CardioToxicity of Implantation and defibrillation testing in TransvenoUs and Subcutaneous implantable defibrillators.

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To compare acute cardiotoxicity, measured by Troponin difference pre- and post-implantation, induced by implantation and defibrillation testing of transvenous and subcutaneous ICDs.

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

Summary

ID

NL-OMON47092

Source
ToetsingOnline

Brief title
TITUS Study

Condition

- Cardiac arrhythmias

Synonym
ICD implantation and defibrillation

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, ICD

Outcome measures

Primary outcome

Delta troponin level pre versus post ICD implantation

Secondary outcome

Not applicable

Study description

Background summary

The new subcutaneous ICD requires more energy to meet the defibrillation requirements and may therefore cause more myocardial injury than the lower energy shocks from transvenous devices, but lacks an endocardial lead and may in that respect actually cause less myocardial injury. One previous animal study by Killingworth et al. compared cardiac enzyme release after implantation and five shocks at maximum output. Four pigs were implanted with a transvenous ICDs (35 Joules per shock) and four with a subcutaneous ICDs (65 Joules per shock). The interesting result from this study was that only in the transvenous ICD group the cardiac enzymes increased and in none of the pigs implanted with a subcutaneous ICD. This indicates that transvenous ICD implantation and testing causes myocardial injury, whether implantation and subsequent mandated device test of a subcutaneous ICD does not cause myocardial injury. However, no human data on cardiac injury after subcutaneous ICD implantation and testing has been published thus far.

Study objective

To compare acute cardiotoxicity, measured by Troponin difference pre- and post-implantation, induced by implantation and defibrillation testing of transvenous and subcutaneous ICDs.

Study design

This study is a prospective non-randomized comparison three study arms.
- Arm A: 20 patients with de novo transvenous ICD implantation that subsequently undergo defibrillation threshold testing.

- Arm B: 20 patients with transvenous ICD pulse generator replacement that subsequently undergo defibrillation threshold testing.
- Arm C: 20 patients with de novo subcutaneous ICD implantation that subsequently undergo defibrillation threshold testing.
- Arm D: 20 patients with de novo transveneus ICD implantation that do not undergo subsequent defibrillation testing.

Study burden and risks

Prior to the implantation of the ICD, a blood sample will be drawn from the intravenous line that is place as part of routine care. Six to eight hours after defibrillation threshold testing a second blood sample will be drawn from the IV-line.

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 with an ICD indication, according to the European society of cardiology guidelines, who will undergo ICD implantation.

Exclusion criteria

- (Potential) pregnancy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-07-2016
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	22-12-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-03-2018
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	NL55212.018.15