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RESynchronisation in Patients with heart failure and a Normal QRS Duration (RESPOND)

Submission date	Recruitment status	[ ] Prospectively registered
08/06/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/03/2013	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
NCT00480051

Secondary identifying numbers
07/MRE00/57

Study information

Scientific Title
RESynchronisation in Patients with heart failure and a Normal QRS Duration (RESPOND): A randomised controlled trial

Acronym
RESPOND

Study objectives
Biventricular pacing in patients with heart failure and Quick Release System (QRS) less than 120 ms will improve patient exercise tolerance.

Please note that as of 19/02/10 the title and acronym of this study has been updated. The study was previously known as:
Title: Birmingham biventricular pacing in patients with heart failure unselected for dyssynchrony
Acronym: BIPIDS (BIventricular Pacing In patients unselected for DysSynchrony)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Scotland A Research Ethics Committee on the 15th June 2007 (ref: 3. 07/MRE00/57).

Study design
Randomised open label active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cardiac failure

Interventions
The patients will be randomised to the control and intervention groups (50% each). The patients in the intervention group will have the cardiac resynchronisation therapy (CRT) implant.

Please note that as of 19/02/10 data collection and enrollment for this trial has now ended.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Improvements in 6-minute walking distance (distance that the patient can walk at their own pace in 6 minutes) assessed at baseline, 6 weeks and 6 months. 20% increase in distance walked in 6 minutes, or any increase from 0 will be taken as a significant endpoint.

Secondary outcome measures
1. Symptomatic improvement in quality of life at baseline, 6 weeks after intervention and 6 monthly thereafter, assessed using the Minnesota Living with Heart Failure questionnaire
2. Change in N-terminal pro-beta natriuretic peptide (NT pro-BNP) and echocardiographic parameters of LV function at baseline, 6 weeks after intervention and 6 monthly thereafter. 15% decrease in end systolic volume will be taken as a significant endpoint
3. Assessing whether magnetic resonance imaging (MRI) Dyssynchrony Index (cardiovascular magnetic resonance tissue synchronisation imaging [CMR-TSI]) predicts responders (at baseline)
4. Packer outcome at 6 weeks after intervention and 6 monthly thereafter
5. Hospitalisation will be monitored at 6 weeks after intervention and 6 monthly thereafter
6. Mortality will be monitored at 6 weeks after intervention and 6 monthly thereafter

Overall study start date
01/07/2007

Completion date
01/07/2009

Eligibility

Key inclusion criteria
1. Sinus rhythm
2. Symptomatic heart failure - New York Heart Association (NYHA) class III or IV
3. Electrocardiogram (ECG) QRS duration less than 120 milliseconds
4. Left ventricular (LV) ejection fraction of less than 35% on echocardiography using Simpsons methodology
5. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Age below 18
2. Current or planned pregnancy
3. Patient refusal
4. Ventricular tachycardia or ventricular fibrillation
5. Current or recent (within last 30 days) involvement in other studies
6. Requires implantable cardioverter defibrillator (ICD)

Date of first enrolment
01/07/2007

Date of final enrolment
01/07/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cardiology
Sutton Coldfield
United Kingdom
B75 7RR

Sponsor information

Organisation
Heart of England Foundation NHS Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

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

Funder(s)

Funder type
Government

Funder Name
Good Hope Hospital NHS Trust (UK) - Cardiology Clinical Research Fund

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2011		Yes	No