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The effect of MultiPoint™ pacing on reverse remodelling and the incidence of ventricular arrhythmias – The MPP VARR Study

Submission date
13/02/2017

Recruitment status
Suspended

Registration date
20/02/2017

Overall study status
Completed

Last Edited
23/05/2020

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
Heart failure patients may benefit from Cardiac Resynchronisation Therapy (CRT), which involves having a special pacemaker implanted to help the heart pump in a more coordinated and efficient way. These pacemakers involve attaching a lead to the heart muscle in within the main heart chambers which delivers current to help the heart beat effectively (pacing leads). Current pacing leads stimulate the main chamber of the heart from one location. Only two thirds of people respond to CRT and this may be due to the need to stimulate the heart from more than one position. Previous attempts at using two pacing leads in the main chamber of the heart have proved technically difficult. Due to new technologies it is now possible to stimulate the heart from more than one site using one lead - MultiPoint™ Pacing (MPP). This lead can also function as a conventional pacing lead if the MPP mode is switched off. The aim of this study is to use this specialised lead in the main chamber of the heart and study the outcomes of patients with the MPP on and MPP off.

Who can participate?
Adults who are scheduled to have a CRT device implanted.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group have their pacemaker set using the conventional method of pacing the left side of the heart from one location. Those in the second group have their pacemaker set to stimulate the left side from two locations. Participants in both groups are followed up for two years in order to find out how many episodes of irregular heart rate problems participants experience after they have had their pacemakers placed.

What are the possible benefits and risks of participating?
Participants may not benefit from taking part in this study. It is not known as to whether stimulating the main chamber of the heart from two locations will improve the effectiveness of pacemaker treatment. Although early work suggests that this will be beneficial, these benefits have not been proven in large studies yet, and this is one of the reasons that this research is

being carried out. The information from this study may therefore help with the treatment of other patients in the future. There are no notable risks involved with participating.

Where is the study run from?
1. St Thomas Hospital (UK)
2. Basildon Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2016 to October 2020

Who is funding the study?
St Jude Medical UK Ltd (UK)

Who is the main contact?
Matthew Osmond
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32782

Study information

Scientific Title

Does MultiPoint™ pacing (MPP) result in a greater rate of reverse remodelling in participants receiving cardiac resynchronisation therapy (CRT) when compared to conventional CRT and to assess if the rate of ventricular arrhythmias is affected with MPP?

Acronym
MPP VARR

Study objectives
MultiPoint™ Pacing (MPP) will increase the proportion of responders to Cardiac Resynchronisation Therapy (CRT) and this will also result in a reduction in the frequency of abnormal heart rhythms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
01/09/2016, ref: 16/EM/0344

Study design
Randomised; Interventional; Design type: Treatment, Device

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Abnormal heart rhythms

Interventions
Participants undergoing CRT- D implant will either be randomised to have the pacemaker set at the conventional method of pacing the left side of the heart from one location (MPP off) or will have the pacemaker set to stimulate the left side from two locations (MPP on).

Participants randomised into the study will have a 6 month follow up for the primary end-point and a further 2 year follow up to evaluate the secondary endpoints. The total duration of the investigation will be 2 years.

Intervention Type

Device

Phase
Not Applicable

Primary outcome measure
Rate of left ventricular reverse remodelling is measured using LV volume reduction at 6 months.

Secondary outcome measures
Changes in the incidence of treated ventricular arrhythmias is measured by the number of incidents reported over the duration of the 2 years participant is in the study.

Overall study start date
26/10/2016

Completion date
26/10/2020

Eligibility

Key inclusion criteria
1. Scheduled to undergo an implant of a CRT-D system with approved standard indication by ESC /EHRA guidelines
2. Ability to provide informed consent for study participation and be willing to comply with the enrolment and follow up evaluations
3. Aged 18 years and over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 344; UK Sample Size: 344

Key exclusion criteria
1. Recent myocardial infarction within 40 days prior to enrolment
2. Cardiac surgery or coronary revascularisation procedure within 3 months prior to enrolment or be scheduled for such procedures in the following 7 months
3. Intravenous inotropic support within the last 30 days
4. Under 18 years of age
5. Be pregnant or plan to become pregnant over the next 7 months

Date of first enrolment
26/10/2016

Date of final enrolment
26/10/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Thomas Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Basildon Hospital
Nethermayne
Basildon
United Kingdom
SS16 5NL

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Charity

Funder Name
St Jude Medical UK Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
26/10/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No