Lead Motion Study

Published: 18-03-2015
Last updated: 21-04-2024

Obtain information on the spatial movement and deflection of implanted leads by capturing three cardiac cycles with a simultaneous biplane cinefluoroscopy imaging system. The lead movement and deflection data will be used to evaluate the lead strain...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON41829

Source
ToetsingOnline

Brief title
Lead Motion Study

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
documentation of lead movement, patients with ICD therapy

Research involving
Human

Sponsors and support

Primary sponsor: BIOTRONIK SE & Co. KG
Source(s) of monetary or material Support: BIOTRONIK SE & Co. KG

Intervention

Keyword: ICD lead, Implantable Cardioverter Defibrillator (ICD)

Outcome measures

Primary outcome

No primary or secondary endpoints were defined.

Secondary outcome

Data of interest in addition to the biplane cinefluoroscopy are:

- Patient characteristics

- ICD/CRT-D therapy characteristics, including data about implantation procedure

- X-ray procedural data

- Termination of individual patient study participation

- Adverse and serious adverse events

Exploratory data analyses will be used to describe the patient population.

Study description

Background summary

An Implantable Cardioverter Defibrillator (ICD) system or a Cardiac Resynchronization Therapy (CRT) device with Defibrillator function (CRT-D) system consist of the device itself and one or more connected lead(s), that are placed with their electrical active electrodes into the heart.
In vivo lead motion and performance became a new focus in the clinical and regulatory field with the reported lead-related complications such as perforation issues reported for Riata or Sprint Fidelis leads.
During implantation or relocation procedures a physician uses X-ray imaging sequences from different views (angles) routinely to assess lead positioning and performance in dependence of the current patient and procedure situation. But these data can not be used to systematically reproduce lead positioning and behaviour due to the absence of an obligatory standardized preset for the imaging system and projection.
Moreover the development of a new ISO standard is in progress to formulate requirements on lead fatigue performance based on in vivo lead motion data. Currently, the ISO standard is based on well established harmonized testing

methods, but they do not take account of product specific characteristics [6]. It is currently under discussion if new different testing procedures are necessary for different lead models. Therefore the analysis of in vivo lead motion (use condition) is a prerequisite.

Study objective

Obtain information on the spatial movement and deflection of implanted leads by capturing three cardiac cycles with a simultaneous biplane cinefluoroscopy imaging system. The lead movement and deflection data will be used to evaluate the lead strain.

Study design

Prospective, non-randomized, single-center feasibility investigation with an enrollment target of 45 patients

Study burden and risks

The study related risks that are based on the cinefluoroscopy procedure are potential long term effects related to exposing the patients to X-ray during the cinefluoroscopy procedure (maximal two attempts of approximately 4 seconds and the previous positioning process).It is known, that each radiation exposure can lead to an increase of risk to development cancer or other radiation side effects, most likely on an incremental pattern. On the other hand, fluoroscopy and CT procedures are the common clinical standard for in vivo imaging procedures, particularly in cases of suspicion of potential lead issues. The compliance to the ALARA principle for the application of radiation is mandatory for each physician and medical staff and minimizes the risk for all involved persons.
The patient may directly benefit from possible findings or observations, eventuated by the cinefluoroscopy, which could prevent potential unobserved risks.
The main long term clinical benefit will derive from substantial improvements in lead development and testing, ultimately affecting patient safety and prolonging lead replacement cycles.

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

· Patient has provided written informed consent
· Patient has a BIOTRONIK ICD or CRT-D
· Patient has at least a BIOTRONIK Linoxsmart S-DX lead or any other BIOTRONIK lead model
· Data about the implantation of the ICD/CRT-D, the lead(s) and the implanting physician are available at the investigation site
· Patient is able to attend the X-ray procedure following a routine follow-up visit
· None of the leads was implanted within the last three months
· Patient had no cardiac intervention within the last two months
· Patient has legal capacity and ability to consent

Exclusion criteria

· Age <18 years
· Patient is pregnant or breastfeeding
· Any complication of the implanted system at the time of enrollment
· Applicable patient subgroup is closed for enrollment

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):	27-06-2015
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO

Date:	18-03-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL51377.078.14

Study results

Results posted: 06-05-2021

First publication
01-01-1900