Title: Rationale and Design of the PRAETORIAN-DFT trial: A Prospective Randomised CompArative trial of SubcutanEous ImplanTable CardiOverter-DefibrillatoR ImplANtation with and without DeFibrillation Testing.

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Short title: Design of the PRAETORIAN-DFT trial
Word count abstract: 232
Word count manuscript: 2185
Figures and tables: 2 tables, 3 figures

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Background

In transvenous implantable cardioverter-defibrillator (TV-ICD) implants, routine defibrillation testing (DFT) does not improve shock efficacy or reduce arrhythmic death but patients are exposed to the risk of complications related to DFT. The conversion rate of DFT in subcutaneous ICD (S-ICD) is high and first shock efficacy is similar to TV-ICD efficacy rates.

Study Design

The PRAETORIAN-DFT trial is an investigator-initiated, randomized, controlled, multicenter, prospective two-arm trial designed to demonstrate non-inferiority of omitting DFT in patients undergoing S-ICD implantation in which the S-ICD system components are optimally positioned. Positioning of the S-ICD will be assessed with the PRAETORIAN score. The PRAETORIAN score is developed to systematically evaluate implant position of the S-ICD system components which determine the defibrillation threshold on post-operative chest X-ray. A total of 965 patients, scheduled to undergo a *de novo* S-ICD implantation without contra-indications for either DFT strategy, will be randomized to either standard of care S-ICD implantation with DFT, or S-ICD implantation without DFT but with evaluation of the implant position using the PRAETORIAN score. The study is powered to claim non-inferiority of S-ICD implantation without DFT in *de novo* S-ICD patients in respect to the primary endpoint of first shock efficacy in spontaneous arrhythmia episodes. Patients with a high PRAETORIAN score (≥ 90) in the interventional arm of this study will undergo DFT according to the same DFT protocol as in the control arm.

Conclusion

The PRAETORIAN-DFT trial is a randomized trial that aims to gain scientific evidence to safely omit a routine DFT after S-ICD implantation in patients with correct device positioning.

Background

The subcutaneous implantable defibrillator (S-ICD) was introduced as a safe and effective alternative to the transvenous ICD (TV-ICD) for the prevention of sudden cardiac death, in patients without an indication for bradycardia- or antitachycardia pacing(1, 2). Currently, defibrillation testing (DFT) is rarely performed for left-sided transvenous ICDs implanted for primary prevention indications. Reasons for omitting DFT testing in this population of TV-ICD patients include i) lack of clinical benefit: the SIMPLE and NORDIC trials demonstrated that DFT does not improve shock efficacy or reduce arrhythmic death in this patient population(3, 4), ii) safety: DFT testing has been associated with hemodynamic decompensation, need for inotropic support, stroke and death, and iii) logistical considerations: in many institutions additional personnel (e.g anesthesia) are required to perform DFT (5-8). The lack of benefit on the one hand, and the risk of complications and logistical burden on the other hand have created a substantial move toward TV-ICD implantation without DFT. This movement has already started prior to the outcome of the SIMPLE and NORDIC trials. Although DFT in S-ICD is linked with mostly similar risks of complications and logistic burden as transvenous devices there are currently only a few studies available on the efficacy of DFT in S-ICD (9-12). Nevertheless, DFT is already omitted for a substantial number of patients receiving S-ICD, as was demonstrated by the Subcutaneous ICD Post-Market Approval Study (PAS). This study showed that 13.7% (225/1637) of the patients did not undergo DFT testing (13) and analysis of the National Cardiovascular Data Registry ICD registry showed that DFT was omitted in 25% of the S-ICD recipients (14). Indeed the User's Manual for the S-ICD indicates that whereas 'defibrillation testing is recommended at implant and at replacement procedures' this is in fact not mandatory.(15) Still, as the positioning of the components of the S-ICD is crucial for its functioning and defibrillation threshold (1, 14), an alternative method to evaluate the correct position may be desired when omitting DFT. A recent computer modelling study analyzed which factors have the greatest impact on the actual defibrillation threshold in S-ICD patients(16). An exponentially increasing defibrillation threshold was observed when fat tissue is present between the S-ICD generator, S-ICD coil and the thoracic wall.

Anterior placement of the S-ICD generator was also associated with an elevated threshold. Especially in obese patients, it can be difficult for the implanter to determine whether the device is positioned directly onto the thoracic wall during implant. A reliable method of feedback on implant technique is highly clinically relevant since a general trend towards omitting routine DFT after S-ICD implantation has started. Therefore a novel scoring method, the PRAETORIAN score, was developed to evaluate the S-ICD implant position using a post-implant bidirectional chest X-ray(17). This score evaluates the three most important factors of defibrillation success in S-ICD patients: sub-coil fat tissue, placement of the generator in the sagittal axis and sub-generator fat tissue. The outcome of the score ranges between 30 and 900 and represents an estimation of the minimal energy required to terminate a ventricular arrhythmia (figure 1).

The aim of the PRAETORIAN-DFT trial is to compare S-ICD implantation with and without DFT. The primary objective is to study non-inferiority of S-ICD implantation in patients with a low PRAETORIAN score with respect to first shock efficacy.

Study Design

Trial oversight

This study is an investigator-initiated, prospective, multicenter, international, randomized, controlled comparative trial to test for non-inferiority of S-ICD implantation without DFT in *de novo* S-ICD patients on first shock efficacy during spontaneous episodes of fast ventricular arrhythmias. Endpoints will be adjudicated by an independent committee, blinded for randomization results. An independent data and monitoring safety board was formed to monitor safety. First approval of the study was given by the Medical Ethics Committee of the Academic Medical Center in Amsterdam. Approximately 35 experienced S-ICD implanting centers in The Netherlands, Germany, United Kingdom, France and the United States of America will participate.

Hypothesis

The primary objective of this study is to determine if omitting DFT following S-ICD implantation is non-inferior to performing DFT as measured by first shock efficacy in the treatment of spontaneous

ventricular arrhythmias when adequate implant position is confirmed by a low PRAETORIAN score. First shock efficacy is defined as the percentage of episodes terminated by the first successful shock. A successful ICD shock is defined as an appropriate shock for VT or VF that leads to termination of VT/VF in less than 5 seconds from appropriate shock delivery. Secondly we hypothesize non-inferiority of omitting DFT after S-ICD implantation on secondary endpoints which include: DFT related complications, complications within 30 days post-implant, S-ICD implant position determined by the PRAETORIAN score, evaluation of three different anaesthesia methods, mortality, re-operations and re-DFT following the initial implant procedure, successful therapy, inappropriate therapy, time to therapy, time to successful therapy, cardiac decompensation, length of hospitalization and cardiac syncope. Endpoint definitions are described in supplemental table 1.

Patient selection

Patients of 18 years and older, meeting current guidelines for ICD therapy and receiving a *de novo* S-ICD who are willing and capable of complying with follow-up visits and who are eligible for both DFT strategies per physician discretion meet the inclusion criteria for this study. Exclusion criteria are presented in table 1.

Randomization and treatment

The flowchart of this study is presented in figure 2. A total of 965 patients will be randomized 1:1, stratified by center, to either standard of care treatment including a routine DFT post-implant versus S-ICD implantation without DFT. In the interventional arm S-ICD implant position will be evaluated by the PRAETORIAN score and DFT will only be omitted in case of a low PRAETORIAN score, < 90(17). DFT will be performed according to a pre-specified protocol as shown in figure 3. In case two consecutive tests fail to convert an induced ventricular arrhythmia at 65J the DFT is considered failed, this is handled according to physician's discretion, which usually includes either repeating the DFT at a later stage or repositioning the device. In the interventional arm, in case of an intermediate (>90) or high PRAETORIAN score (≥ 150) the study protocol requires a DFT according to the same pre-specified steps as in the standard of care arm to ensure functionality of the S-ICD.

S-ICD zones are not mandated according to predefined settings in the study protocol. Programming is performed per site discretion but must be similar in both arms. Programming will be monitored to confirm this is indeed similar in both arms. If a difference seems to arise, actions may be taken to prevent a difference in overall number of shocks between study arms as the primary endpoint, failed first shocks, is dependent on this.

Anaesthesia

In both study arms different methods of anaesthesia may be used and will be evaluated. The different anaesthesia methods will be classified in three groups: general anaesthesia, monitored anaesthesia care (MAC) and local anaesthesia. Choice of either three methods is left up to the discretion of the physician and may be influenced by the randomization result. Implanters may decide to use more local or regional anaesthesia in patients who will not undergo DFT. On the other hand, when a DFT is required, logistics may allow for more use of general anaesthesia. Therefore the study protocol does not prescribe any type of anaesthesia during the procedure, but data on these different methods will be collected and evaluated on a patient level by collecting visual-analog pain scores (VAS) at different time points pre- and post-implant. Additionally, the location of pain patients are experiencing will be scored at these time points (supplemental material).

The PRAETORIAN score

Effectiveness of the S-ICD is mostly determined by the position of the S-ICD system components, the coil and generator. Computer modelling has shown three major determinants of defibrillation failure, sub-coil fat tissue, anterior placement of the generator and sub-generator fat tissue. The PRAETORIAN score was developed to evaluate the position of the S-ICD system components on a bidirectional, posterior-anterior (PA) and lateral, chest X-ray and estimate the actual defibrillation threshold, within a range of 30 up to 900, corresponding with each individual patient. Details of the PRAETORIAN score and retrospective validation of the score in two large cohorts are published elsewhere(17). The current study will prospectively validate the predictive power of a low PRAETORIAN score on defibrillation success. Patients with a low PRAETORIAN score will be

discharged without DFT, patients with an intermediate (>90) or high PRAETORIAN score (≥ 150) will undergo DFT post-implant according to the same pre-specified DFT protocol as patients in the control group (figure 3). Figure 1 shows how to determine the PRAETORIAN score step by step. An e-learning was designed to assure a baseline level of training for physicians to calculate the score. All implanters will calculate a PRAETORIAN score for their own implants.

Follow-up

Follow-up data and information on events will be collected through standard of care follow-up visits in each participating center. Centers are encouraged to use remote monitoring for collection of arrhythmic events. Data collection includes electrical cardiograms of all treated episodes in the S-ICD, adverse events and post-operative pain questionnaires (supplemental material). All patients will be followed until a median follow-up of 40 months is reached or shorter when an event rate of 2% is reached. When a patient's S-ICD is extracted for any reason, study participation ends. Patients who have their device changed will remain in the trial and will be treated according to the arm they were randomised to. All deaths will be investigated by pursuing post-mortem device interrogations.

Safety Monitoring

A data safety and monitoring board (DSMB) is established to perform ongoing safety surveillance. The DSMB will compare the occurrence of the primary endpoint, serious adverse events (SAE) and mortality between both arms. The DSMB will report a formal advice to continue or (temporarily) suspend the trial or take other measurements necessary to improve performance of the trial. SAEs are defined in the supplements of this manuscript.

Statistical considerations

This study is designed to demonstrate that S-ICD implantation without DFT is non-inferior to S-ICD implantation with DFT with respect to the primary endpoint failed first shock during spontaneous episodes of fast ventricular arrhythmias (VT and VF) when the S-ICD is properly positioned. This study is powered by using a 2% event rate of the primary endpoint (failed first shock by the S-ICD in a

spontaneous episodes of VT or VF), based on the most recent published appropriate shock event rate of 5.2-6.6% per year, which would result in the assumed cumulative appropriate shock event rate of 20%, thus resulting in a 2% event failed first shock rate(18). The anticipated population for this trial is expected to be similar to this study's 'all comer' population as the in- and exclusion criteria of this trial do not select a specific subgroup of S-ICD patients. The incidence of failed first shocks was 0.375% per year in the Effortless/IDE study and 0.839% in the SIMPLE study(2, 3). When a patient has recurrent arrhythmia episodes, the patient remains at risk for the primary endpoint until an episode has occurred with a failed first shock. Study follow-up will therefore continue until a 2% event rate for failed first shock has been reached or until the median follow-up duration has reached 40 months.

Non-inferiority margin

The S-ICD delivers a maximum of five shocks per arrhythmia episode. An episode is only terminated when VT of VF is terminated, either spontaneously or by shock delivery. Based on the first shock efficacy in EFFORTLESS and IDE the norm for shock efficacy of the S-ICD for the first shock was set at 90% (12, 13, 14). We assume that the shock efficacy remains unchanged for subsequent shocks. This translates to arrhythmia termination in 99.999% of patients after five shocks (table 2). The lower boundary for shock efficacy for this study was set at 75% first shock success. Under the same assumption that shock efficacy remains constant over subsequent shocks, this translates to a conversion efficacy of 99.900% after five shocks which we believe to be a clinically acceptable non-inferiority margin. With a 20% cumulative event rate of ventricular arrhythmia episodes, 75% first shock efficacy translates into a 5% event rate and a non-inferiority margin of 3% (5% in the intervention arm minus 2% in the control arm). With an event rate of 2% for the primary endpoint and a non-inferiority margin of 3% and a power of 90%, the sample size was calculated at 458 patients per arm (916 in total). Attrition is estimated at 5%: 916*1.05 = 965 patients.

Event rate evaluation

When 500 patients are enrolled, a blinded evaluation of the total event rate will be made. In this

evaluation the combined event rate in both arms will be compared with anticipated event rate. The trial steering committee can decide to take measures to assure sufficient events at the end of follow up.

Funding

This is an investigator-driven trial, designed by the steering committee, and conducted by the trial bureau and the local investigators. This trial is facilitated by an unrestricted research grant that was obtained through the Boston Scientific investigator-sponsored research program. The authors are solely responsible for the design and conduct of this study, all study analyses, the drafting and editing of the paper and its final contents.

Discussion

The use of the S-ICD therapy is increasing steadily worldwide(19). Current guidelines recommend performing DFT after S-ICD implantation to ensure adequate device function(15, 20). The PRAETORIAN-DFT trial is a large randomized comparative evaluation of S-ICD implantation with and without DFT and is designed to demonstrate non-inferiority of omitting DFT in patients with adequate device positioning evaluated by the PRAETORIAN score.

Endpoint

The choice for failed first shock in spontaneous episodes per patient was chosen as a practical, achievable and objective endpoint, acting as a surrogate endpoint for arrhythmic death. Designing a randomized controlled trial with arrhythmic death as a primary endpoint would require >10,000 patients to reach sufficient power with a low event rate. Additionally, including arrhythmic death as a composite endpoint in combination with first shock efficacy could be considered unethical since non-inferiority could theoretically be claimed in case of a skewed mortality rate in one of the study arms, compensated by first shock efficacy in the other arm. Mortality, including all-cause death, cardiovascular death, arrhythmic death, non-cardiac death and unexplained death will be evaluated in one of the pre-specified secondary analyses. The S-ICD provides 5 shocks per episode, which

results in a high shock efficacy per episode even in case of a low first shock efficacy.

PRAETORIAN score

In TV-ICD patients several measures other than DFT, such as sensing and capturing tests, are obtained during implant to confirm adequate function and stable positioning of the electrodes. Conversely, anatomic position of the TV-ICD electrodes has not been systematically evaluated recently related to omitting DFT testing with outcomes data. As the S-ICD does not have a lead in the heart, these additional tests are not performed during S-ICD implant making DFT of the S-ICD mostly confirmation of anatomic position of the S-ICD electrodes. Therefore, the PRAETORIAN score was developed to ensure proper positioning such that DFT can be omitted safely in S-ICD patients.(17) As the PRAETORIAN score provides more information on device positioning it may give more accurate information on device functioning than a DFT, which is probabilistic by nature. By introducing a routine chest X-ray evaluation after S-ICD implantation the PRAETORIAN score also aims to improve implant technique by creating awareness of suboptimal implant position and the effect it has on the defibrillation threshold. Additionally, one might expect a positive effect of the PRAETORIAN score on other problems related to implant position of the S-ICD system components such as sensing issues and inappropriate shocks.

Summary

Routine DFT has fallen out of favour in TV-ICD patients, in S-ICD patients however, a DFT is still recommended post-implant. The PRAETORIAN-DFT trial is designed to test the hypothesis that S-ICD implantation without DFT, in patients with a low PRAETORIAN score, is non-inferior to S-ICD implantation with DFT with regard to first shock efficacy in treating spontaneous arrhythmic events. Implant position is evaluated in patients randomized to the non-DFT strategy by the PRAETORIAN score which evaluates the major determinants of an increased defibrillation thresholds in a three-step manner.

Disclosures

This is an investigator-driven trial, designed by the steering committee, and conducted by the trial bureau and the local investigators. This trial is facilitated by an unrestricted research grant that was obtained through the Boston Scientific investigator-sponsored research program.

Quast, Baalman, Smeding do not report any disclosures. Betts is consultant and proctor for Boston Scientific. Boersma reports consultancy fees for Boston Scientific and Medtronic which are paid out to the cardiology department. Boveda reports consultancy fees for Boston Scientific. Brouwer reports research grants and consulting fees from Boston Scientific. Burke received speaking honoraria and research grants from Boston Scientific, research grants from Biosense Webster and consultant for Abbott. Delnoy receives consultancy fees for Boston Scientific. El-Chami receives consultancy fees from Medtronic and Boston Scientific. Lambiase reports speaker, advisory fees and research grants from Boston Scientific and is supported by UCL Biomedicine and NIHR. Marquie received consulting fees from Boston Scientific. Miller received consulting fees and grand support from Boston Scientific. Wilde reports consultancy fees from LivaNova. Knops reports consultancy fees, speaker fees and research grants from Boston Scientific, Abbott and Medtronic.

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Table 1.

Inclusion Criteria	Exclusion Criteria
Patients must be ≥ 18 years of age, willing and able of giving informed consent.	Patients with life expectancy shorter than 12 months due to any medical condition
Patients who meet current guidelines for ICD therapy and intent to undergo a *de novo* implant procedure for an S-ICD.	Patients who are known to be pregnant
Patients must pass S-ICD screening per local routine.	Patients with an intracardiac thrombus
Patients willing and capable of complying with follow-up visits.	Patients with atrial fibrillation without appropriate anticoagulation
Patients must be eligible for both DFT strategies per physician discretion.	Patients likely to undergo heart transplant within 12 months
	Patients with LVAD
	Patients with other contra-indications for DFT per physician's discretion

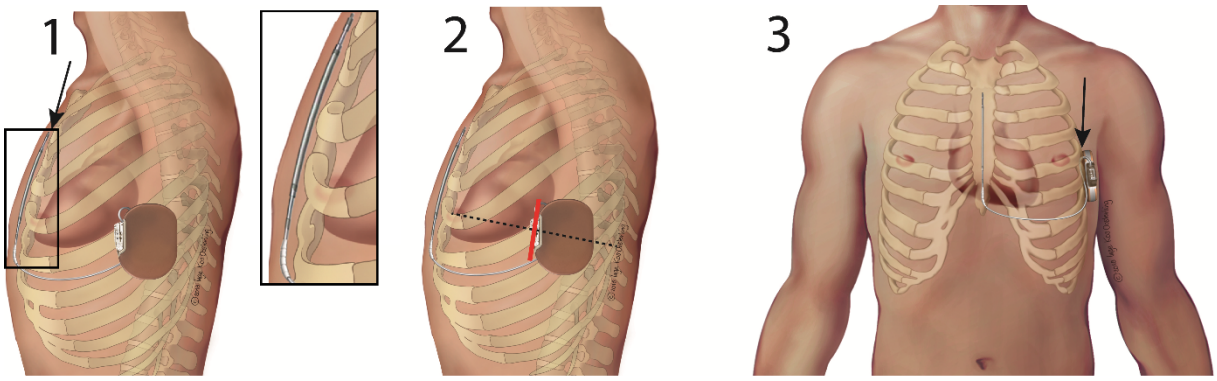
DFT = Defibrillation test. LVAD = Left Ventricular Assist Device. S-ICD = Subcutaneous implantable cardioverter-defibrillator.

Table 2.

	1st shock	2nd shock	3rd shock	4th shock	5th shock
Norm	90.00%	99.00%	99.90%	99.99%	99.999%
NI margin 1%	85.00%	97.75%	99.66%	99.95%	99.99%
NI margin 2%	80.00%	96.00%	99.20%	99.84%	99.97%
NI margin 3%	75.00%	93.75%	98.43%	99.61%	99.90%

NI = Non-inferiority

Figure 1. The PRAETORIAN score.



Step 1)
Determine the number of coil widths of fat tissue between the **nearest** half of the S-ICD coil and the sternum or ribs.

≤ 1	coil-width	**30**
> 1 ≤ 2	coil-widths	**60**
> 2 ≤ 3	coil-widths	**90**
> 3	coil-widths	**150**

Step 2)
Determine the position of the S-ICD generator in relation to the mid-line (**red line**).

Generator is on or posterior of the mid-line	**x 1**
Entire generator is anterior of the mid-line	**x 2**
Entire generator is > 1/2 length anterior	**x 4**

Step 3)
Determine the amount of fat tissue between the **nearest** point of the generator and the thoracic wall.

< 1 generator-width	**x 1**
≥ 1 generator-width	**x 1.5**

Step 4)

PRAETORIAN score ≥ 90:
BMI ≤ 25 kg/m² **- 40**
BMI ≥ 25 kg/m² **= Final score**

Final PRAETORIAN score

< 90	**Low risk of conversion failure**
90 < 150	**Intermediate risk of conversion failure**
≥ 150	**High risk of conversion failure**

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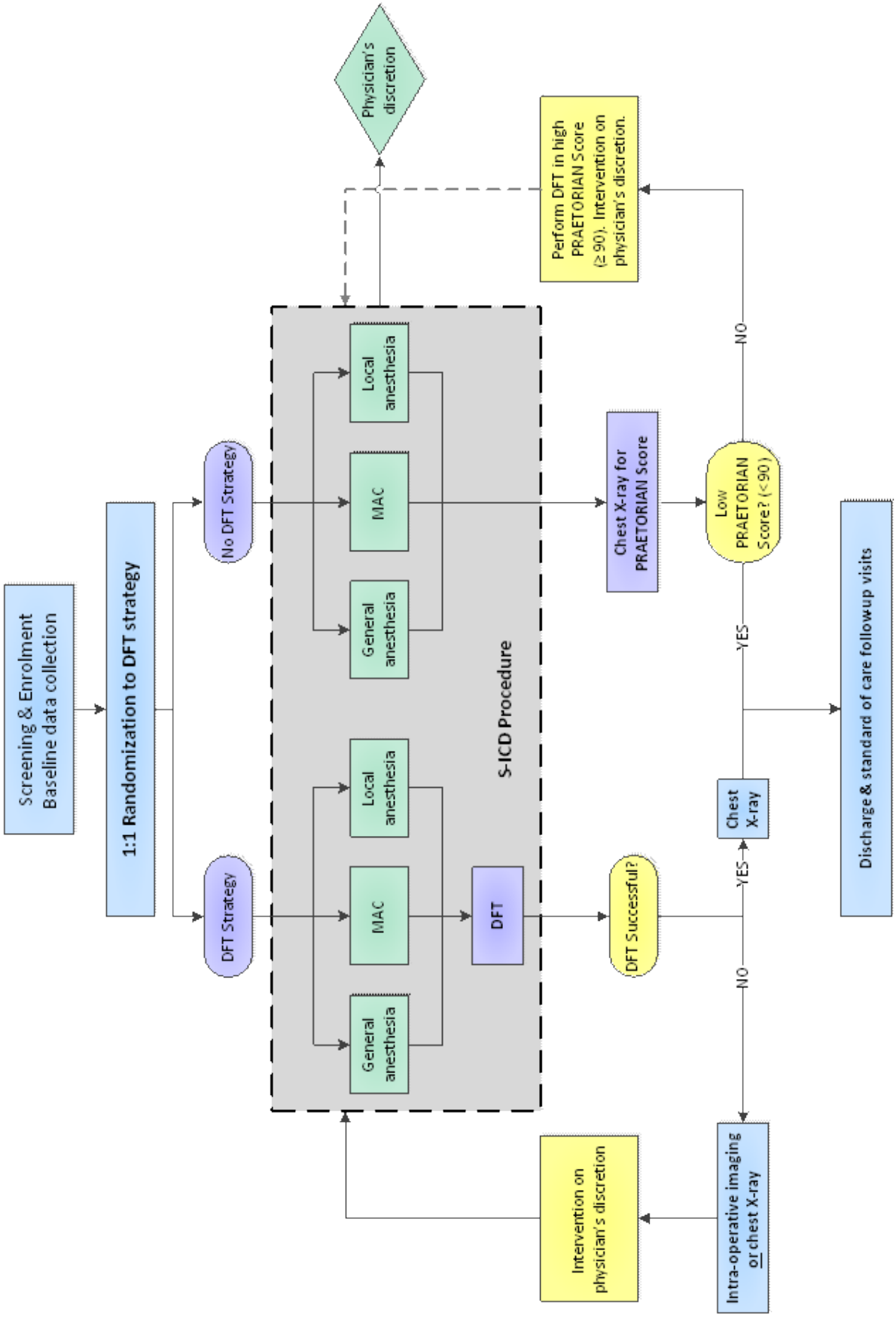
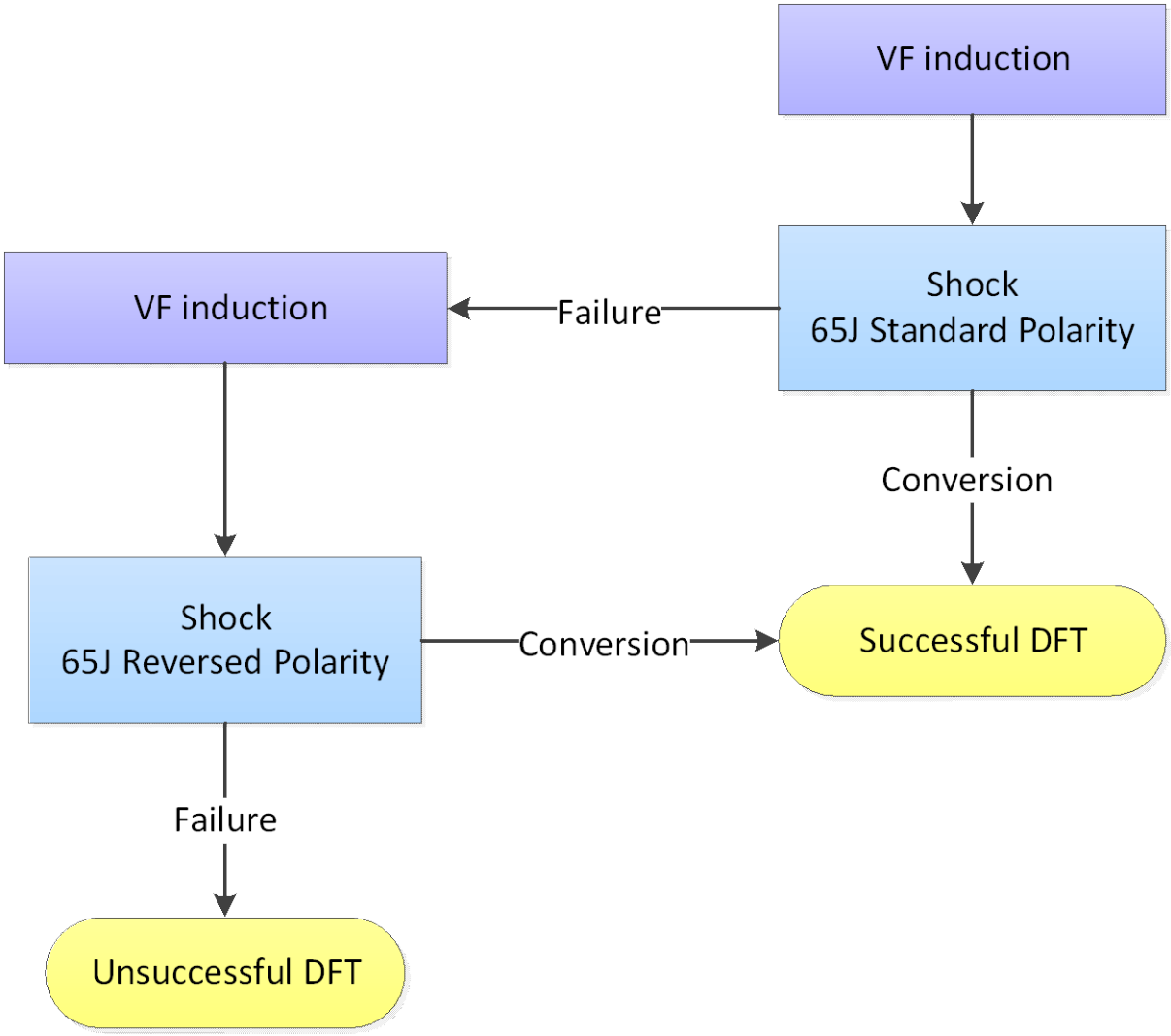
319 **Figure 2. Study flowchart**



320

321 DFT = Defibrillation test. MAC = Monitored Anasthesia Care.

Figure 3. Defibrillation test protocol.



DFT = Defibrillation test. VF = Ventricular fibrillation.