

Biventricular Pacing and Cardiac Physiology

Submission date 29/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/07/2012	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact details
Cardiac Medicine
Queen Elizabeth Hospital
Birmingham
United Kingdom
B15 2TH

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 Pacemaker 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 Frenneaux's 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