

# Biventricular Pacing and Cardiac Physiology

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

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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 LBNP 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(s)**

Not provided at time of registration

### **Key secondary outcome(s)**

Not provided at time of registration

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

## **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**

United Kingdom

England

### **Study participating centre**

#### **Cardiac Medicine**

Birmingham

United Kingdom

B15 2TH

## **Sponsor information**

### **Organisation**

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

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

University Hospital Birmingham NHS Trust (UK)

## **Results and Publications**

## **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration