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Can new computer software technology be used to help place the pacing lead on the left side of the heart in the most beneficial position when a participant has a cardiac resynchronisation therapy device (CRT-D) implant?

Submission date 24/06/2019	**Recruitment status** Suspended	[X] Prospectively registered
Registration date 02/07/2019	**Overall study status** Completed	[ ] Protocol [ ] Statistical analysis plan [ ] Results
Last Edited 23/05/2020	**Condition category** Circulatory System	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Researchers have known for some time that certain people who have heart failure may benefit from having a special pacemaker implanted which aims to make the pumping chambers of the heart beat more efficiently. To make the heart pump as efficiently as possible it is necessary to place the pacing leads in good positions. The CRT device lead to the left side of the heart is very important as this is responsible for re-coordinating the heart's contraction. This, however, is the most technically challenging part of the CRT implant and there are often a variety of different options in terms of where the lead to the left side of heart is placed. This study aims to see whether new advanced imaging technologies and computer software can be used to help guide lead placement and thus allow more people to respond to treatment.

Who can participate?

Patients aged 18 or over who require a Cardiac Resynchronisation Therapy Device (CRT-D)

What does the study involve?

Participants are randomly allocated to either standard treatment or to an advanced technology group. The patients in the advanced technology group undergo special imaging (cardiac MR and 2D echo) before implantation of their pacemaker. The images obtained are superimposed on to the standard X-ray images usually taken during the procedure using special computer software that has been newly developed. The idea is that the patient's anatomical data (coronary veins, scar) and physiological dyssynchrony (assessment of the coordination of heart muscle contraction) information derived from these imaging techniques will help the operator implant the lead and also choose the best site for it.

What are the possible benefits and risks of participating?
There may be no benefit from participating in this study as it is not known whether having an extra heart scan (MRI) and using this information to guide the CRT implant will help improve the response to CRT device therapy. Some participants may be unable to undergo an MRI scan if they are claustrophobic.

Where is the study run from?
Guys and St Thomas NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
November 2018 to July 2022

Who is funding the study?
Siemens Healthcare GmbH

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
41689

Study information

Scientific Title
A prospective randomised multi-centre Trial comparing cArdiac MRI guided CRT versus Conventional CRT implantation in patients with Ischaemic Cardiomyopathy - TACTIC CRT

Acronym
TACTIC CRT

Study objectives
The principal question is to find out whether there is a difference in the proportion of patients responding to treatment in the conventional treatment arm of the study compared to the advanced imaging arm.

The secondary research objectives are to see whether patients' left ventricles have reduced in size (often referred to as remodelling). The left ventricle (the main pumping chamber of the heart) usually becomes quite large in heart failure and therefore the researchers hope to see a reduction in the size of the left ventricle following cardiac resynchronisation therapy (CRT) pacing. CRT pacemakers are specialised heart failure pacemakers.

The researchers will be able to judge whether the left ventricle has reduced in size by an ultrasound scan before and after the CRT pacemaker procedure. They will also assess how far patients can walk over 6 minutes and perform a symptom questionnaire before and after the procedure to assess their response to the treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/06/2019, London – Stanmore Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH; Tel: +44 (0)20 7972 2561; Email: NRESCommittee.London-Stanmore@nhs.net), ref: 19/LO/0461

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Ischaemic cardiomyopathy

Interventions
Patients in this study receiving CRT will be randomly assigned to either an 'advanced technology' arm or a conventional treatment arm.

In the advanced technology arm, cardiac MR scans will be used to get 2D images of the heart anatomy and scar. Special computer software will then be used to superimpose these pictures on x-ray images at the time of implantation. MR and 2D echo data will then be used to determine the best site for lead placement by identifying the area of maximal mechanical delay (last area of the heart to contract). Pacing in this area should improve the overall function of the heart the most.

Pre-implant assessment
All patients will answer an MLHF questionnaire and undergo a 12 lead ECG. All patients will have an ultrasound of their heart (echo). This will measure the size of the left ventricle (main heart pumping chamber) so that the response to CRT can be measured after the implant (the size is expected to decrease if the patient responds to treatment). Patients in the control arm will otherwise undergo the standard CRT implantation treatment.

The Advanced Imaging Arm
Pre-procedure, patients will undergo a cardiac MR scan to assess anatomy, scar, function, volumes and mechanical delay of the left ventricle. At implant, the MR images will be superimposed on to the x-ray images usually used at implant, using computer technology that has been developed by KCL Imaging Sciences Department and Philips Medical Systems. This will allow the anatomy of the heart veins and scar tissue to be available for planning and performance of the pacemaker implant. Using special computer software, the researchers will also superimpose the site of latest mechanical activation of the left heart from the MR and echo data on to the x-ray screen. This information will help to choose the ideal site for pacemaker lead placement i.e. away from scar but in an area of late contraction.

Post implant
Patients will be seen 4-8 weeks after their implant for a pacing check. At 6 months post-implant, patients will answer a MLHF questionnaire and undergo a 12 lead ECG and an echo to assess their response to therapy.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
End systolic volume (ESV) in (ml) measured using a 2D echocardiogram at baseline and 6 months

Secondary outcome measures

1. End diastolic volume (ESV) in (ml) measured using a 2D echocardiogram at baseline and 6 months
2. Ejection fraction (%) measured using a 2D echocardiogram at baseline and 6 months
3. Quality of life measured using a Minnesota Living with Heart Failure Questionnaire score at baseline and 6 months
4. Efficacy of device implant measured using clinical composite score at 6 months
5. Class of heart failure measured using NYHA class at baseline and 6 months

Overall study start date
01/11/2018

Completion date
30/07/2022

Eligibility

Key inclusion criteria
1. >= 18 years of age
2. Standard indication for CRT-P or CRT-D according to ESC/EHRA guidelines
3. Stable on optimal medical therapy for at least 3 months
4. Ischaemic aetiology
5. Patients with atrial fibrillation can be included

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 218; UK Sample Size: 100

Key exclusion criteria
1. Any contraindication to pacing/implantable cardioverter-defibrillator (ICD) implant
2. Requirement for endocardial pacing
3. Contraindication to magnetic resonance (MR) scanning
4. Claustrophobia
5. Significant renal impairment with estimated glomerular filtration rate (eGFR) < 30 ml/minute
6. Existing pacemaker or ICD system or extraction of a CRT system within the last 6 months
7. Be pregnant or plan to become pregnant over the next 7 months
8. Participation in other studies

Date of first enrolment

05/07/2019

Date of final enrolment
05/07/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Trust Offices
Guy's Hospital
Great Maze Pond
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SE1 9RT

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/Home.aspx

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Sponsor type
University/education

Funder(s)

Funder type
Industry

Funder Name
Siemens Healthcare Limited

Results and Publications

Publication and dissemination plan
1. Additional documents unavailable but can be provided on request
2. Peer-reviewed scientific journals
3. Internal report
4. Conference presentation

Intention to publish date
30/07/2023

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

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