ISRCTN43384180 https://doi.org/10.1186/ISRCTN43384180

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

Contact name
Dr Andreas Kyriacou

Contact details
St Mary's Hospital
International Centre for Circulatory Health
London
United Kingdom
NW1 5QH

Additional identifiers

Protocol serial number
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

Study type(s)
Diagnostic

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(s)
1. Acute improvement in systolic blood pressure
2. Cardiac efficiency

Timepoints: End of first year and end of second year

Key secondary outcome(s))
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Imperial College Healthcare NHS Trust (UK)

ROR
https://ror.org/056ffv270

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (BHF) (UK)

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

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration