

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

Submission date 25/10/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 17/11/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 23/07/2014	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

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