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Myocardial preconditioning in coronary artery bypass surgery

Submission date	Recruitment status	[ ] Prospectively registered
28/05/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/05/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/04/2017	Circulatory System	[ ] Record updated in last year

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
5201

Study information

Scientific Title
A clinical study investigating myocardial preconditioning in Type II diabetic patients in the setting of coronary artery bypass surgery

Study objectives
Aims and objectives:
1. Does remote ischaemic preconditioning (RIPC) using brief upper-limb ischaemia reduce myocardial injury in diabetic patients undergoing coronary artery bypass grafting (CABG) surgery? Previous animal studies suggest that the diabetic heart may be resistant to cardioprotection elicited by preconditioning.
2. How many cycles of brief upper-limb ischaemia and reperfusion are required to reduce myocardial injury in patients undergoing elective CABG surgery? We currently use three cycles of 5 minutes upper-limb ischaemia to elicit RIPC, but it is unknown whether one or two cycles would be sufficient to reduce myocardial injury in patients undergoing elective CABG surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Joint UCL/UCLH Committees on Ethics of Human Research (Committee Alpha), 05/07/2001, ref: 01/0128

Study design
Single-centre randomised interventional prevention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
The stimulus for RIPC that will be used will be inflation of a blood pressure cuff placed around the upper arm. The cuff will be inflated to 200 mmHg for 5 minutes after which it will be deflated for 5 minutes. This procedure will be repeated upto three times in total based on

randomisation protocol. In the control arm, an uninflated blood pressure cuff will be placed on the patients's upper arm for the duration of 30 minutes.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Myocardial injury, assessed by Troponin T and creatine kinase myocardial band (CK-MB) levels over the 72 hours post-CABG surgery.

Secondary outcome measures
1. Ionotropic score, measured at first week post-operative period
2. Ventilation times, measured at the timepoint when patients are weaned from ventilator in the ITU (first 2 days post-operative period)
3. Intensive care unit (ITU) stay, measured at first week post-operative period

Overall study start date
20/02/2006

Completion date
01/06/2011

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Patients undergoing coronary bypass surgery with or without concomitant heart valve surgeries
3. Male and female patients

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 500

Key exclusion criteria

1. Aged under 18 years
2. Patients with severe renal impairment (estimated glomerular filtration rate less than 45 ml /min/1.73m2)
3. Patients with severe hepatic impairment
4. Patients with cardiac arrest in the previous 6 weeks

Date of first enrolment
20/02/2006

Date of final enrolment
01/06/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hatter Cardiovascular Institute
London
United Kingdom
WC1E 6HE

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