

# Enhanced External Counterpulsation (EECP) in Patients with Ischaemic Heart Disease and Chronic Left Ventricular Systolic Dysfunction Evaluation

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/04/2012	<b>Condition category</b> 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**  
Dr Poay Huan Loh

**Contact details**  
Academic Cardiology Department  
University of Hull  
3rd Floor Houghton Building  
Hull Royal Infirmary  
Hull  
United Kingdom  
HU3 2JZ  
+44 (0)1482 675009  
huan.loh@hey.nhs.uk

## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N0084151408

## Study information

**Scientific Title**

### Study objectives

1. Whether enhanced external counterpulsation (EECP) results in improvement of heart muscle pumping function in ischaemic heart disease and heart failure patients.
2. The degree of improvement in the heart pumping function is related to the extent of impaired but viable heart muscle.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Added 27 August 2008: approved by South Humber LREC in 2004, ref 04/Q1105/7.

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Not Specified

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Cardiovascular: Heart failure

### Interventions

This is a randomised controlled trial comparing a course (35 sessions over 4 to 7 weeks) of standard (one hour) versus brief (5 minutes) sessions of EECP in patients with ischaemic heart disease and left ventricular systolic dysfunction to determine whether there is a difference between these interventions. Data from EECP suggests that 5-minute sessions are, in effect, a placebo. The intended follow-up period is 6 months after completion of EECP treatment course.

At baseline, patients will be investigated by physical examination, Minnesota Living with Heart Failure Questionnaires, echocardiogram (Echo), metabolic treadmill exercise test, blood tests, forearm flow-mediated dilatation (an ultrasound test of vascular function), and gadolinium-enhanced rest-stress cardiac cine-magnetic resonance imaging (CMR). The blood tests include N-terminal brain natriuretic peptide (or NT-BNP which is a marker for the presence of impaired heart muscle), troponin-T (marker for recent heart muscle injury or death), angiogenic factors (growth factors that stimulate the formation and growth of new blood vessels including vascular endothelial growth factor [VEGF], basic fibroblast growth factor [bFGF] and hepatocyte growth factor [HGF]), cytokines (protein molecules that involve in inflammation including highly specific C-reactive protein [hs-CRP], interleukin-1 beta [IL-1b], interleukin-6 [IL-6] and tumour necrosis factor alpha [TNF-a]) and creatinine (a marker for kidney function). A 24-hour urine collection will be done for urinary electrolytes and creatinine clearance (an estimation of kidney function).

Patients will then be randomised to the above interventions (ratio 1:1). Baseline investigations will be repeated 2 weeks and again 6 months after completion of the EECP course. All tests will be repeated at 3 months after treatment except CMR.

These data will provide the prevalence of a various substrates of heart muscle impairment in this patient population, their natural history over 6 months and their response to EECP treatment. The principal analyses will be a comparison between the randomised groups at baseline and during post-EECP follow-up.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

1. Improvement in left ventricular function and coronary perfusion reserve based on assessment by gadolinium-enhanced rest/stress (adenosine) cine CMR.
2. To confirm the hypothesis that the degree of improvement in left ventricular function is affected by the extent of viable myocardium.

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

31/08/2004

### **Completion date**

31/12/2008

### **Reason abandoned (if study stopped)**

"Participant recruitment issue"

## **Eligibility**

### **Key inclusion criteria**

Blood and urinary samples will be collected for the purpose of this study. Blood samples will be collected by a medical doctor or specialist nurse according to standard venesection method. 6mls of the blood will be analysed immediately by the local laboratory for NT-BNP, Troponin-T and hs-CRP. The other 8mls will be centrifuged and the plasma will be stored below -20 degree celcius. These will later be analysed using commercially available kits (R & D System, Abingdon, UK) for VEGF, bFGF, HGF, IL-1beta, IL-6 and TNF-a. This will be carried out by experience doctor with support from laboratory technician within the department. 24-hour urinary collection will be analysed in the local laboratory.

**Inclusion criteria:**

1. Over 18 years old
2. Male or female
3. Presence of LVSD with ejection fraction less than 40%
4. Known IHD stable on treatment 3 months prior to randomisation

**Participant type(s)**

Patient

**Age group**

Not Specified

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Total number of patients is 60 (randomised 1:1)

**Key exclusion criteria**

1. Patients who have had an ischaemic event within the last 3 months
2. Contraindication to EECp

**Date of first enrolment**

31/08/2004

**Date of final enrolment**

31/12/2008

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Academic Cardiology Department**  
Hull  
United Kingdom  
HU3 2JZ

## **Sponsor information**

### **Organisation**

Department of Health

### **Sponsor details**

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**

The North and South Bank Research and Development Consortium (UK), NHS R&D Support Funding

## **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