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Clinical relevance of cardiotomy blood salvage during cardiopulmonary bypass

Submission date	Recruitment status	[_] Prospectively registered
26/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/03/2009	Circulatory System	

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
MCT-44149; MCT-70885

Study information

Scientific Title
Clinical relevance of cardiotomy blood salvage during cardiopulmonary bypass: a randomised controlled trial

Study objectives
Blood collected in the pericardial wall during cardiopulmonary bypass (cardiotomy blood) is a contributor to diffuse neurologic injury after cardiac surgery. This effect may be ameliorated by the processing of the blood such that only the red cell component is returned, however this step may compound bleeding after heart surgery due to loss of coagulation factors.

Objective:
To evaluate the effects of cardiotomy blood centrifugation & filtration on:
1. Intra- and post-operative blood loss and homologous transfusion requirements
2. Neuropsychologic deficits following CPB
3. Early pulmonary function & gas exchange after CPB

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Ottawa Heart Institute Human Research Ethics Board-HREB approved on the 1st June 2001

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
Coronary Artery Disease - Cardiopulmonary bypass

Interventions
The control group receives the current practice of cardiotomy blood re-infusion during the operation. The experimental group is re-infused with centrifugally washed blood, which is passed through an additional lipid/leukocyte filter.

Trial details received: 12 Sept 2005

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The proportion of patients requiring one or more red cell transfusions during hospital stay
2. Incidence of cognitive deficits at 5 - 7 days

Secondary outcome measures
1. Blood loss (protamine administration to chest closure and first 24 hours)

Within 3 - 5 days after surgery:
2. Total non-red cell transfusion requirements (blood factors, platelets)
3. Pulmonary function after CPB (pulmonary vascular resistance, A-a gradient, pO2 after CPB, shunt, dynamic pulmonary compliance, oxygen delivery index, oxygen extraction rate)
4. Incidence of emboli during CPB by trans-cranial Doppler (TCD)
5. Quality of life at 3 months
6. Cognitive deficits at 3 months

Overall study start date
01/10/2001

Completion date
31/03/2006

Eligibility

Key inclusion criteria
1. Adult patients scheduled for coronary artery bypass grafting requiring CPB
2. Aged greater than or equal to 18 years old, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
274

Key exclusion criteria
1. Emergency surgery
2. Patients unable to undergo cognitive testing (visual or motor problems, unable to speak English or French)
3. Undergoing reoperative surgery
4. Patients undergoing non-CABG procedures or other cardiac procedures in addition to CABG
5. Patients with preoperative coagulopathy, bleeding diathesis or thrombocytopenia (less than 140,000 /µl)
6. Patients with renal insufficiency (creatinine 2 x normal) or hepatic insufficiency (elevated liver function tests, elevated baseline international normalised ratio [INR])
7. Mini-Mental State Examination (MMSE) less than 24/30 at pre-operative visit

Date of first enrolment
01/10/2001

Date of final enrolment
31/03/2006

Locations

Countries of recruitment
Canada

Study participating centre
Room H3403
Ottawa
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Sponsor information

Organisation
University of Ottawa Heart Institute (Canada)

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Sponsor type
University/education

Website
http://www.ottawaheart.ca/UOHI/Welcome.do

ROR
https://ror.org/03c4mmv16

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-44149 and MCT-70885)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/09/2007		Yes	No
Results article	results	01/10/2008		Yes	No