

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

Dr Prajej Ruangkanchanasetr

Contact details

Assistant Professor, Division of Nephrology
Department of Medicine
Phramongkutklao Hospital (Royal Thai Army Hospital)
315 Rajavithi Road
Rajathevi
Bangkok
Thailand
10240
+66 (0)2 644 4676
prajej@gmail.com

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 EECF 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 EECF 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 EECF 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 Ruangchanasetr

998 Rimklongsamsen Rd (Rama 9 Rd)

Bangkapi, Huaykwang

Bangkok

Thailand

10310

+66 (0)81 311 7815

prajej@gmail.com

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