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Non-invasive haemodynamics to probe physiology and echocardiographic dyssynchrony in chronic heart failure

Submission date 29/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/04/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 11/08/2014	**Condition category** Circulatory System	[_] 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

Protocol serial number
7356

Study information

Scientific Title

Acronym
DRN 374 (V3E)

Study objectives
Patients with heart failure and pre-existing cardiac resynchronisation therapy (biventricular pacemakers) will be recruited from the pacemaker and heart failure clinics of our institution. Patients will be positioned on the couch. Continuous blood pressure monitoring will be undertaken on a beat by beat basis using the Finapres® device, and electrocardiogram (ECG) recordings will be made simultaneously. Data analysis will occur off line after measurements have been taken.

Hypothesis 1:
The patient will have the pacemaker settings altered while undergoing simultaneous measurements of 3D echo and blood pressure monitoring. These will be taken for 10 consecutive beats before and after the change in the pacemaker setting. The AV delay will be kept constant throughout. Analysis of data will occur offline once measurements are acquired. We will identify whether stroke volume measured in this way provides a reliable method for measuring the best interventricular delay when compared to non-invasive blood pressure.

Hypothesis 2:
We will identify the VV delays (pacemaker settings) giving the smallest amount of intraventricular dyssynchrony, hence allowing the most coordinated contraction by: 2.1. 2-segment TDI echo
2.2. On 12-segment 3D model

2-segment dyssynchrony measurements will be taken using pulse wave Doppler from the septum and lateral wall. 12-segment dyssynchrony measurements will be taken from the septal, lateral, anteroseptal, posterior, anterior and inferior regions at two different levels. The average of 5 measurements for each setting will be used. After offline analysis, the patient will return on a subsequent visit for haemodynamic comparison of the two echocardiographically optimal VV delays, by performing multiple transitions between the two optima while recording non-invasive blood pressure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved, ref: 08/H0708/5

Primary study design
Interventional

Study design
Non-randomised interventional process of care treatment trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Diabetes Research Network; Subtopic: Type 2; Disease: Cardiovascular disease

Interventions
Patients are recruited and pacemaker settings are changed. Echocardiographic measurements are taken multiple times at each setting and the optimal for each parameter identified.

Study entry: registration only

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The optimal pacemaker setting from echo techniques is compared against our gold standard (BP).

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/12/2011

Eligibility

Key inclusion criteria
1. Aged 18 years or above, either sex
2. Ejection fraction less than 40%
3. Biventricular pacemaker in situ

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Poor lead position
2. Pure diastolic dysfunction in the absence of systolic dysfunction
3. Decompensated heart failure

Date of first enrolment
01/12/2008

Date of final enrolment

01/12/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
59 North Wharf Road
London
United Kingdom
W2 1LA

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