The influence of different anatomical positions on the location of the S-ICD pulse generator

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Primary Objective:* The primary objective of this study is to determine the influence of different anatomical positions on step 2 of the PRAETORIAN score.Secondary Objective(s):* The influence of the different anatomical positions on the total...

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

Summary

ID

NL-OMON50888

Source
ToetsingOnline

Brief title
LOCATE S-ICD

Condition

- Cardiac arrhythmias

Synonym
internal defibrillator, subcutaneous ICD

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anatomical positions, Displacement, PRAETORIAN score, S-ICD

Outcome measures

Primary outcome

The agreement on step 2 of the PRAETORIAN score between the different anatomical positions.

Secondary outcome

- The agreement on the total PRAETORIAN score between the different anatomical positions

- The agreement on the PRAETORIAN score categories between the different anatomical positions

- The difference in generator position in cm between the different anatomical positions

Study description

Background summary

The subcutaneous implantable cardioverter defibrillator (S-ICD) is developed to overcome complications seen in patients with a transvenous ICD (TV-ICD). The S-ICD is therefore completely extravascular (figure 1.).

The position of the S-ICD generator and lead is related to the shock efficacy (1). For a correct position, a good implantation technique and experience of the implanter are important (2). Over the years new improved implantation techniques are adopted (3). The shock efficacy is currently tested by performing a defibrillation test (DFT) after implantation. The benefit of DFT after implantation is debated and performing a DFT is not without a risk of complications. The PRAETORIAN score is developed to estimate the shock efficacy based on the implant position of the S-ICD using the standard of care taken chest X-ray after implantation (4).

The PRAETORIAN score is calculated by 3 steps (figure 2). Step 1 and 3 are related to the amount of fat between the coil and the sternum and between the generator and the thoracic wall respectively. Step 1 and 3 will therefore not be influenced by different anatomical positions. Step 2 however, can possibly be influenced by a different anatomical position as this step is related to the position of the generator towards the midline. A PRAETORIAN score * 90 is described as an intermediate or high risk for shock failure and therefore requires action, often a repositioning of the lead or generator.

Importance of arm position on the chest X-ray to avoid retakes
The PRAETORIAN score is based on a bidirectional chest X-ray after implantation. Step 2 is based on the lateral chest X-ray with the arms in standard upward position. However, lateral chest X-rays with the arms downwards are frequently seen after S-ICD implantation. One explanation may be that this arm position is recommended after TV-ICD implantation to avoid dislocation of the TV-ICD lead. The influence of a different arm position on the S-ICD generator position and therefore on the PRAETORIAN score is unknown. Knowledge about this effect may avoid retakes of chest X-rays or may emphasize the importance of the correct arm position regarding the PRAETORIAN score.

Future of a more efficient implantation process to avoid re-interventions
Currently, the standard of care chest X-ray is taken outside the catheterization laboratory or operating room and after the patient wakes up. In case of a high PRAETORIAN Score, re-intervention would be necessary. This can be avoided if a supine chest X-ray immediately after implantation can be made. On a standing chest X-ray gravity can influence spine angles and positioning (5). Taking into account the fact that the S-ICD is implanted intermuscular under the m. latissimus dorsi, which has his origin on the thoracic spine, differences in spine angle may influence the generator position. The influence of the supine and 90 degree angle of the arm versus the standard standing chest X-ray on the generator position are unknown. This study will give information on whether calculating the PRAETORIAN score on a supine chest X-ray is feasible.

Study objective

Primary Objective:
* The primary objective of this study is to determine the influence of different anatomical positions on step 2 of the PRAETORIAN score.

Secondary Objective(s):
* The influence of the different anatomical positions on the total PRAETORIAN score.
* The influence of the different anatomical positions on the PRAETORIAN score categories.
* The possible displacement of the generator, measured in centimetres, in the

different anatomical positions.

Study design

This is an observational descriptive, single center, study in which the influence of arm positon and supine position on the generator position is studied in 30 patients. Patients who underwent an S-ICD implantation in the Amsterdam UMC will be asked for participation. At least 9 patients will be included with a step 2 PRAETORIAN score of x2 or x4 to study a possibly stronger influence of generator displacement from a more anterior starting point.

For all patients a standard standing chest X-ray will be performed following standard protocols (PA arms downwards (A), lateral arms upwards (B) in figure 3.). Additionally, a lateral chest X-ray will be taken with the arms downwards (C. in figure 3.) and a lateral supine chest X-ray will be taken with the left arm at 90 degrees (D. in figure 3.). In total there will be 4 chest X-rays executed.

The two standing lateral chest X-rays, with arms downwards and upwards (B. and C. figure 3.), will be compared and step 2 of the PRAETORIAN score will be determined. The lateral standing and lateral supine chest X-ray will also be compared (B. and D. figure 3.) and step 2 of the PRAETORIAN score will be determined. The PA chest X-ray (A. figure 3.) in combination with a lateral chest X-ray (B., C. or D. figure 3.) will be used to determine the total PRAETORIAN score. The distance in centimeters from the sternum (measured with a 90 degree angle) to the anterior side of the generator will be used to calculate the exact possible dispalcement of the generator between two different anatomical position. To avoid different scales of the X-ray to influence the measurement, the distance will be calculated using the known measurements of the S-ICD. Rating of the PRAETORIAN score will be performed by 2 independent raters and decision will be made on consensus.

Study burden and risks

Patients will not benefit directly from participating in this study. However, this study will contribute to the understanding of the influence of different anatomical positions on the generator position. This can contribute to the avoidance of future retakes of chest X-rays. If there is agreement between the different anatomical positions regarding the PRAETORIAN score this may benefit the implantation process in the future. If patients need an S-ICD replacement in the future they may benefit from this themselves.

There is no serious direct risk for patients participating in this study. Patients who participate are exposed to radiation by 4 chest X-rays, see radiation dose and risk estimates for further information. There is a

possibility that the chest X-rays show unknown findings. If so, the patient will be informed about this by one of the investigators. Also the general practitioner of the patient will be contacted to discuss the findings with the patient if necessary and to take further steps if necessary.

Radiation dose and risk estimates
Patients participating in this study will receive 4 chest X-rays. One chest X-ray can reach up to 0.1mSv. In total patients participating in this study will therefore receive a maximum of 0.4 mSv. According to, Human Exposure to Ionising Radiation for Clinical and Research Purposes: Radiation Dose & Risk Estimates guidelines this translates to the risk category IIa. This category represents an intermediate level of risk. The range of 0.1 to 1 mSv corresponds with a maximum risk of five in hundred thousand and is less than the annual background dose. To justify these risks a research proposal should at least lead to potential health benefit for future patients. Our study has clear health benefits for future patients and can even, depending on the outcome, reduce the radiation exposure in future patients.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
* Patients must be * 18 years of age, willing and capable of giving informed consent
* Patients who underwent an S-ICD implantation in the Amsterdam UMC

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
* Patients who are known to be pregnant
* Patients with other contra-indications for extra X-rays per physician*s discretion

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-01-2022
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	05-08-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-02-2022
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	NL78031.018.21