Acute Feasibility Investigation of a New S-ICD Electrode Arrangement for Reduction of Defibrillation Energies

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

Summary

ID

NL-OMON55513

Source
ToetsingOnline

Brief title
ASE Study protocol C2081

Condition

- Cardiac arrhythmias
- Cardiac therapeutic procedures

Synonym
cardiovascular disease; tachyarrhythmia

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific
Source(s) of monetary or material Support: Boston Scientific

Intervention

Keyword: S-ICD, subcutaneous electrode, VF conversion test

Outcome measures

Primary outcome

Defibrillation Threshold (DFT) of the two-electrode shock configuration

(Parallel and 90º)

Secondary outcome

* VF conversion success for the two-electrode shock configuration (Parallel and

90º)

* Shock impedance of both the one- and two-electrode shock configurations

(Parallel and 90º)

Study description

Background summary

The current S-ICD system pulse generator (PG) is 59 cc in size and delivers a maximum energy shock of 80 J. Any significant reduction in PG size would require a reduction in the maximum energy output. Reducing the defibrillation energy requirement would increase the percentage of S-ICD patients that could receive a smaller PG.

Computer modeling of the electrical fields in a realistic human torso showed that a wider parasternal electrode, two parallel standard S-ICD electrodes, or two S-ICD electrodes inserted at a 90º angle reduced shock impedance, improved current delivery and reduced defibrillation energy. Swine defibrillation studies of the subcutaneous systems with one vs. two left parasternal electrodes showed smaller and less consistent reduction in shock impedance and delivered energy than the computer models. However, swine have anatomy and electrophysiologic properties that are substantially different than humans that affect defibrillation efficiency.

Thus, an acute human study with two left parasternal electrodes is necessary to determine the feasibility of improving the defibrillation efficacy using the

new electrode configuration.

Study objective

The primary objective of this acute feasibility study is to assess the defibrillation threshold (DFT) when adding a second left parasternal electrode to an S-ICD system.

The secondary objective is to assess the efficacy of the 2-electrode configuration (Parallel and 90º) to convert VF.

The tertiary objective is to assess factors that influence the DFT when adding the second electrode (eg spacing and orientation or angle between electrodes).

Study design

This is a prospective, multi-site, single-arm, acute feasibility study.

Intervention

NA

Study burden and risks

While the risks of VF conversion testing are not zero, the risks in a carefully controlled clinical trial with experienced investigators are very low. Many such studies have been performed previously that led to many important developments in ICD and S-ICD therapy that have benefited hundreds of thousands of recipients. Improvements to S-ICD therapy simply cannot be made without studies of this type.

The risk to benefit ratio for this study is reasonable because the subject is already undergoing an S-ICD implant that includes sedation and/or anesthesia, insertion of a subcutaneous electrode and VF conversion testing. Since the standard implant and VF conversion test will be done prior to investigational procedures, it provides a high degree of assurance that the VF conversion testing is well tolerated. The protocol includes criteria to exclude subjects from the investigational testing should the initial standard of care VF conversion test suggest that the subject may be at higher risk for adverse events.

Individual subjects may not receive direct benefit from participation in this study.
The study may have a significant benefit to future S-ICD recipients if the results of this study are favorable and allow the development of new S-ICD systems that reduce defibrillation energies with significantly smaller pulse

generators. Thus, a patient participating in this study may receive an indirect benefit at a later date * for example at the time of pulse generator replacement.

Contacts

Public
Boston Scientific

Lambroekstraat (Green Square) 5D
Diegem 1831
BE
Scientific
Boston Scientific

Lambroekstraat (Green Square) 5D
Diegem 1831
BE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Subject is scheduled to receive a de novo S-ICD system implant per labeled indication
2. Passing S-ICD screening ECG performed per applicable user's manual.
3. Subject is expected to be implanted with a left parasternal S-ICD electrode.
4. Subject*s planned S-ICD implant procedure will include at least one VF conversion testing at 65 J.
5. Subject is willing and capable of providing informed consent specific to

local and national laws.
6. Subject is age 18 or above, or of legal age to give informed consent specific to local and national law.

Exclusion criteria

1. Subject has an unusual chest anatomy (eg. pectus excavatum and pectus carinatum) that might impede the ability to temporarily insert a second S-ICD electrode.
2. Subject has a left ventricular ejection fraction less than or equal to 20% within 3 months prior to enrollment.
3. Subject has NYHA Class IV or unstable Class III heart failure.
4. Subject that, in the opinion of the investigator, cannot tolerate the DFT testing required by this protocol.
5. Subject that, in the opinion of the investigator, is at increased risk for VF conversion failure.
6. Subject is morbidly obese, defined as BMI greater than or equal to 35.
7. Subject has an active infection or has been treated for infection within the past 30 days.
8. Subject that, in the opinion of the investigator, has an increased risk of infection.
9. Subject is currently requiring/receiving dialysis.
10. Subject has insulin-dependent diabetes.
11. Subject had/has any prior or planned other surgical procedure within ±30 days of enrollment.
12. Subject is receiving immunosupressive therapy or has a condition that compromises their immune system.
13. Subject had episodes of atrial fibrillation or atrial flutter within the 4 week period prior to enrollment or during the period of time between enrollment and the start of implant procedure.
14. Subject that, in the opinion of the investigator, has an increased risk for thromboembolic event.
15. Subject that, in the opinion of the investigator, has an increased risk of excessive bleeding.
16. Subject is currently on an active heart transplant list.
17. Subjects with documented life expectancy of less than 12 months.
18. Subject has any other electrically active implanted device that cannot be temporarily deactivated during the implant (includes components or accessories present such as pulse generators, non-capped leads or leads with breached insulation, implantable cardiac monitors, implantable stimulators).
19. Subject is enrolled in a concurrent study, with the exception of local mandatory governmental registries and observational studies/registries, without prior written approval from Boston Scientific.
20. Women of childbearing potential who are or might be pregnant at the time of

the S-ICD implant procedure.

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):	30-11-2018
Enrollment:	42
Type:	Actual

Medical products/devices used

Generic name:	Investigational S-ICD Y-Adapter
Registration:	No

Ethics review

Approved WMO Date:	27-07-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-08-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-01-2020

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-02-2021
Application type:	Amendment
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	NL62605.018.17