

# 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## Secondary study design

Randomised controlled trial

## 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

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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/06/2007

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned sample size: 400

**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**

England

United Kingdom

**Study participating centre**

The Hatter Institute for Cardiovascular Studies

London

United Kingdom

WC1E 6DB

**Sponsor information****Organisation**

University College London (UCL) (UK)

**Sponsor details**

UCL Biomedicine Research & Development Unit

Maple House

149 Tottenham Court Road

London

England

United Kingdom

W1T 7NF

**Sponsor type**

University/education

**Website**

<http://www.ucl.ac.uk/>

**ROR**

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

## Funder(s)

**Funder type**

Charity

**Funder Name**

British Heart Foundation (BHF) (UK)

**Alternative Name(s)**

the\_bhf, The British Heart Foundation, BHF

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

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