S-ICD System Clinical Investigation

Published: 12-10-2010
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The objective of the study is demonstrate the safety and efficacy of the subcutaneous defibrillation system.

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

Summary

ID

NL-OMON36228

Source
ToetsingOnline

Brief title
S-ICD System IDE Clinical Study

Condition

- Cardiac arrhythmias

Synonym
Ventricular tachyarrhythmias

Research involving
Human

Sponsors and support

Primary sponsor: Cameron Health
Source(s) of monetary or material Support: Cameron Health

Intervention

Keyword: defibrillation, implantable defibrillator, subcutaneous, ventricular tachyarrhythmias

Outcome measures

Primary outcome

The primary endpoints are afety and efficacy. Safety is defined a

complication-free rate of 79% at 6 months follow-up.

Efficacy will be assessed by measuring the conversion efficacy rate of

ventricular fibrillation, which has to exceed 88%.

Secondary outcome

not applicable

Study description

Background summary

The implantable cardioverter-defibrillator (ICD) is an established and effective therapy to prevent arrhythmic mortality from life-threatening ventricular arrhythmias. Conventional ICDs use at least one lead which is placed in or on the heart, predominantly the right ventricular lead.
Both the implantation procedure and the lead itself are associated with complications, like infection, lead dysfunction or dislocation. The subcutaneous defibrillation system has been developed to prevent these complications associated with the implantation procedure or the transvenous lead. The subcutaneous system uses a lead which is placed subcutaneous by anatomical landmarks.

Study objective

The objective of the study is demonstrate the safety and efficacy of the subcutaneous defibrillation system.

Study design

Prospective cohort study in patients with an indication for ICD therapy. The intervention is the implantation of the subcutaneous defibrillation system, and subsequently the study is observational in nature.

Intervention

The intervention is the implantation of the subcutaneous defibrillation system according to the standard protocol at the Erasmus MC.

Study burden and risks

No additional burden and risks are present for patients participating in the study. The number and frequency of visits is similar to the standard procedure of scheduled visits to the outpatient clinic for ICD patients.

Contacts

Public
Cameron Health

905 Calle Amanecer, Suite 300
San Clemente, CA 92673
US
Scientific
Cameron Health

905 Calle Amanecer, Suite 300
San Clemente, CA 92673
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with a Class I / Class II indication for ICD therapy according to the International

guidelines for ICD therapy

Exclusion criteria

Patients with symptomatic bradycardia
Patients with ventricular tachycardia which can be reliably terminated by antitachycardia pacing therapy
Patients with renal failure

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):	07-12-2010
Enrollment:	90
Type:	Actual

Medical products/devices used

Generic name:	Implantable defibrillator
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	12-10-2010
Application type:	First submission
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
ClinicalTrials.gov	NCT01064076
CCMO	NL31901.078.10