Randomized trial to study the efficacy and adverse effects of the subcutaneous ICD in patients with a class I or IIa indication for ICD without an indication for pacing

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To determine the efficacy endpoint whether the lack of ATP function will cause more appropriate but unnecessary shock therapy in patients with a S-ICD. Furthermore we will study the complication endpoint whether the S-ICD is superior to the TV-ICD…

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

Summary

ID

NL-OMON34509

Source
ToetsingOnline

Brief title
Sub-ICD

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: implantable defibrillator, randomized controlled trial, sudden cardiac death, ventricular arrhythmia

Outcome measures

Primary outcome

Number of appropriate shock treatments in ATP or conditional zone in both

groups.

Secondary outcome

- Major Adverse Cardiac Event (MACE), defined as cardiac death, myocardial

infarction, percutaneous coronary intervention, coronary artery bypass grafting

and/or any valve surgery.

- Number of appropriate and inappropriate shocks

- Number of complications, defined as infections, bleedings, thrombotic events,

pneumothorax, perforation/tamponade and lead- or device failures

- Quality of life

- Time to therapy

- First shock conversion efficacy

- Implant procedure time

- Hospitalization rate (ICD related)

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 new subcutaneous ICD (S-ICD) has been introduced, eliminating the need for transvenous lead placement in or on the heart which is mandatory in the transvenous ICD (TV-ICD). The new S-ICD therapy already proved to be feasible and safe and is an accepted therapy in Europe. It is likely that the eliminated need for transvenous lead placement substantially reduces the implantation related complications and inappropriate shock therapies and elongates lead longevity. On the other hand it is unclear whether the lack of capability to provide antitachy-pacing (ATP) in the S-ICD may be a limitation for patients with frequent recurrent ventricular tachycardia. This randomized controlled trial will outline the advantages and disadvantages of the S-ICD.

Study objective

To determine the efficacy endpoint whether the lack of ATP function will cause more appropriate but unnecessary shock therapy in patients with a S-ICD. Furthermore we will study the complication endpoint whether the S-ICD is superior to the TV-ICD in respect to major adverse events (i.e. inappropriate shocks, acute and chronic implant related complications and lead- or device related complications).

Study design

Single center, randomized controlled, prospective proof of concept trial with either treatment with the TV-ICD or S-ICD.

Intervention

none

Study burden and risks

Possibly there are more appropriate but unnecessary shocks in patients treated with the S-ICD. However, we also expect less inappropriate shocks, less complications and a better longevity of the ICD leads. The total amount of shocks will be diminished, according to our expectation.

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

Class I or IIa indication for ICD

Exclusion criteria

Indication for pacing therapy

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-03-2011
Enrollment:	208
Type:	Actual

Medical products/devices used

Generic name:	Subcutaneous ICD and transvenous ICD
Registration:	Yes - CE intended use

Ethics review

Approved WMO

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	NL34725.018.10
Other	Nog aan te vragen nr bij NCT