

# Elucidating the mechanistic pathways of ischaemic preconditioning and postconditioning in the clinical setting

<b>Submission date</b> 18/06/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/03/2014	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
4058

## Study information

**Scientific Title**

A multicentre randomised interventional treatment trial to explore the mechanistic pathway of ischaemic preconditioning and postconditioning in the clinical settings of myocardial ischaemia-reperfusion injury

**Acronym**

ACE - CABG/PPCI

**Study objectives**

The aim of the study is use pharmacological agents that have been shown to activate survival kinases and inhibit mPTP opening to explore the mechanistic pathway of ischaemic preconditioning and postconditioning in the clinical settings of myocardial ischaemia-reperfusion injury. Patients who are due to undergo planned cardiac surgery will be recruited to receive an interventional agent. These patients will be randomised and compared against a group of controls. Blood tests would be taken post-operatively to assess the primary end points.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The Joint UCL/UCLH Committees on the Ethics of Human Research Committee (Alpha) approved on the 23/11/2006 (ref: 06/Q0502/83)

**Study design**

Multicentre randomised interventional treatment trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

**Interventions**

1. Intervention 1: Cyclosporin A at dose of 2.5 mg/kg; diluted in 100 ml of normal saline. Once only dose given over 30 minutes prior to surgery.
2. Intervention 2: Atorvastatin at a dose of 160 mg; given on the morning of surgery and a second dose of 160 mg repeated 24 hours later
3. Intervention 3: Erythropoietin at a dose of 50,000 IU; given as an infusion of 50 ml over 30 minutes prior to revascularisation. A second dose is repeated 24 hours later.

**Intervention Type**

Other

**Phase**

Phase III

**Primary outcome(s)**

Serum cTnT and CK-MB (bloods taken before intervention and at 6, 12, 24, 48 and 72 hours post-intervention).

### **Key secondary outcome(s)**

1. Inotropic score: calculated using the maximum inotropic dose used on day 1 post-op
2. Ventilation time: assessed from the time of admission into ITU to the time of extubation
3. ITU stay: assessed from the time of admission into ITU to the time of discharge from the unit

### **Completion date**

30/06/2010

## **Eligibility**

### **Key inclusion criteria**

Patients experiencing an event or procedure which will bring about myocardial injury:

1. Coronary artery bypass surgery +/- valve surgery
2. Primary angioplasty for ST elevation myocardial infarction
3. Thrombolysis for ST elevation myocardial infarction
4. Non-ST elevation myocardial infarction
5. High risk and undergoing percutaneous coronary intervention
6. Aged 18 - 85 years, either sex

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Significant co-morbidity
2. Known intolerance to trialled intervention
3. Renal/liver failure
4. In patients undergoing an elective procedure-chest pain within the last 3 days, lack of consent

### **Date of first enrolment**

01/06/2007

### **Date of final enrolment**

30/06/2010

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

**The Hatter Institute for Cardiovascular Studies**

London

United Kingdom

WC1E 6DB

# Sponsor information

## Organisation

University College London (UCL) (UK)

## ROR

<https://ror.org/02jx3x895>

# Funder(s)

## Funder type

Charity

## Funder Name

British Heart Foundation (BHF) (UK)

## Alternative Name(s)

The British Heart Foundation, the\_bhf, BHF

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

## Location

United Kingdom

# 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?
<a href="#">Results article</a>	results	01/04/2014		Yes	No