Preliminary evaluation of defibrillator lead curvature in vivo

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

Summary

ID

NL-OMON47524

Source
ToetsingOnline

Brief title
Lead Curvature study

Condition

- Cardiac arrhythmias

Synonym
ICD (implantable cardiac defibrillator), implantation technique

Research involving
Human

Sponsors and support

Primary sponsor: Cardiologie
Source(s) of monetary or material Support: Boston Scientific, 4100 Hamline Ave N, VS,Boston Scientific;4100 Hamline Ave N;VS

Intervention

Keyword: Implantable defibrillator (ICD), Implantation technique, Lead design, X-ray

Outcome measures

Primary outcome

To quantify the in vivo cyclic curvature in the extravenous region and connector region of Reliance 4-Site and Reliance 4-Front leads for a random sample of patients implanted with ICD and CRT-D systems.

Secondary outcome

1) to correlate in vivo cyclic curvature in the extravenous region and connector region with certain predefined dimensions that locate the defined lead trajectory and locate the pulse generator with respect to anatomical landmarks.

2) to compare in vivo cyclic curvature between the Reliance 4-Site and Reliance 4-Front leads. The stiffness of both leads is different, which could influence curvature

Study description

Background summary

Implantable cardiac defibrillator (ICD)-leads are intended to last a lifetime without repair or replacement. However the leads are subject to degradation and can be damaged by forces when implanted in vivo. These forces are caused by use of the arm leading to scraping of the lead to other structures causing abrasion, or metal fatigue. Engineers perform bench tests to optimize lead design. However the current bench tests do not account for forces applied on the leads in vivo. This information can be obtained by studying in vivo 3D-curvatures of ICD-leads in patients with an ICD.

Study objective

The study will gain information on 3D movements / curvatures of the Reliance 4-Front and Reliance 4-Site ICD leads in vivo. We expect that the movements will be influenced by the type of lead (lead stiffness, which is different between the 2 lead types), location of ICD generator, lead length between vein entry site and generator. This knowledge can be used to improve implantation techniques and ICD-lead design to prevent degradation of ICD-leads. The long-term reliability of ICD-leads will be improved and future patients will benefit.

Study design

It is a prospective observational study in patients.

Study burden and risks

Patients are asked to visit the UMC Utrecht once, the visit will take 2 hours.
We will use radiation with an expected dose of 0,35 mSv. As a comparison: the usual background radiation in The Netherlands is ~2,5 mSv each year. The amount of radiation that will be used has a low risk of harmful effects.

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

-Age 18-90 years
-Patients with implantable defibrillator systems with either Reliance 4-Site or Reliance 4-Front leads who are followed at the University Medical Center, Utrecht
-Patients capable of providing informed consent.

Exclusion criteria

Pregnancy

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):	11-04-2018
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	06-03-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL62029.041.17