ISRCTN30610605 https://doi.org/10.1186/ISRCTN30610605

Cellular stress and inflammation with miniature cardiopulmonary bypass

Submission date	Recruitment status	[X] Prospectively registered
12/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/08/2014	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Bao Nguyen

Contact details
Department of Cardiothoracic Sciences
National Heart and Lung Institute
Hammersmith Hospital
Du Cane Road
London
United Kingdom
W12 0NN

Additional identifiers

Protocol serial number
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-kB, 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

Study type(s)
Treatment

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

Key secondary outcome(s))
Supporting conventional markers of the inflammatory response will be measured including white cell count

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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 µmol/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
United Kingdom

England

Study participating centre
Department of Cardiothoracic Sciences
London
United Kingdom
W12 0NN

Sponsor information

Organisation
Imperial College NHS Healthcare Trust (UK)

ROR
https://ror.org/056ffv270

Funder(s)

Funder type
Research organisation

Funder Name
Heart Research UK (UK)

Alternative Name(s)
HRUK

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

Study outputs

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