# Blood conservation using antifibrinolytics in cardiac surgery

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
01/09/2005		☐ Protocol		
<b>Registration date</b> 01/09/2005	Overall study status Completed	Statistical analysis plan		
		[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

Dr Paul C. Hebert

### Contact details

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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

725 Parkdale Avenue Ottawa, Ontario Canada K1Y 4E9 +1 613 761 4395 phebert@ohri.ca

### 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