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Collect therapy coil electrograms from insulation breaches study

Submission date	Recruitment status	[ ] Prospectively registered
28/07/2016	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/08/2016	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
31/10/2017	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
An implantable cardioverter defibrillator (ICD) is a small device that is used to treat people with dangerously abnormal heart rhythms. An ICD can give the heart electric pulses or shocks to get the heart rhythm back to normal. The ICD is inserted just under the collar bone and is connected to one or more electrode leads that are placed into the heart through a vein. Lead failures involving the insulation of the high-voltage part of the ICD lead may cause an electrical short during high-voltage shocks, preventing treatment from being delivered. There are currently limited means for detecting these lead failures. The aim of this study is to collect data to try to detect possible high-voltage insulation breaches.

Who can participate?
Participants aged 18 or over who have been implanted with an ICD and whose defibrillator lead has a possible high-voltage insulation breach

What does the study involve?
Participants wear a Holter monitor for up to 24 hours. A Holter monitor is a portable device that is attached to the skin via electrodes and collects data from the ICD. The collected data is used to try to detect possible high-voltage insulation breaches. Participants are followed up for up to 180 days after Holter monitoring to assess the functioning of their leads.

What are the possible benefits and risks of participating?
Participants may benefit if an insulation breach is detected. There are no risks of participating in the study other than possible mild skin irritation from the Holter monitor electrodes.

Where is the study run from?
Asheville Cardiology Associates (USA)

When is the study starting and how long is it expected to run for?
July 2016 to January 2019

Who is funding the study?
Medtronic (USA)

Who is the main contact?
Scott Sarazin

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
Version 2, 05 APR 2016

Study information

Scientific Title
Collect therapy coil electrograms from insulATion breaCHes (CATCH) Study: a prospective non-randomized multi-center post-market feasibility study

Acronym
CATCH

Study objectives
The primary objective of the study is to collect electrogram (EGM) data from subjects with potential insulation breaches in the high-voltage portion of defibrillator leads. This feasibility study is not powered to formally test a hypothesis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Mission Health Institutional Review Board, 22/06/2016, Ref: 16-06-1578

Study design
Prospective non-randomized multi-center post-market feasibility study

Primary study design
Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied
Implanted defibrillator lead high-voltage insulation breach

Interventions
Study subjects will wear a telemetry Holter monitor that stores continuous implanted device data for up to 24 hours. The study will be reviewing electrogram (EGM) data collected by the Holter monitor to try and determine potential lead insulation breaches in the high voltage portion of defibrillation leads. The duration of observation is between 2 and 24 hours. Study follow-up is up to 180 days after Holter monitoring to allow physician to determine lead function status.

Intervention Type
Device

Primary outcome(s)
Lead insulation breaches in the high-voltage portion of defibrillation leads, measured using EGM data at any time between the end of Holter monitor use to up to 180 days post-Holter use

Key secondary outcome(s))
There are no secondary outcome measures for this study

Completion date
05/01/2019

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Subject (or subject's legally authorized representative) is willing and able to provide written informed consent
2. Subject is at least 18 years of age (or older, if required by local law)
3. Subject is willing and able to wear a Holter monitor for at least 2 hours and up to 24 hours
4. Subject has been implanted with a Medtronic ICD or CRT-D device
5. Subject's defibrillator lead has a possible high voltage insulation breach, as suggested by device diagnostics exhibiting any of the following three characteristics:
5.1. Abrupt high voltage impedance decrease (25% decrease in daily impedance from baseline)
5.2. Non-physiologic noise on high voltage EGM
5.3. Less than 50% programmed shock energy delivered

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Subject has medical conditions that would limit study participation (per physician discretion)
2. Subject is enrolled in one or more concurrent studies that would confound the study results of this study as determined by Medtronic

Date of first enrolment
05/07/2016

Date of final enrolment
05/01/2019

Locations

Countries of recruitment
United States of America

Study participating centre
Asheville Cardiology Associates, PA
United States of America
28803

Sponsor information

Organisation
Medtronic, Inc. (USA)

ROR
https://ror.org/00grd1h17

Funder(s)

Funder type
Industry

Funder Name
Medtronic

Alternative Name(s)
Medtronic Inc.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available