

Protection against acute renal failure following cardiac surgery

Submission date 12/09/2003	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 29/08/2012	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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/01/2009

Eligibility

Key inclusion criteria

Not provided at time of registration

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

01/01/2006

Date of final enrolment

01/01/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Cardiac Services

Birmingham

United Kingdom

B15 2TH

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

University Hospital Birmingham NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration