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

Submission date 18/06/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/06/2010	**Overall study status** Completed	
Last Edited 07/03/2014	**Condition category** 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
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 recuited 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?
Results article	results	01/04/2014		Yes	No