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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
08/06/2007		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
12/09/2007	Completed	[X] Results		
Last Edited 04/03/2013	Condition category Circulatory System	[] Individual participant data		
UT/UJ/2U1J	Circulatory System			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Good Hope Hospital
Rectory Road
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England
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B75 7RR
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dawn.richardson@heartofengland.nhs.uk

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