03-2015
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	External neurostimulator system
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	21-10-2014
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	NL49580.044.14
Other	nog niet bekend