Remote ischaemic postconditioning in the clinical setting

Submission date 18/06/2010	Recruitment status No longer recruiting	Prospectively registered
		Protocol
Registration date 18/06/2010	Overall study status Completed	Statistical analysis plan
		Results
Last Edited	Condition category	Individual participant data
	Circulatory System	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre University College London

London United Kingdom WC1E 6BT

Sponsor information

Organisation

University College London (UCL) (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

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?

Participant information sheet 11/11/2025 No Yes