ISRCTN75745362 https://doi.org/10.1186/ISRCTN75745362

Biventricular Pacing and Cardiac Physiology

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 29/09/2006	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 16/07/2012	**Condition category** Circulatory System	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof MP Frenneaux

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Cardiac Medicine
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0265160803

Study information

Scientific Title

Study objectives
1. Does biventricular pacing improve heart function on exercise?
2. What effect does a reduction of blood in the heart have on blood vessels in the forearm?
3. How does heart wall movement relate to heart contraction and the volume of blood within the heart chambers?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
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
Cardiovascular

Interventions
Plan of investigation
Morning study (8.30-11.00 a.m.) - Lower Body Negative Pressure (LBNP) studies.
Patient will be allocated to pacemaker ON or OFF (Investigators will be blinded to the pacemaker mode)

08.30
9.00 Injection of Stannous Agent - patient will then enter LBNP
9.20 Radio-labelling of red blood cells with technetium
9.30 Re-injection of red blood cells

Study begins
9.30 LBNP switched on at 0 mmHg and baseline echo
9.30 LBNP switched to 30 mmHg and repeat echo
9.40 LBNP switched to 40 mmHg and repeat echo
9.45 LBNP off and rest period
9.55 LBNP switched on at 0 mmHg and baseline LV volume and FVR
10.00 LBNP switched to 30 mmHg and LV volume and FVR
10.05 LBNP switched to 40 mmHg and LV volume and FVR

10.10 LNBP off and rest period
10.20 Patient will repeat the above study in the opposite (ON/OFF) mode

Lunch break (11.00am -12.00pm) - During this period the pacemaker will be returned to the ON mode.

Afternoon study (12.00 - 1.40 pm) - Exercise studies

Patients will be allocated to pacemaker ON or OFF (Investigators will be blinded to the Pacemake mode)

Subject will sit on a recline cycle ergometer - Study Begins

12.00 Baseline cardiac radionuclide scan (CRS) and Cardiac output (CO)
12.05 Exercise at 30% of pre-determined maximal exercise capacity with CRS + CO
12.10 Exercise at 50% of pre-determined maximal exercise capacity with CRS + CO
12.15 Exercise at 70% of pre-determined maximal exercise capacity with CRS + CO
12.20 Rest period
13.20 Patient will repeat the above study in the opposite (ON/OFF) mode
13.40 Study completed

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
13/07/2005

Completion date
13/07/2008

Eligibility

Key inclusion criteria
Patients will be identified from Professor Frenneauxs Heart Failure clinic who have already had a biventricular pacemaker implanted for clinical reasons. These patients will be approached by Professor Frenneaux or a member of his Research team and informed of the study. If the patients are interested in taking part they will be sent a copy of the patient information sheet and a reply letter. If they agree to take part they will be contacted and recruited into the study.

Inclusion criteria:
1. NYHA Class I-III heart failure
2. Implanted with a biventricular pacemaker in the preceding 12 months
3. Physically capable of performing a cycle exercise test

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
1. NYHA Class IV heart failure
2. Terminal illness
3. Women of child-bearing potential
4. Women currently breast-feeding
5. Significant arthritis limiting ability to perform a cycle exercise test

Date of first enrolment
13/07/2005

Date of final enrolment
13/07/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cardiac Medicine
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (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