

Clinical relevance of cardiotomy blood salvage during cardiopulmonary bypass

Submission date 26/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/03/2009	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

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
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 / μ l)
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

Canada

K1Y 4W7

Sponsor information

Organisation

University of Ottawa Heart Institute (Canada)

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

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