

# Does routine peri-operative continuous cell salvage in cardiac surgery reduce exposure to allogeneic blood? A randomised controlled trial

<b>Submission date</b> 20/04/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/05/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/10/2008	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PO1003

# Study information

## Scientific Title

## Study objectives

Widespread use of new cell salvage technology will reduce the numbers of patients receiving red cells as well as the total units used.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from Peterborough and Fenland Local Research Ethics Committee on the 22nd April 2005.

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Prevention

## Participant information sheet

## Health condition(s) or problem(s) studied

Blood transfusion following cardiac surgery

## Interventions

Patients will be randomised to either the cell saver or control group. A Continuous Auto-Transfusion System (CATS, Fresenius Hemocare) cell saver will be used intra- and post-operatively with the aim of using all processed blood prior to the use of donor blood. Patients in the control group will be managed according to the Papworth hospital protocol.

Please note that as of 06/11/2007 the anticipated end date of this trial was changed from 31st December 2007 to 21st May 2007. This trial has now finished recruiting.

## Intervention Type

Procedure/Surgery

## Phase

Not Specified

**Primary outcome measure**

The proportion of patients exposed to allogeneic blood. All outcomes measured at 30 days post surgery.

**Secondary outcome measures**

1. The number of units of allogeneic red blood cells transfused during first-time cardiac surgery
2. The use of blood products such as fresh frozen plasma and platelet concentrates
3. Adverse events
4. Resource use and cost savings of using CATS in this specific group of patients

All outcomes measured at 30 days post surgery.

**Overall study start date**

01/05/2005

**Completion date**

21/05/2007

**Eligibility****Key inclusion criteria**

Patients for non-emergency first-time Coronary Artery Bypass Grafting (CABG) with planned use of cardiopulmonary bypass, and patients for valve repair or replacement, or combined CABG and valve procedure.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

206

**Key exclusion criteria**

1. Refusal to receive blood or blood products
2. Previous cardiac or thoracic surgery
3. Having an unacceptable risk, as per investigator judgement
4. Known serious coagulation disorders
5. Known blood disorder (thalassemia, chronic anaemia, lymphoproliferative disorder etc.)
6. Any contra-indication to antifibrinolytics
7. The receipt of any investigational drug or participation in a device trial during the course of this trial
8. Where a specific request for cell salvage has been made by the surgeon

**Date of first enrolment**

01/05/2005

**Date of final enrolment**

21/05/2007

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Papworth Hospital NHS Trust**

Cambridge

United Kingdom

CB3 8RE

## **Sponsor information**

**Organisation**

Papworth Hospital NHS Trust (UK)

**Sponsor details**

Papworth Hospital

Papworth Everard

Cambridge

England

United Kingdom

CB3 8RE

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/01qbebb31>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Devices and consumables are being provided free of charge by Fresenius Hemocare (UK). No other source of funding secured to date.

## 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?
<a href="#">Results article</a>	Results	01/11/2008		Yes	No