

Remote ischaemic postconditioning in the clinical setting

Submission date 18/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/04/2017	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
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 percutaneous coronary interventions in the elective and emergency 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

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