

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

Submission date 17/08/2006	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 27/09/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/06/2016	Condition category Circulatory System	☐ Individual participant data

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

Protocol serial number

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.

Primary study design

Interventional

Study design

Non-blinded randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Heart failure

Interventions

A total of 80 patients will be recruited to the study:

1. Arm A: impedance 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(s)

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.

Key secondary outcome(s)

Quality of Life using the Minnesota Living with Heart Failure questionnaire.

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

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**

United Kingdom

England

Study participating centre

Cardiology Department

Sutton Coldfield

United Kingdom

B75 7RR

Sponsor information

Organisation

Good Hope Hospital NHS Trust (UK)

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

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