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Extravascular pacing acute clinical evaluation

Submission date
05/03/2015

Recruitment status
No longer recruiting

Registration date
18/03/2015

Overall study status
Completed

Last Edited
13/07/2016

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The purpose of this study is to see if it is possible to pace the heart using a market released EP catheter (plastic tube) as part of a research system. The results of the study will provide data to support Medtronic in the research and development of a potential extravascular Implantable Cardioverter-Defibrillator (ICD) system. A ICD is a tiny, battery run computer that is implanted just under the skin on the chest. It is designed to treat heart palpitations (heart beating rapidly and irregularly).This system uses a catheter temporarily inserted into the body to read the electrical activity of the heart (sensing) and send electrical signals to the heart to modify its rhythm (pacing). In this study, pacing will be used to attempt to speed up the heart rate a little.

Who can participate?
Adults (over 18) undergoing one of the following surgical procedures: cardiothoracic surgery, VT ablation or subcutaneous ICD implant.

What does the study involve?
This trial is testing the feasibility of pacing the heart with a research system. The results of the study will provide data to support Medtronic in the research and development of a potential extravascular Implantable Cardioverter-Defibrillator (ICD) system. Each participant has the procedure before they undergoe their planned surgery and it takes about 20 minutes from the first incision until the point where all the research components are removed. Pacing, sensing, and extracardiac muscle stimulation is collected during this time. Participants are followed through their routine post-surgery follow-up visit to ensure that the catheter tunneling track used for the pacing is appropriately recovering, and to collect data on new or updated adverse events, device deficiencies, study deviations, study exit, and death. This visit occurs between 7 and 50 days after the procedure.

What are the possible benefits and risks of participating?
There is no direct benefit to subjects participating in this study. Potential risks and discomforts associated with participating in this study include, but are not limited to, inappropriate modification of the heart rhythm, arrhythmia (irregular heart beat), electronic shock, palpitations, stimulation of the body other than the heart and muscle pain. Risks of the surgery include damage to the heart muscle, tissues, veins, arteries, diaphragm or lungs, blood or air embolism, bleeding, or bruising, pneumothorax (blood in the lungs), or arrhythmia. Participants may also be at an increased risk of infection, stroke, and a skin irritation or allergy to the

adhesive on the ECG electrode patch that is used. Some of the risks mentioned may lead to death.

Where is the study run from?
This is an international study taking place in 13 hospitals in Canada, The Netherlands and the USA.

When is the study starting and how long is it expected to run for?
August 2014 to December 2015

Who is funding the study?
Medtronic (USA)

Who is the main contact?
Mr Michael Bennett
space@medtronic.com

Contact information

Type(s)
Public

Contact name
Mr Michael Bennett

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G140211

Study information

Scientific Title
Feasibility of extravascular pacing from a novel lead location, an acute clinical evaluation

Acronym

SPACE

Study objectives
This study uses a market-released diagnostic catheter placed in the proposed novel lead location to assess the feasibility of pacing the heart from this location, collect sensing data, and observe the degree of non-cardiac muscle stimulation.

This feasibility study is not powered to formally test a hypothesis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. US FDA IDE, 15/01/2015, ref: G140211
2. Health Canada ITA, 29/01/2015, ref: 233524

Study design
Prospective global multi-center non-randomized acute feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
This is an acute data collection study for pacing feasibility

Interventions
This trial will be testing the feasibility of pacing the heart with a research system. The results of the study will provide data to support Medtronic in the research and development of a potential extravascular Implantable Cardioverter-Defibrillator (ICD) system. The procedure will precede the subject’s planned surgical procedure and is expected to take approximately 20 minutes from first incision till the point where all research components are removed from the patient. Pacing, sensing, and extracardiac muscle stimulation will be collected during this visit.

Subjects will be followed through their routine post-surgery follow-up visit to ensure that the catheter tunneling track used for the pacing is appropriately recovering, and to collect data on new or updated adverse events, device deficiencies, study deviations, study exit, and death. The time required to assess for potential adverse events at this visit is expected to be approximately 5 minutes. This visit must occur between 7 and 50 days post-procedure.

Intervention Type
Device

Primary outcome measure
Primary Objective: Pacing Efficacy
1. Endpoint Definition
Subjects will demonstrate a successful pacing outcome if heart capture is observed for at least 3 consecutive beats after pacing stimuli are delivered into at least one out of all tested pacing vectors using pacing current ≤ 20 mA and pacing PW ≤ 10 ms.
2. Analysis Methods
The proportion of subjects who have successful pacing outcome will be calculated along with the lower bound of the one-sided 95% confidence interval. The exact method will be used to calculate the lower 95% confidence bound.
3. Determination of Subjects for Analysis
All subjects who complete pacing testing according to the CIP will be included in the analysis.

Secondary outcome measures
1. Collection of Sensing Data
R-wave amplitude will be summarized using mean and standard deviation for each ECG vector collected via EP recording system for future sensing algorithm development
2. Determine the Degree of Muscle Stimulation During Pacing
The degree of muscle stimulation (e.g., high, low, none) will be visually assessed and summarized for each pacing vector collected to provide information about non-cardiac muscle stimulation when pacing

Overall study start date
01/08/2014

Completion date
28/12/2015

Eligibility

Key inclusion criteria
Subject must be:
1. Undergoing surgical procedure for approved indications for cardiothoracic surgery where a midline sternotomy is planned or
2. VT ablation procedure with epicardial access indicated, or
3. Implant of a subcutaneous ICD
4. Subject must be willing to provide informed consent
5. Subject must be > 18 years old

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Subject is considered to be at high risk for infection,
2. Subject has NYHA Class IV,
3. Subject has subcutaneous ICD (S-ICD®) implanted,
4. Subject has an implanted active cardiac or non-cardiac device (e.g., ICD, Pacemaker, Neuro stimulator) that is enabled and can produce electrical stimuli during study procedure
5. Subject at high risk of stroke, Subject is pacemaker dependent
6. Subject had previous pericarditis or prior sternotomy
7. Subject has hiatus hernia or moderate or worse pectus excavatum
8. Subject has significant RV dilation caused by pulmonary hypertension or tricuspid disease 9. Subject has had myocardial infarction within the last 3 months
10. Subject has unstable angina
11. Subject has known skin irritations to the Physio Control Fast-Patch® ECG Electrode
12. Subject is enrolled in a concurrent study that may confound the results of this study without documented pre-approval from a Medtronic study manager
13. Subject has medical conditions that would limit study participation
14. Subject is pregnant
15. Subject meets exclusion criteria required by local law (e.g. age, breast feeding, etc.)

Date of first enrolment
28/02/2015

Date of final enrolment
09/10/2015

Locations

Countries of recruitment
Canada

United States of America

Study participating centre
CHI Saint Luke's Health - Baylor Saint Luke's Medical Center
6720 Bertner Ave
Houston
United States of America
TX 77030

Study participating centre

Drexel University College of Medicine
Philadelphia
United States of America
-

Study participating centre
University Institute of Cardiology and Pneumology Quebec (Institute Universitaire de Cardiologie et de Pneumologie de Quebec (IUCPQ))
2725, chemin Sainte-Foy
Québec
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Study participating centre
London Health Sciences Centre - University Campus
London
London
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-

Study participating centre
Lourdes Cardiology Services
63 Kresson Rd
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United States of America
08034

Study participating centre
Northwestern University
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United States of America
60208

Study participating centre
Royal Columbian Hospital
330 E Columbia Street

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Study participating centre
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Sponsor information

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Sponsor type
Industry

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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

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available