

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

<b>Submission date</b> 08/06/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/03/2013	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**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 months 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 months 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 months thereafter
5. Hospitalisation will be monitored at 6 weeks after intervention and 6 months thereafter
6. Mortality will be monitored at 6 weeks after intervention and 6 months 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?
<a href="#">Results article</a>	results	01/07/2011		Yes	No