

Cellular stress and inflammation with miniature cardiopulmonary bypass

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| Submission date 12/05/2010 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 12/05/2010 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 11/08/2014 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data |

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
7937

Study information

Scientific Title

Does mini-cardiopulmonary bypass (CPB) reduce cellular stress and inflammation compared with standard CPB?

Study objectives

Ischaemia-reperfusion, mechanical trauma and other stimuli associated with cardiopulmonary bypass (CPB) can lead to the generation of intracellular reactive oxygen species (ROS). ROS can enhance inflammatory activation via activation of NF- κ B, p38 MAP kinase and other pathways. Given that CPB leads to ischaemia and mechanical stimulation of leucocytes, it is likely to induce ROS in leukocytes and other cell types.

Hypotheses:

1. CPB leads to rapid induction of ROS in leukocytes which is associated with early activation of pro-inflammatory signalling (e.g. p38 activation) and with delayed activation of anti-inflammatory/anti-oxidant mechanisms
2. Mini-CPB is associated with reduced ROS/pro-inflammatory activation in leucocytes and attenuated systemic inflammation compared to conventional CPB

Ethics approval required

Old ethics approval format

Ethics approval(s)

Brompton, Harefield and NHLI Research Ethics Committee, 24/07/2008, ref: 08/H0708/67. Amendment approved on 29/04/2010, ref: AM02.

Study design

Single-centre randomised interventional diagnosis, prevention, process of care and treatment

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions

All patients referred for primary elective coronary artery bypass grafting (CABG) will be considered for inclusion within the clinical trial. Trial participants will be randomised into one of three different treatment groups:

1. Positive control group in whom standard CPB is used
2. Negative control group in whom CPB is not used at all ('off pump' group)
3. Investigative group in which the mini-CPB technique is used ('miniCPB' group)

Participants will be reviewed up until they are discharged from hospital. Intervention timings are as follows:

Blood tests:

1. Pre-op (baseline)
2. Post induction
3. Start of CPB
4. 15 minutes CPB
5. 30 minutes CPB
6. 45 minutes CPB
7. 60 minutes CPB
8. 2 hours CPB
9. 6 hours CPB
10. 24 hours CPB

Cantharadin blister tests:

1. Pre-op (baseline)
2. CPB 5 hours

Myocardial tissue sampling:

1. Start of CPB
2. Before end of CPB

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Blood parameters of cellular stress - reactive oxygen species detection; p38 MAP kinase signalling

Secondary outcome measures

Supporting conventional markers of the inflammatory response will be measured including white cell count

Overall study start date

01/06/2010

Completion date

01/06/2011

Eligibility

Key inclusion criteria

1. Age range 18+ years
2. No gender discrimination
3. Patients referred for elective coronary artery bypass grafting (CABG)
4. Not participated in any other clinical trial

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned sample size: 48

Key exclusion criteria

1. Patients less than 18 years of age
2. Emergency cases
3. Combined valvular procedures
4. Redo operations
5. Poor left ventricular function (ejection fraction less than 30%)
6. Cerebro-vascular accident within 3 months pre-operatively or more than 75% carotid artery obstruction as shown by carotid Doppler scan
7. Serum creatinine in excess of 177 $\mu\text{mol/L}$
8. Pre-existing coagulopathy
9. Pre-existing liver dysfunction
10. Recent (within 5 days) use of antiplatelets (aspirin/clopidogrel)

Date of first enrolment

01/06/2010

Date of final enrolment

01/06/2011

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Department of Cardiothoracic Sciences
London
United Kingdom
W12 0NN

Sponsor information

Organisation

Imperial College NHS Healthcare Trust (UK)

Sponsor details

Hammersmith Hospital
Research & Development Office
1st Floor, Ham House
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United Kingdom
W12 0HS
becky.ward@imperial.ac.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.imperial.nhs.uk/research>

ROR

<https://ror.org/056ffv270>

Funder(s)

Funder type

Research organisation

Funder Name

Heart Research UK (UK)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

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

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|------------------|--------------|------------|----------------|-----------------|
| Results article | substudy results | 01/10/2014 | | Yes | No |