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

Submission date
30/09/2005

Recruitment status
Stopped

Registration date
30/09/2005

Overall study status
Stopped

Last Edited
05/04/2012

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 determined 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 specify 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

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Sponsor information

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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