

# Myocardial preconditioning in coronary artery bypass surgery

|  |   |  |
|--|---|--|
| <b>Submission date</b><br>28/05/2010   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered    |
|  |   | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>28/05/2010 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>06/04/2017       | <b>Condition category</b><br>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

**Contact name**  
Dr Vinod Venugopal

**Contact details**  
Hatter Cardiovascular Institute  
13-15 Gower Street  
London  
United Kingdom  
WC1E 6HE  
-  
v.venugopal@ucl.ac.uk

## Additional identifiers

**Protocol serial number**  
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

## **Study type(s)**

Prevention

## **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(s)**

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

## **Key secondary outcome(s)**

1. Inotropic 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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Aged under 18 years
2. Patients with severe renal impairment (estimated glomerular filtration rate less than 45 ml/min/1.73m<sup>2</sup>)
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**

United Kingdom

England

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

## 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 British Heart Foundation, the\_bhf, 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