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Maximising clinical applicability of non-invasive methods for optimisation of cardiac pacemakers and effect of optimisation on cardiac efficiency

Submission date
29/04/2010

Recruitment status
No longer recruiting

Registration date
29/04/2010

Overall study status
Completed

Last Edited
11/05/2017

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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

Secondary identifying numbers
7354

Study information

Scientific Title
Maximising clinical applicability of non-invasive methods for optimisation of cardiac pacemakers and effect of optimisation on cardiac efficiency: a non-randomised interventional validation of investigational process trial

Acronym
DRN 453 (BivPace Optimisation)

Study objectives
Assessment of atrioventricular (AV) optimisation on acute systolic blood pressure changes and the effect of this on cardiac efficiency at higher heart rates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
St Mary's REC, 01/10/2008, ref: 08/H0712/65

Study design
Non-randomised interventional and observational treatment validation of investigational /therapeutic process trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Topic: Diabetes Research Network; Subtopic: Type 2; Disease: Cardiovascular disease

Interventions
Optimisation of CRT devices:
1. Patients with existing devices are invited to attend for non-invasive haemodynamic optimisation
2. Patients are temporarily paced biventricularly at high heart rate and optimised using invasive and non-invasive haemodynamic parameters

Study entry: registration only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Acute improvement in systolic blood pressure
2. Cardiac efficiency

Timepoints: End of first year and end of second year

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/01/2009

Completion date
01/04/2011

Eligibility

Key inclusion criteria
1. Chronic systolic heart failure and a biventricular device
2. In sinus rhythm (or atrially paced at rest)
3. Free of frequent ectopy
4. No aortic stenosis
5. Either sex, aged 40 - 90 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned sample size: 50; UK sample size: 50

Key exclusion criteria
1. Severe lung disease
2. Any condition that would preclude participants from lying comfortably on a couch for the duration of the study

3. No admissions, other than the admission related to the procedure for the invasive substudy in the prior month
4. No changes to medications (other than diuretic dose) in the prior month

Date of first enrolment
01/01/2009

Date of final enrolment
01/04/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Mary's Hospital
London
United Kingdom
NW1 5QH

Sponsor information

Organisation
Imperial College Healthcare NHS Trust (UK)

Sponsor details
International Centre for Circulatory Health
59 North Wharf Road
London
England
United Kingdom
W2 1LA

Sponsor type
Hospital/treatment centre

Website
http://www.imperial.nhs.uk/

ROR
https://ror.org/056ffv270

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (BHF) (UK)

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
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration