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Protection against acute renal failure following cardiac surgery

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 29/08/2012	**Condition category** Surgery	

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
N0265006268

Study information

Scientific Title

Study objectives
Derangements of renal haemodynamics occur during Cardio-Pulmonary Bypass (CPB), but the degree of derangement can be ameliorated by appropriate pharmacological intervention.

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)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Acute renal failure during cardiopulmonary bypass surgery.

Interventions
1100 patients undergoing cardiac surgery with the use of CPB will be allocated randomly to one of four groups. The administration of the allocated intervention will be as follows:

1. Group 1: dopamine 3 mg/kg/min intravenous infusion from induction for 24 hours
2. Group 2: frusemide 2 mg/h intravenous infusion from induction for 24 hours
3. Group 3: mannitol 0.5 g/kg in the CPB circuit
4. Group 4: control - no intervention

Anaesthetic, cardiopulmonary bypass and postoperative regimes will be standardised to current departmental protocols. Serum creatinine will be measured pre- and post-operatively at two and five days. A 5 ml urine sample will be taken from the patient's catheter bag at induction of anaesthesia and immediately at the end of the operation. This will be aliquoted into two polypropylene tubes and frozen to -20°C prior to analysis. Strict records will be kept of additional dopamine, frusemide and other diuretic requirement during the study period.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Dopamine, frusemide and mannitol

Primary outcome measure
1. Oliguria, defined as a urine output of less than 0.5 ml/kg/h for two consecutive hours, or less than 400 ml urine over any 24 hour period postoperatively. In addition, the need for frusemide or dopamine to maintain adequate urine output
2. Creatinine change, an increase of 50% from the baseline creatinine (i.e. a 33% reduction in Glomerular Filtration Rate [GFR])
3. Glomerular permeability (monitored by urinary albumin excretion)
4. Renal replacement therapy
5. Death

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2006

Completion date
01/01/2009

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
1100

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2006

Date of final enrolment
01/01/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cardiac Services
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

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