ISRCTN43177829 https://doi.org/10.1186/ISRCTN43177829

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	[_] Prospectively registered [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 13/03/2014	**Condition category** Surgery	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2004

Completion date
01/01/2007

Eligibility

Key inclusion criteria
Patients undergoing elective CABG

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
40

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
England

United Kingdom

Study participating centre

Cardiac Services
Birmingham
United Kingdom
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

Funder Name
Research Funds

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