

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

Submission date 20/04/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 24/05/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 22/10/2008	Condition category Surgery	☐ 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

Protocol serial number

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.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Papworth Hospital NHS Trust
Cambridge
United Kingdom
CB3 8RE

Sponsor information

Organisation

Papworth Hospital NHS Trust (UK)

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

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	01/11/2008		Yes	No