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A comparison of intermittent aortic cross clamping and intermittent aortic warm blood cardioplegia for myocardial protection during coronary artery bypass surgery

Submission date
30/09/2005

Recruitment status
No longer recruiting

Registration date
30/09/2005

Overall study status
Completed

Last Edited
13/03/2014

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Protocol serial number
N0265006856

Study information

Scientific Title

Study objectives
Is the newer technique of intra-aortic warm blood cardioplegia superior to the established technique of intermittent aortic cross-clamping for myocardial protection during coronary surgery?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Surgery: Coronary artery bypass grafting (CABG)

Interventions
40 patients undergoing elective CABG will randomly be allocated into two groups of 20 patients each, to receive either intermittent cross clamp with fibrillation (XCF) or intermittent warm blood cardioplegia (WBC). Blood will be taken from in-situ intra-arterial or intravenous cannulae, at the following 12 time points: Following induction of anaesthesia; Following institution of cardiopulmonary bypass, but prior to the application of an aortic cross clamp with resultant myocardial ischaemia; 30,60,90,120 minutes and 4,6,8,12,24,28 hours following final release of the aortic cross clamp. The blood will be centrifuged for serum, which will be stored frozen at -70 C until batch analysis. The analysis will be performed blind.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/01/2007

Eligibility

Key inclusion criteria
Patients undergoing elective CABG

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2004

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cardiac Services
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

Funder Name
Research Funds

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration