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Remote ischaemic postconditioning in the clinical setting

Submission date 18/06/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 18/06/2010	**Overall study status** Completed	
Last Edited 11/04/2017	**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
5199

Study information

Scientific Title
A study investigating the cardioprotective benefits of remote ischaemic postconditioning in different clinical settings of myocardial ischaemia-reperfusion injury

Study objectives
The study proposes to examine the cardioprotective potential of 'remote ischaemic postconditioning' in the clinical setting of percutaneous coronary angioplasty using transient fore-arm ischaemia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Joint UCL/UCLH Committees on Ethics of Human Research (Committee Alpha), 15/09/2005, ref: 05/Q502/102

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Cardiovascular, Neurological; Subtopic: Cardiovascular (all Subtopics), Neurological (all Subtopics); Disease: Cardiovascular, Nervous system disorders

Interventions
Control arm:
Uninflated blood pressure cuff will be placed on the patients's upper arm for the duration of 30 minutes.

Intervention arm:
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 up to three times in total based on randomisation protocol.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Myocardial injury, measured by cTnT and CK-MB release over 24 hours after PCI.

Secondary outcome measures
1. All-cause mortality, recurrence of symptoms, heart failure and hospitalisation at 1 year after primary percutaneous coronary intervention (PCI)
2. Major adverse cardiovascular events (MACE) at 1 year
3. Myocardial infarct size, 3 months after primary PCI as measured by cardiac magnetic resonance imaging (MRI)
4. Myocardial infarct size and myocardial salvage ratio (infarct size/area at risk) as measured by cardiac MRI

Overall study start date
01/06/2008

Completion date
06/11/2011

Eligibility

Key inclusion criteria
1. Patients undergoing percutanous coronary interventions in the elective and emergecy setting and patients undergoing thrombolysis for acute myocardial infarction
2. Aged greater than 18 years and less than 85 years
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 less than 18 years and greater than 85 years
2. Patients with severe renal impairment (estimated glomerular filtration rate [EGFR] 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
01/06/2008

Date of final enrolment
06/11/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
London
United Kingdom
WC1E 6BT

Sponsor information

Organisation
University College London (UCL) (UK)

Sponsor details
UCL Biomedicine Research & Development Unit
Maple House
149 Tottenham Court Road
London
England
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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