

Pacing the ventricle from the atrium in heart failure patients

Submission date 29/08/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/09/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/01/2023	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

Patients whose doctors recommend that the patient be implanted with a market-released Cardiac Resynchronization Therapy (CRT) device to correct heart failure are being studied. The purpose of a CRT device is to restore natural electrical rhythm (called resynchronization). Resynchronization is normally delivered using a lead in the left heart and a lead in the right heart connected to a CRT device. In this study, a potential method is being evaluated to provide ideal cardiac resynchronization using an investigational system, called the VFAHF system. The purpose of this study is to collect data to evaluate safety and resynchronization capabilities of the VFAHF Research System.

Who can participate?

Patients who have Heart Failure and meet other inclusion/exclusion criteria.

What does the study involve?

Before study patients are implanted with a market-released (approved) CRT device, they will first be temporarily implanted with a lead the right heart. Images will be taken of the heart and the placement of the lead during the implant procedure, using echocardiography (imaging of the heart using sound waves) or fluoroscopy (which uses X-ray images on a monitor similar to an X-ray movie). During these implant procedures, heart rhythm will be monitored using a Medtronic Electrocardiogram (ECG) Belt Research System. After these measurements and images are taken, the temporary lead will be removed and CRT implant will proceed normally. Patients will also have a follow-up visit one month after their implant, to assess for medication changes and adverse events.

What are the possible benefits and risks of participating?

Patients may not have any direct medical benefits. The information from this study may benefit other subjects with heart failure in the future.

The potential risks associated with participating in the VFAHF study are similar to normal CRT implant risks but may increase some risks. These potential risks may include, but are but are not limited to, the following:

1. Increased risk of infection

2. Increased risk of embolus (a clot that travels through the bloodstream)
3. Increased risk of hematoma (bruise)
4. Pneumothorax (abnormal accumulation of air in the space between the chest wall and lung causing a collapsed lung)
5. Hemothorax (abnormal accumulation of blood in the space between the chest wall and lung)
6. Increased risk of cardiac perforation (puncture of the heart)
7. Increased risk of cardiac tamponade (blood or fluid in the space between the sac around the heart and the heart muscle)
8. Increased risk of cardiac arrest (when the heart stops pumping blood)
9. Lethargy (a lack of energy and enthusiasm)
10. Dizziness
11. Rapid or irregular heartbeats/heart rhythms
12. Increased risk of tissue damage, inflammation, or fibrillation due to electrical currents and/or leads introduced into the heart
13. Valve dysfunction (when a flap in the heart is not working properly)
14. Increased risk of conduction system damage (the cardiac muscle cells in the wall of the heart that are sending out the signals to the heart muscle causing it to contract)
15. Perforation into the left ventricular chamber
16. Interaction of the Model 09108 lead with a coronary artery
17. Increased risk of loss of the MR Conditional labeling due to the lead abandonment
18. Extraction of the Model 09108 lead-related complications
19. Bio incompatibility, including toxicity, sensitivity and allergenic reactions from the ECG Belt material and Model 09108
20. Increased risk of infection due to lengthened procedure duration
21. Increased risk of infection due to additional access points
22. Increased risk of kidney damage due to additional contrast use
23. Increased risk of complications at the catheter insertion site
24. Stimulation of muscle other than heart muscle or stimulation of a nerve
25. Nerve damage (at incision/puncture points)
26. Inflammation or redness around the incision
27. In addition to the routine procedures patients will undergo, the x-ray exams used for this study could include possible increased CT scans of the heart, which minimally increases radiation doses.

Where is the study run from?

The sponsor of the study is Medtronic, Inc, located at 3200 Coral Sea St. NE, Mounds View, MN, USA. There are study sites in Australia, Brunei, Hong Kong, Malaysia, and Singapore.

When is the study starting and how long is it expected to run for?

July 2015 to February 2023

Who is funding the study?

Medtronic, Inc. (USA)

Who is the main contact?

Joy A. Aso, Clinical Research Specialist, Medtronic, Inc. (joy.a.aso@medtronic.com)

Contact information

Type(s)

Public

Contact name

Ms Joy Aso

Contact details

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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information**Scientific Title**

Ventricle from Atrium Heart Failure

Acronym

VFAHF

Study objectives

The aim of the study is to characterize the acute cardiac resynchronization therapy (CRT) response of ventricle from atrium (VfA) pacing and traditional CRT using the standard deviation of activation times (SDAT) from the ECG belt technology

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 10/07/2019, Institut Jantung Negara Research Ethics Committee (145, Jalan Tun Razak, Kuala Lumpur; 03 26178200), ref: IJNREC/411/2019.
2. Approved 09/09/2019, Bellberry Limited (123 Glen Osmond Road, Eastwood, South Australia, 5063; bellberry@bellberry.com.au; +61 8 8361 3222), ref: 2019-06-484.
3. Approved 09/07/2019, South Metropolitan Health Service Human Research Ethics Committee (Level 2, Education Building, Fiona Stanley Hospital, 14 Barry Marshall Parade, Murdoch, Western Australia, 6150), ref: RGS0000003291.
4. Approved 14/02/2020 National Healthcare Group Domain Specific Review Board (Nexus@One-North (South Tower) 3 Fusionopolis Link 03-08, Singapore, Singapore), ref: 2019/00790
5. Approved 29/10/2019. Joint Chinese University of Hong Kong-New Territories East Cluster

Clinical Research Ethics Committee (8/F Lui Che Woo Clinical Sciences Building, Prince of Wales Hospital, Shatin, HK), ref: 2019.452-T

Study design

Prospective interventional non-randomized multicenter global investigational research feasibility study

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Heart failure

Interventions

Subjects indicated for a CRT device will be recruited and implanted with a Model 09108 lead to test for CRT response. ECG Belt, EGM and 12 lead ECG will be collected during multiple pacing maneuvers. The Model 09108 lead will be removed, and the subject will receive their permanent CRT system.

Subjects will undergo assessments at baseline, implant, pre-hospital discharge and 1-month post-implant.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Medtronic model 09108 lead

Primary outcome(s)

1. Characterize the absence of complications related to either the Model 09108 lead implant procedure or the temporarily implanted Model 09108 lead through the first month of follow-up
2. Characterize the proportion of Model 09108 lead implants with ventricular pacing capture at baseline, implant, pre-hospital discharge and 1-month post-implant.

Key secondary outcome(s)

At baseline, implant, pre-hospital discharge and 1-month post-implant:

1. Characterize the acute CRT response of Ventricle from Atrium (VFA) pacing and traditional CRT using the standard deviation of activation times (SDAT) from the ECG belt technology
2. Characterize the implant success rate of the Model 09108 lead
3. Characterize the resynchronization success rate of the Model 09108 lead via the ECG belt
4. Characterize the voltage pacing capture thresholds, sensing and pacing impedance of the Model 09108 lead at implant
5. Characterize the implant procedure duration

Completion date

20/02/2023

Eligibility

Key inclusion criteria

1. Indicated for a CRT device system according to local guidelines
2. Implanted with a market-released Medtronic CRT device and a market-released Medtronic LV lead
3. Able to sign and date the study Informed Consent (IC) form
4. 18 years of age or older, or of legal age to give informed consent per local law
5. Subject is willing and able to comply with the study protocol

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Permanent/persistent AF or presenting with AF with ventricular rate \geq 90 BPM
2. CIED or has another confounding device (e.g. Left Ventricular Assist Device, Vagal Nerve Stimulator). Insertable cardiac monitors (ICMs) are acceptable.
3. Requires right-sided venous access or a right-sided device implant
4. Contraindication for standard transvenous cardiac pacing (e.g. mechanical right heart valve)
5. History of valve repair or replacement
6. Previous LV lead implanted or previous implant attempt within 30 days of enrollment or has ongoing AEs from a previous unsuccessful implant attempt
7. Post heart transplant (subjects waiting for heart transplants are allowed in the study)
8. Unstable angina pectoris or has had an acute myocardial infarction (MI) within the past 30 days
9. Currently enrolled or planning to enroll in a concurrent study that may confound the results of this study. Pre-approval from the study manager is required for enrollment of a patient that is in a concurrent study.
10. Congenital heart disease
11. Hypertrophic cardiomyopathy
12. History of chronic dialysis therapy
13. Less than 1-year life expectancy
14. Pregnant
15. Contraindicated for \leq 1.0 mg of dexamethasone acetate
16. Subject meets any exclusion criteria required by local law
17. Weighs more than 300 lbs (136 kg)
18. Vulnerable adults

Date of first enrolment

15/07/2019

Date of final enrolment

11/01/2023

Locations**Countries of recruitment**

Australia

Brunei Darussalam

Hong Kong

Malaysia

Singapore

Study participating centre**Institut Jantung Negara**

Department of Cardiology

Institut Jantung Negara Sdn Bhd

145 Jalan Tun Razak

50400 Kuala Lumpur

Selangor

Malaysia

50400

Study participating centre**Prince of Wales Hospital**

Department of Medicine and Therapeutics

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30-32 Ngan Shing Street

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Study participating centre**Fiona Stanley Hospital**

Department of Cardiology

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Australia
6150

Study participating centre
Warringal Private Hospital
216 Burgindy St.
Heidelberg
Australia
3084

Study participating centre
National University Hospital
5 Lower Kent Ridge Road
Singapore
Singapore
119074

Sponsor information

Organisation
Medtronic, Inc

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

The datasets generated during and/or analysed during the current study are not expected to be made available to anyone other than Medtronic and investigators in the study. This is a small, early feasibility study. There is not currently a publication plan for the study.

IPD sharing plan summary

Not expected to be made available