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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/05/2005	**Overall study status** Completed	
Last Edited 22/10/2008	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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?
Results article	Results	01/11/2008		Yes	No