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The His optimised pacing evaluated for heart failure trial

Submission date	Recruitment status	[_] Prospectively registered
20/01/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
20/01/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/11/2023	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02671903

Secondary identifying numbers
20226

Study information

Scientific Title
AV optimisation delivered with direct His bundle pacing, in patients with heart failure, long PR without left bundle branch block: A randomised multi--centre clinical outcome study

Acronym
HOPE -- HF

Study objectives
The aim of this study is to investigate the effects of direct His bundle pacing in patients with heart failure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First Medical Research Ethics Committee, 15/10/2015, ref: 15/LO/1402

Study design
Multi-centre prospective randomised double-blinded cross over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

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
Heart failure

Interventions
All patients will be implanted with a pacemaker or implantable cardioverter defibrillator with one of the leads positioned on the His bundle in order to obtain direct His-bundle capture. If it is not possible to successfully implant a His-bundle lead with selective direct His bundle capture or non-selective capture with <40 ms prolongation of the QRS duration, then a lead will be implanted in a lateral branch of the coronary sinus as an alternative approach.

Patients will then be allocated in random order to 6-month treatment periods in each of the following two states
1. No pacing
2. AV-optimised direct His-bundle pacing

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Pacemaker or implantable cardioverter defibrillator (ICD) with one of the leads positioned on the His bundle

Primary outcome measure
Exercise capacity is determined by measuring peak oxygen uptake (VO2) at baseline, 6 and 12 months.

Secondary outcome measures
1. Changes in B-type Naturietic Peptide (BNP) are measured at baseline, 6 and 12 months
2. Changes in Quality of Life Scores are measured at baseline, 6 and 12 months
3. Cost effectiveness analysis is completed at baseline, 6 and 12 months
4. Echocardiographic measurement of left ventricular function and remodeling is measured at baseline, 6 and 12 months
5. Fluoroscopy time during device insertion is measured 2 months pre-randomisation and during device insertion
6. Percentage pacing, arrhythmia burden, pacing threshols, R wave amplitude and lead impedance are measured at baseline, 6 and 12 months

Overall study start date
22/12/2015

Completion date
31/10/2020

Eligibility

Key inclusion criteria
1. Aged 18 or above
2. Ventricular Ejection Fraction (EF) < 35%
3. New York Heart Association (NYHA) class II-IV
4. PR interval =200ms
5. Narrow QRS duration (=140ms) or prolonged QRS duration with typical Right Bundle Branch Block (RBBB) morphology on 12 lead ECG and sinus rhythm

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 160; UK Sample Size: 160; Description: A total of 160 patients will be recruited to allow for patient drop-out. 126 patients will be needed to detect the expected effect size on the primary endpoint with 90% power.

Total final enrolment
198

Key exclusion criteria
1. Permanent or persistent atrial fibrillation
2. Paroxysmal atrial fibrillation with history of sustained AF (more than 24 hours) in the 6 months prior to screening
3. Patients who are unable to perform cardiopulmonary exercise testing
4. Other serious medical condition with life expectancy of less than 1 year or if it is anticipated patients will require MRI scanning
5. Lack of capacity to consent
6. Pregnancy (female participants of reproductive age will be eligible for inclusion in the study, subject to a negative pregnancy test prior to randomisation)

Date of first enrolment
22/12/2015

Date of final enrolment
31/01/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hammersmith Hospital
Cardiovascular Medicine Unit
Du Cane Road
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Sponsor information

Organisation
Imperial College London

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

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

Intention to publish date
31/10/2021

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Basic results			17/11/2023	No	No
Results article		01/02/2023	17/11/2023	Yes	No
Statistical Analysis Plan	version 1.2 (pages 1-20)	15/09/2020	17/11/2023	No	No
Statistical Analysis Plan	version 1.2 (pages 21-40)	15/09/2020	17/11/2023	No	No