

Extravascular pacing acute clinical evaluation

Submission date 05/03/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/03/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/07/2016	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 undergo 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

Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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Study participating centre

University Institute of Cardiology and Pneumology Quebec (Institute Universitaire de Cardologie et de Pneumologie de Quebec (IUCPQ))

2725, chemin Sainte-Foy

Québec

Canada

G1V 4G5

Study participating centre

London Health Sciences Centre - University Campus

London
London
Canada

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**Study participating centre
Lourdes Cardiology Services**

63 Kresson Rd
Cherry Hill
New Jersey
United States of America
08034

**Study participating centre
Northwestern University**

633 Clark Street
Evanston
Illinois
United States of America
60208

**Study participating centre
Royal Columbian Hospital**

330 E Columbia Street
New Westminster
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**Study participating centre
Sequoia Hospital**

170 Alameda de las Pulgas
Redwood City
California
United States of America
94062

**Study participating centre
University of Calgary**

2500 University Dr NW
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University of Minnesota Medical Center Fairview
2450 Riverside Ave
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United States of America
55454

Study participating centre

University of Washington Medical Center
1959 NE Pacific Street
Seattle
United States of America
98195

Sponsor information

Organisation

Medtronic (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