Acute Subcutaneous Defibrillation Study

Published: 04-07-2013
Last updated: 24-04-2024

The primary purpose is to assess the defibrillation efficacy of Medtronic subcutaneous defibrillation system.

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

Summary

ID

NL-OMON40354

Source
ToetsingOnline

Brief title
ASQ Study

Condition

- Cardiac arrhythmias

Synonym
cardiac arrest, ventricular fibrillation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Defribillation Test, Subcutaneous ICD, VF induction test

Outcome measures

Primary outcome

To assess the defibrillation efficacy of a subcutaneous defibrillation system

using a sternal-lateral electrode configuration.

Secondary outcome

To assess the feasibility to induce VF via the same sternal-lateral electrodes

used for defibrillation, using a Medtronic-built Subcutaneous Induction Device

(SQID).

Study description

Background summary

Protocol page 9, 10; Study Backgroud

Implantation of a defibrillation system that does not require entry into the subject*s venous system offers several advantages over transvenous systems. Such a system may be easier to implant because it removes the necessity to enter the venous system and heart chamber. It also may eliminate the need for fluoroscopic guidance because the implant procedure can potentially be based on anatomical landmarks. Given that leads are not implanted in the vasculature, such a system may also be more easily manageable in the event lead complications arise in the subject. Without a defibrillation electrode within the heart, a portion of energy delivered to the subject will not pass through the heart.
Energy required for successful defibrillation is expected to be higher for a subcutaneous defibrillator compared to current transvenous systems. In fact, the Cameron Health S-ICD is currently approved in several countries and delivers up to 80J. Thus, Medtronic is proposing to study defibrillation efficacy from induced VF episodes of up to 20 seconds in duration at energies up to 65J to ensure adequate defibrillation efficacy at a maximum device output of up to 80J. Medtronic is exploring a non-transvenous defibrillation system intended to improve upon the commercially available system manufactured by Cameron Health Inc. by offering a more optimal shock waveform that could achieve required defibrillation efficacy with less energy and smaller device size. The proposed study is required to determine and test the defibrillation efficacy prior to development of this implantable subcutaneous defibrillation system.

To maintain the advantage of performing implants without accessing the venous space, a subcutaneous device-based method for inducing VF during implant testing is preferred. Medtronic is exploring a non-transvenous method of VF induction intended to improve upon the commercially available system.

Study objective

The primary purpose is to assess the defibrillation efficacy of Medtronic subcutaneous defibrillation system.

Study design

This is a prospective, multi site, non-randomized, pre-market acute feasibility study.
Data is collected at baseline, implantation, the routine post-ICD implantation visit (between 30 and 80 days).
An analysis is performed after 20 subjects completed the defibrillation testing according to the protocol. It is then decided whether the study will continue according to the protocol or that the protocol will be changed. The decision is taken by the Medtronic study team based on interim analysis.

Intervention

In the Netherlands only patients who will receive a S-ICD will be enrolled in the study.

The extra interventions for the subjects in the Netherlands are;
- An transvenous catheter (or RV lead) and an additional incision for temporary lead placement (for protocol version 1 and potentially for protocol version 2).

- In order to test the defibrillation efficacy of the test system, a maximum of 3 VF inductions wil be done and terminated with the test system.

- There are two fluoroscopy images taken when the test system is implanted.

Study burden and risks

See protocol page 35-40
Risks associated with the implantation of a (subcutaneous) ICD, the extended procudure time, additional incisions and the additional VF inductions and defibrillation.

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

Subject must be undergoing implant of an ICD or S-ICD® for approved indications
(In the Netherlands only patients who will recieve a S-ICD will be asked)

Exclusion criteria

* Subject has LVEF < 15%
* Subject at high risk of stroke
* Subject having a device replacement
* Subject is indicated for CRT
* Subject is pacemaker dependent

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):	28-01-2014
Enrollment:	24
Type:	Actual

Medical products/devices used

Generic name:	Subcutaneous Defibrillation System
Registration:	No

Ethics review

Approved WMO Date:	04-07-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-09-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-03-2014
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NCT01771172
CCMO	NL42919.100.13