MiniImal Defibrillation Threshold in With a Subcutaneous Implantable-Defibrillator Patients Undergoing Elective Generator Replacement.

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To determine the lowest energy which successfully converts induced ventricular arrhythmias in S-ICD patients who underwent elective generator replacement and compare these data to average DFT results in de novo S-ICD patients from previous studies.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON48785

Source
ToetsingOnline

Brief title
MINI Two Study

Condition

- Cardiac arrhythmias

Synonym
Abnormal heart rhythm, ventricular arrhythmias

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Defibrillation, Subcutaneous ICD, Testing, Threshold

Outcome measures

Primary outcome

Outcome

The main outcome will be the lowest energy on which defibrillation of the

induced ventricular arrhythmia was successful after replacement of the S-ICD

generator.

Secondary outcome

Not applicable.

Study description

Background summary

Implantable cardioverter defibrillators (ICDs) have proven to be effective in treating life-threatening ventricular arrhythmias. For Transvenous ICDs (TV-ICD) many studies have been performed on defibrillation treshold (DFT) and programming a shock output with a safety margin of 10J above the DFT is considered safe and effective. The relatively new subcutaneous ICD (S-ICD) is implanted entirely extracardiac. Due to the extracardiac design the S-ICD requires a higher energy output compared with the TV-ICD. The shock output of the S-ICD is based on the results of defibrillation thresholds (DFT) tests in two early acute studies with temporarily implanted S-ICDs following a step-down protocol. The average DFT was 32.5J ± 17.0J determined by testing 61 patients in the first study and 36.6J ± 19.8J determined by testing 49 patients in the second study. Based on these results, the default shock output of the S-ICD was set at 80J, which is higher than in TV-ICDs. New studies performed in S-ICD patients report lower average DFT and may be the first step in reducing S-ICD generator size by reducing the standard programmed shock output of 80J, which is the main determinant for the device size. However it is important to note that S-ICD DFT studies have only been performed directly post implant in de novo S-ICD patients. Following guideline recommendations all patients implanted

with an S-ICD should be tested directly post-implant and all patients undergoing a elective generator replacement should also be tested. Currently a large randomized trial has begun enrolment with the goal of omitting DFT in de novo S-ICD patients (NCT03495297). Patients undergoing S-ICD generator replacement will not be included in this study. Considering these trends surrounding DFT testing in S-ICD patients it is likely that DFT testing in S-ICD patients will become obsolete in the near future. Whether this change in practice can safely be extrapolated to S-ICD patients undergoing elective generator replacement is unknown. During the years post-implant and prior to generator replacement the pocket around the S-ICD generator is formed by fibrotic tissue, whether this has a positive or negative effect on the actual defibrillation threshold and consequently affects shock efficacy of the S-ICD is unknown. There is no data available on DFT after generator replacement.

In this study, we assess the lowest energy which successfully converts the induced ventricular arrhythmia following a predetermined step-down protocol, to explore whether the average DFT in S-ICD patients undergoing elective generator replacement is similar to patients directly post-implant. The aim of this study is to explore whether results of DFT studies in de novo S-ICD patients can safely be extrapolated to patients undergoing generator replacements.

Study objective

To determine the lowest energy which successfully converts induced ventricular arrhythmias in S-ICD patients who underwent elective generator replacement and compare these data to average DFT results in de novo S-ICD patients from previous studies.

Study design

This study is a prospective non-randomized single-arm study of 45 patients undergoing a subcutaneous implantable cardioverter-defibrillator replacement. We aim to enrol 20 patients with a BMI > 25 kg/m². If this is not achieved within the first 40 consecutive enrolments of this study we will continue enrolment of only patients with a BMI above 25 kg/m² with a maximum of 20 patients, to ensure enough variability in BMI in this explorative study.

In this study a standardized step-down DFT protocol will be used to obtain accurate DFT data with the use of a minimal number of shocks. Performing a step-down DFT protocol is a commonly used method during implant, which does not expose patients to an increased risk. The DFT in a patient is determined by the anatomy of the patient, the positioning of the device and the shock vector, which is created by the positioning of the device in relation to the patients* anatomy. These factors will not be altered in the setting of this study, therefore there is no variability in DFT values within a patient that is tested multiple times. The specific steps in the step-down protocol have been

pre-determined for this study (figure 3 in the protocol).

Study burden and risks

The participant will not benefit directly from this study, although a lower defibrillation threshold could mean that the shock output will be programmed lower than 80J in the future, which is currently the default setting of the S-ICD. Battery longevity increases with lower shock output if S-ICD therapy is given. There are no additional post-procedural limitations or visits required for this study. The study does not increase the risks associated with ICD generator replacement nor does it increase the radiation burden. ICD generator replacement and subsequent defibrillation threshold testing are done as part of routine clinical care in our hospital. In the current hospital protocol generally 1 or 2 shocks of 65J are given (depending on shock success).The total shock output of defibrillation testing in this study protocol will be lower than the standard of 2 x 65J currently considered standard of practice. Additional defibrillation tests will be performed following a step-down protocol as shown in figure 3. Increasing the number of shocks during DFT testing is not associated with an increased risk for heart failure, or death, or future VT/VF episodes. For the majority of patients two shocks will be required, with a lower total output than the current standard of practice, which is 2 shocks of 65J, a total of 130J. In a small percentage of patients three of four shocks will be required to determine the minimal defibrillation threshold, however, the total amount of energy according to the study protocol will not exceed 190J.

Risks discussed with the participants:
What will be discussed with the patient is that defibrillation testing is being performed routinely during generator replacement of the S-ICD and with this study protocol we will determine the actual defibrillation threshold using a step-down protocol instead of performing two defibrillation tests at 65J. For the majority of patients this will require two conversion tests at lower output than 65J. A small proportion of patients will require three or four conversion test to determine the actual defibrillation threshold. In these patients the maximum amount of energy given will not exceed 190J. An increase in number of shocks does not add any additional risk to the procedure.

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

Patients can be included if they:
- are over 18
- are able to give informed consent
- will undergo S-ICD generator replacement and subsequent defibrillation threshold testing (DFT)

Exclusion criteria

Patients who will not undergo defibrillation testing as part of their regular care due toa contra-indication.
Patients with a BMI < 18.5 kg/m2

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-09-2018
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	15-08-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-06-2019
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	NL66422.018.18