A Prospective Randomised CompArative trial of SubcutanEous ImplanTable CardiOverter-DefibrillatoR ImplANtation with and without DeFibrillation Testing

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

Summary

ID

NL-OMON54525

Source
ToetsingOnline

Brief title
PRAETORIAN DFT

Condition

- Cardiac arrhythmias
- Cardiac and vascular disorders congenital

Synonym
heart rhythm disturbances

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Defibrillation test, Subcutaneous ICD, Ventricular arrhythmia

Outcome measures

Primary outcome

Primary endpoint of this study is the first shock efficacy in spontaneous

events.

Secondary outcome

Secondary endpoints include DFT related complications, PRAETORIAN Score (chest

X-ray implant score), pain score at baseline and after implant, Mortality

(all-cause, arrhythmic death, cardiovascular death, unexplained death), Device

or lead repositioning, MACE within 30 days post-implant, successful shock (in

both DFT and spontaneous events), time to (successful) therapy, inappropriate

therapy, cardiac (pre-)syncope, cardiac decompensation, length of

hospitalization post implant and ICD related infection.

Study description

Background summary

Implantable Cardioverter Defibrillator (ICD) implant improves survival in patients with a higher risk for sudden cardiac death. There are 2 types of ICD available; transvenous ICD (TV-ICD) and subcutaneous ICD (S-ICD). During ICD implant, defibrillation testing (DFT) is performed to test functionality of the device. However, DFT can be associated with complications such as inability to convert, complications arising from general anaesthesia, prolonged resuscitation, stroke and death. Whereas DFT may be associated with

complications, the benefit of DFT is debated as literature shows there is only a modest average effect of DFT, if any, on mortality, shock efficacy or safety. Recently it was shown in a randomized controlled trial called 'SIMPLE' that routine defibrillation testing of TV-ICDs at the time of implant does not improve shock efficacy or reduce arrhythmic death. For S-ICD there is only limited data available of the effect of DFT on S-ICD efficacy. Data have however shown that the conversion efficacy of the S-ICD is comparable to TV-ICD.

DFT is currently performed in standard S-ICD implants, but is omitted in specific cases. However, an alternative method to evaluate the correct position may be desired when omitting DFT. The PRAETORIAN Score is developed using computer modelling data on factors influencing defibrillation thresholds. The PRAETORIAN score represents the chance of a patient having an elevated defibrillation threshold and consequently failing a DFT or conversion of a spontaneous arrhythmia episode. THe score was retrospectiely validated in two studies with 180 and 321 patients.

It was reported that most S-ICD implants are performed under general anesthesia, however other anesthesia protocols are used as well. One of the most predominant factors to use general anesthesia is the performance of the DFT. If this is omitted, other anesthesia protocols may be a good option for many patients as well.

Study objective

The primary objective is to test the hypothesis that S-ICD implant without DFT with PRAETORIAN Score is non-inferior to S-ICD implant with DFT with regard to first shock efficacy in spontaneous events. The secondary objective is to evaluate the PRAETORIAN score and to evaluate anaesthesia protocols for implantation.

Study design

A single-blinded, prospective, multicenter, international, two-arm randomised comparative trial.

Intervention

Patients will be randomised between S-ICD implant with or without defibrillation test.

Study burden and risks

This study is designed to minimally interfere with standard of care procedure in participating hospitals. There will be no extra study visits, patients will

visit the outpatient clinic according to the regular S-ICD follow-up routine as determined by the participating hospital. The risk associated with this study is minimal as DFT is recommended but not mandatory in these patients and already being omitted in certain patients. Furthermore, previous studies have shown that DFT in TV-ICD patients does not reduce the risk of arrhythmic death but does expose patients to the risk of complications of DFT. S-ICD studies have shown similar shock efficacy compared to TV-ICD studies, therefore similar effect of omitting of DFT in SICD is expected.

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 must be >= 18 years of age, willing and capable of giving informed consent

• Patients who meet current guidelines for ICD therapy and intend to undergo a de novo implant procedure for an S-ICD.
• Patients must pass S-ICD screening per local routine
• Patients willing and capable of complying with follow-up visits
• Patients must be eligible for both DFT strategies per physician discretion.

Exclusion criteria

• Patients with life expectancy shorter than 12 months due to any medical condition
• Patients who are known to be pregnant
• Patients with intracardiac thrombus
• Patients with atrial fibrillation without appropriate anticoagulation
• Patients likely to undergo heart transplant within 12 months
• Patients with LVAD
• Patients with a BMI > 40
• Patients with other contra-indications for DFT per physician*s discretion

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-05-2018
Enrollment:	305
Type:	Actual

Ethics review

Approved WMO Date:	04-05-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-06-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-09-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-09-2019

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-12-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-05-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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	NL64634.018.18