Minimal Defibrillation Threshold in Patients with a Subcutaneous Implantable-Defibrillator.

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To determine the lowest energy which successfully converts induced ventricular arrhythmias in S-ICD patients.

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

Summary

ID

NL-OMON44495

Source
ToetsingOnline

Brief title
MINI 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.

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 (9). 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.

Since the first, and only, S-ICD DFT studies were performed, significant progress has been made in the understanding of factors which influence the DFT in S-ICD patients. Three of the major components are the amount of fat tissue underneath the coil, the amount of fat tissue under the can and the placement of the S-ICD generator towards anterior on the thoracic wall. Multivariable analysis showed a high Body Mass Index (BMI) as the only predictor for failing a DFT test. With this knowledge implanting physicians have improved their technique of implantation and are taking these factors into consideration.

Besides this acquired knowledge on DFT testing in S-ICD patients, a learning curve was demonstrated for both implanters and institutions with a significant higher complication rate, including failed DFTs, in the first 15 patients. The effect of the improved implant technique on the average DFT has not been examined.

As the DFT in S-ICD patients is higher than in TV-ICD patients, higher output is required. However the DFT in S-ICD patients is expected to be lower than in the first studies due to the improvements in S-ICD implant technique. This is relevant and valuable information as with a lower average DFT , a lower shock output is required. A lower programmed shock output, could result in an increased battery longevity. Moreover, for a high shock output a large battery is required. To accommodate the S-ICDs* larger battery size the S-ICD generator is 59.5 cc. The average TV-ICD generator has a volume of 30-40 cc with a shock output ranging from 36J to 46J. When lower shock output is required, battery size can be reduced, providing an opportunity for the development of smaller S-ICD generators in the future.

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 is lower than previously reported in the first acute S-ICD implants(4).

Study objective

To determine the lowest energy which successfully converts induced ventricular arrhythmias in S-ICD patients.

Study design

Type of study
This study is a prospective non-randomized single-arm 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 specific steps in the step-down protocol have been pre-determined for this study.

Sample size and power calculation
To determine the average DFT in S-ICD patients we will included 12 patients in this single arm study. A sample size of 12 patients is recommended in studies for which no prior information is available to base a sample size on.
Therefore twelve patients will provide sufficient information on mean and variance.

Study intervention

There will be no new intervention in this study. Patients will be tested with lower shock output than current standard of practice of two conversion tests at 65J according to the step-down protocol determined for this study. Patients receive a first conversion test with 30J. If 30J shock is not successful the patient will be converted by an external defibrillator. The next energy tested will be increased by 20J to 50J, after which a 40J test will performed if the 50J test is successful. In case of failure at 50J, the next step will be to test at 70J. If conversion fails with 70J the patient will be treated according to standard of care in patients with failed conversion tests.
Standard of care in these cases will include a chest X-ray to determine whether air is trapped around the S-ICD coil or generator and determine if the device needs to be repositioned.

Study materials
- No additional study materials will be used in this study as all patients were already scheduled to undergo defibrillation testing.

Follow-up
Follow-up in this acute study design stops at discharge.

Statistical analysis
Continuous variable are tested for normality. Values presented are means with standard deviations or median with interquartile ranges. Dichotomous data are presented as proportions and compared with the Fisher*s exact test. Statistical significance is set at an alpha-level of 0.05. Statistical analysis are perform in R 3.3.3., R Foundation, Vienna, Austria.

Study burden and risks

Benefits 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 standard of practice. Battery longevity increases with lower shock output if S-ICD therapy is given. There are no additional limitations or visits required for this study. The study does not increase the risks associated with ICD implantation or generator replacement nor does it increase the radiation burden. ICD implantation and subsequent defibrillation threshold testing are done as part of routine clinical care, 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. 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 150J.

Risks discussed with the participants:
What will be discussed with the patient is: that defibrillation testing is being performed as routinely during implantation of the S-ICD. In 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 150J.

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 > 18 years who will undergo S-ICD implantation.

Patients who are able to give informed consent.
Patients who might be pregnant.

Exclusion criteria

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

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-11-2017
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	10-11-2017
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	NL63428.018.17