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# A randomised study on use of impedance cardiography for optimisation of cardiac resynchronisation therapy

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 17/08/2006 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 27/09/2006 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 29/06/2016 | 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**

**Secondary identifying numbers**
version 1

# Study information

### Scientific Title
A randomised study on use of impedance cardiography for optimisation of cardiac resynchronisation therapy

### Study objectives
We hypothesise that the clinical benefits of cardiac resynchronisation therapy can be optimised by using impedance cardiography both at the time of biventricular pacemaker implantation and during follow up.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Review scheduled for the next committee date of the North Birmingham Ethics Committee.

### Study design
Non-blinded randomised controlled 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
Heart failure

### Interventions
A total of 80 patients will be recruited to the study:
1. Arm A: impedence cardiography - 40 patients will be assessed using Impedence Cardiography (ICG) to optimise treatment.
2. Arm B: standard cardiography - 40 patients will be assessed using the usual optimisation methods.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
The primary objective is to assess whether the clinical benefits of cardiac resynchronisation therapy can be optimised using ICG both at the time of pacemaker implantation and during follow up. The primary endpoint is improvement in six minute walking distance.

### Secondary outcome measures
Quality of Life using the Minnesota Living with Heart Failure questionnaire.

### Overall study start date
30/09/2006

### Completion date
30/03/2008

## Eligibility

### Key inclusion criteria
80 patients who are referred to the cardiology clinic and meet the National Institute for Clinical Excellence (NICE) criteria for biventricular pacemaker implantation will be included in this study. The following inclusion criteria are:
1. Heart Failure
2. Moderate to severe function limitation New York Heart Association (NYHA) class III or IV, or NYHA class II heart failure plus a history of repeated admissions
3. Optimal tolerated treatment with diuretics, angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers, beta blockers, spironolactone and digoxin
4. QRS duration (representing the duration of ventricular depolarisation) more than or equal to 120 ms or evidence of mechanical Left Ventricular (LV) dyssynchrony
5. Left ventricular ejection fraction more than or equal to 40%

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Both

### Target number of participants
80 patients (40 to each arm)

### Key exclusion criteria
1. Contraindications to cardiac pacing
2. Presence of comorbidities likely to threaten survival within 12 months
3. Pulmonary oedema requiring intravenous diuretics in the previous week

### Date of first enrolment
30/09/2006

### Date of final enrolment

30/03/2008

# Locations

### Countries of recruitment
England

United Kingdom

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

# Sponsor information

### Organisation
Good Hope Hospital NHS Trust (UK)

### Sponsor details
Research Department
Trust HQ
Rectory Road
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### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/015hfw664

# Funder(s)

### Funder type
Government

### Funder Name
Application made to National Institute for Health Research Central Commissioning Facility (NIHR CCF) - Research for Patient Benefit (RfPB) programme (UK)

# 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 |