Feasibility of heart rhythm sensing, pacing and defibrillation with an ICD lead in an alternative position

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(1) to determine the feasibility to sense and pace the myocardium with an- ICD lead placed in an alternative position (2) to determine the best position for pacing and sensing in the alternative position(3) to determine the safety and feasibility to...

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

Summary

ID

NL-OMON40830

Source
ToetsingOnline

Brief title
ICD lead in alternative position

Condition

- Cardiac arrhythmias
- Cardiac and vascular disorders congenital

Synonym
heart rhythm disturbances

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: feasibility, Implantable defibrillator, sudden cardiac death, Ventricular arrhythmia

Outcome measures

Primary outcome

This study is a safety and feasibility study. Success rate and complication

rate will be monitored. Other parameters that will be registered include:

- Sensitivity

- Pacing threshold

- Pacing lead impedance

Only in step 3:

- Time to therapy

- Number of shocks per DFT

- First shock efficacy

- Time to successful therapy

- Highest energy during DFT

Secondary outcome

NA

Study description

Background summary

The use of implantable cardioverter defibrillators (ICDs) is an established therapy for the prevention of death from ventricular arrhythmia. Recently a subcutaneous ICD (S-ICD) has been introduced, eliminating the need for transvenous lead placement in or on the heart which is mandatory for traditional ICD*s. This less invasive ICD therapy has the potential of reducing complications associated with traditional ICD systems. The new S-ICD system

already proved to be feasible and safe. With the current S-ICD it is not possible to administer pacing therapy (no brady pacing or anti-tachy- pacing), which renders patients with a pacing indication or therapy-refractory monomorphic ventricular tachycardia*s (VT) ineligible for the S-ICD. Moreover, given the position of the ICD lead, higher voltage shocks are necessary for defibrillation. Therefore, the S-ICD is larger than the traditional ICD. New strategies could potentially resolve these issues.

Study objective

(1) to determine the feasibility to sense and pace the myocardium with an- ICD lead placed in an alternative position
(2) to determine the best position for pacing and sensing in the alternative position
(3) to determine the safety and feasibility to place an ICD lead in the alternative position.
(4) to determine feasibility to detect and terminate VF (shock therapy) with an ICD lead placed in an alternative position

Study design

This is a feasibility and proof of principle study.

Intervention

an ICD lead will be temparily be positioned and standard pace/sense measurements will be performed. If these tests are succesfull, DFT tests will be performed in the final step

Study burden and risks

The participant will not benefit from this study. There are no limitations or additional limitations or visits required for this study. The study increases radiation burden. Moreover, there are risks associated with the introduction of the lead in the closed chest. The potential complications usually do not require treatment. If treatment is required, this may most likely involve opening of the chest. However, this is already required for the original procedure, and is therefore no additional burden for the patient.

Risks discussed per step:
Step 2-3: During placement of the lead, a tamponade or cardiac or pulmonary puncture may occur. Treatment may not be required. However, if treatment is required, this can be done immediately, as participant is already prepared for open-chest surgery.
Step 3: the defibrillation treshold test (DFT) is a standard test during ICD-implants. Although sensing tests are performed in previous steps and prior

to DFT, there is a risk the ICD will not be able to detect or terminate the VF, due to the different position of the leads. For this, participant is connected to the external defibrillator which in that case will give a shock to terminate VF. This is standard practice during ICD-implant.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients undergoing CABG (step1) or valve replacement/reconstruction (step 1,2,3)

Exclusion criteria

(potential) pregnancy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-08-2014
Enrollment:	24
Type:	Actual

Medical products/devices used

Generic name:	ICD
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	20-06-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL48724.018.14