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Blood conservation using antifibrinolytics in cardiac surgery

Submission date	Recruitment status	[_] Prospectively registered
01/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/01/2010	Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ohri.ca

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT-52683

Study information

Scientific Title
Blood conservation using Antifibrinolytics: a Randomised Trial in a cardiac surgery population

Acronym
BART

Study objectives
We hypothesise that aprotinin will result in a 3% absolute risk reduction in massive postoperative bleeding in the initial 24 hours following surgery (6% to 3%) as compared to epsilon-aminocaproic acid or tranexamic acid in patients undergoing high-risk cardiac surgical procedures. We also hypothesise that aprotinin will result in a 10% absolute risk reduction in allogeneic exposure to any blood product (50% to 40%) as compared to the other two antifibrinolytic agents in the 30 days following surgery. Finally, we hypothesise that aprotinin will decrease life-threatening postoperative complications (death, myocardial infarction, and cerebrovascular accidents) in the 30 days following surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Board of The Ottawa Hospital approved on the 6th September 2002.

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
Massive post-operative bleeding in high risk cardiac patients

Interventions

Group 1: Aprotinin (2 million unit bolus and 2 million units in pump prime and 2 million units via infusion over 4 hours)
Group 2: Tranexamic acid (100 mg/kg post induction) or epsilon-amnicaproic acid (10 g loading dose followed by 2 g/hour while on cardiopulmonary bypass)

For further information, please contact Dr. Paul Hebert at the address listed below or Dr. Dean Fergusson at the e-mail address: dafergusson@ohri.ca

Please note that the trial end recruitment date has been extended from 30th September 2005 to 31st December 2008.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Aprotinin

Primary outcome measure
Massive post-operative bleeding.

Secondary outcome measures
1. 30 day all cause mortality
2. Myocardial infarction
3. Cerebrovascular accidents (focal neurologic deficit lasting more than 24 hours
4. Dialysis dependent renal failure by a double of creatinine
5. Need for prolonged invasive mechanical ventilatory support (greater than 48 hours)
6. A prolonged low output state (need for vasopressors, balloon pump or ventricular assist device for more than 48 hours)

Overall study start date
01/04/2002

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Aged 18 years and older, either sex
2. Re-operation for coronary artery bypass graft (CABG)
3. Re-operation for aortic valve replacement with a CABG
4. Mitral valve replacement (initial or re-operation)
5. Aortic and mitral valve replacement with a CABG
6. Multiple valve replacement (initial or reoperation)
7. Other procedures including Bental procedure and re-operation for adult congenital heart procedures

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2970

Key exclusion criteria
1. Less than 18 years of age
2. Refuse consent (refusal from patient or physician)
3. Have a terminal illness with a life expectancy less than 3 months.
4. Have been previously enrolled in this study
5. Are currently enrolled in another perioperative interventional study
6. Are unable to receive blood products
7. Have had previous exposure to aprotinin
8. Have a thrombocytopenia defined as a platelet count less than 100,000/mm^3
9. Have a coagulopathy defined as an International Normalised Ratio (INR) equalling 1.5 prior to surgery or the immediate preoperative use of tPA or streptokinase

Date of first enrolment
01/04/2002

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Canada

Study participating centre
The Ottawa Hospital - General Campus
Ottawa, Ontario
Canada
K1H 8L6

Sponsor information

Organisation
Ottawa Hospital Research Institute (OHRI) (Canada) - formerly Ottawa Health Research Institute

Sponsor details
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Sponsor type
Not defined

Website
http://www.ohri.ca/home.asp

ROR
https://ror.org/03c62dg59

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-52683)

Funder Name
Ontario Ministry of Health (Canada)

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	29/05/2008		Yes	No