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To determine the kidney function in patients before and after enhanced external counterpulsation treatment

Submission date	Recruitment status	[_] Prospectively registered
25/10/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/11/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/07/2014	Circulatory System	

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
N/A

Study information

Scientific Title
To determine the kidney function by using serum cystatin C in patients before and after enhanced external counterpulsation treatment

Study objectives
Enhanced external counterpulsation (EECP) is based on the principle of diastolic augmentation to increase coronary flow while simultaneously decreasing systolic afterload. We proposed that EECP treatment could improve cardiac function, therefore might improve kidney function. The aim of the trial is to see whether EECP treatment can slow the progression of kidney disease in patients with ischemic heart disease and congestive heart failure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of Piyavate Hospital, approved on 25/10/2006 (ref: 006/2006)

Study design
Single-centre observational study

Primary study design
Observational

Secondary study design
Single-centre

Study setting(s)
Hospital

Study type(s)
Treatment

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
Ischaemic heart disease, chronic stable angina, chronic stable heart failure

Interventions
All patients will receive EECP typically involving 35 x 1-h sessions of counterpulsations over a 7-week period.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Serum cystatin C

All primary and secondary outcome measures will be assessed before and within 1 month, and 5-7 months after completion of EECP treatment of 35 sessions.

Secondary outcome measures
1. Calculated glomerular filtration rate (GFR)
2. Serum N-Terminal pro-B-type Natriuretic Peptide (NT-proBNP)
3. Ejection fraction determined by echocardiography

All primary and secondary outcome measures will be assessed before and within 1 month, and 5-7 months after completion of EECP treatment of 35 sessions.

Overall study start date
01/11/2006

Completion date
30/11/2009

Eligibility

Key inclusion criteria
1. Both males and females, age >18 years
2. Patients with refractory angina, chronic stable angina or chronic stable heart failure
3. Willing to participate in the study with informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
26

Key exclusion criteria
1. Patient with the diagnosis of congestive heart failure within 1 month prior to study entry
2. Patient with the diagnosis of acute coronary syndrome within 1 month prior to study entry

3. Patient with uncontrolled blood pressure (>180/110 mmHg)
4. Patient with cardiac arrhythmia (e.g. atrial fibrillation or atrial flutter or frequent premature ventricular contractions) that may interfere with triggering of EECP system
5. Patients with severe lower extremity vaso-occlusive disease
6. Patients with end stage renal disease requiring renal replacement therapy

Date of first enrolment
01/11/2006

Date of final enrolment
30/11/2009

Locations

Countries of recruitment
Thailand

Study participating centre
Assistant Professor, Division of Nephrology
Bangkok
Thailand
10240

Sponsor information

Organisation
Piyavate Hospital (Thailand)

Sponsor details
c/o Dr Prajej Ruangkanchanasetr
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Sponsor type
Hospital/treatment centre

Website
http://www.piyavate.com/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
This is an investigator-initiated study, carried out in collaboration with the following hospitals:

Funder Name
Piyavate Hospital (Thailand)

Funder Name
Ramathibodi Hospital (Thailand)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/09/2013		Yes	No