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

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Francisco Leyva

**Contact details**
Cardiology
Good Hope Hospital
Heart of England Foundation NHS Trust
Rectory Road
Sutton Coldfield
United Kingdom
B75 7RR

## Additional identifiers

**ClinicalTrials.gov (NCT)**
NCT00480051

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)
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.

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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
United Kingdom

England

### Study participating centre
**Cardiology**
Sutton Coldfield
United Kingdom
B75 7RR

# Sponsor information

### Organisation
Heart of England Foundation NHS Trust (UK)

# Funder(s)

### Funder type
Government

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

# Results and Publications

### 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 |