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A randomised controlled trial of red cell washing for the attenuation of transfusion associated organ injury in cardiac surgery

Submission date 21/11/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/11/2013	**Overall study status** Completed	
Last Edited 08/05/2017	**Condition category** Circulatory System	

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
13922

Study information

Scientific Title
A randomised controlled trial of red cell washing for the attenuation of transfusion associated organ injury in cardiac surgery

Acronym
REDWASH

Study objectives
Cardiac surgery is one of the main users of allogeneic blood nationally. Blood transfusion may have unwanted side-effects that increase the risk of inflammation and complications after cardiac surgery which typically affect the kidneys heart and lungs. We believe that this may be due to the release of chemicals and microscopic particles by the red blood cells during storage that collect in the blood bag (the so-called storage lesion). Currently these by-products are transfused to the patient along with the donor blood.

This research study will investigate whether removing the storage by-products by washing blood cells immediately prior to transfusion will improve these common complications in cardiac surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
12/EM/0475

Study design
Randomised; Interventional; Design type: Not specified, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiac Surgery

Interventions

Patients will first be screened and, if they are eligible, they will be randomly allocated to receive either unwashed (standard practice in UK) or washed RBC units, if they require a blood transfusion during or immediately after surgery.

There will be a series of assessments during their hospital stay and 1 follow up visit and it is expected that each participant will be in the study for approximately 6 weeks.

The study is designed to compare both presence and intensity of inflammation and complications in both treatment groups by measuring certain biomarkers in the blood (cytokines) and urine. There will be additional tests aimed at identifying the underlying mechanisms of organ dysfunction. We will also look how safe the study intervention and what side effects, if any it causes.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Severity of the systemic inflammatory response as determined by serial cytokine measures; Timepoint(s): Over the first 96 hours

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2013

Completion date
31/05/2014

Eligibility

Key inclusion criteria
1. Adult cardiac surgery patients (16 years to 80 years) undergoing cardiac surgery with blood cardioplegia
2. Identified as representing a high risk group for massive blood transfusion using a modified transfusion risk score
Target Gender: Male & Female; Upper Age Limit 80 years ; Lower Age Limit 16 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 170; UK Sample Size: 170; Description: 85 participants per treatment arm.

Key exclusion criteria
1. Emergency or salvage procedure
2. Ejection fraction <20%, i.e. very poor left ventricular function
3. Patients with end stage renal failure defined as an estimated Glomerular Filtration rate (eGFR) <15ml/min/1.72m2 calculated from the Modification of Diet in Renal Disease equation [32], or patients who are on long-term haemodialysis or have undergone renal transplantation
4. Patients who are prevented from having blood and blood products according to a system of beliefs (e.g. Jehovahs Witnesses)
5. Patients with a pre-existing inflammatory state (e.g. sepsis, active inflammatory disease including active rheumatoid arthritis, colitis, Lupus, or Crohns disease. NB: consider latter conditions as active conditions when a patient is taking a high dose of oral steroids, for example > 10 mg/day of prednisolone).
6. Patients with congenital or acquired RBC, platelet or clotting factor disorders, (excluding those receiving anti-platelet therapy, warfarin or other systemic oral anticoagulants)
7. Patient in a critical preoperative state (Kidney Disease: Improving Global Outcomes (KDIGO) Stage 3 AKI or requiring ionotropes, ventilation or intra-aortic balloon pump) preoperatively
8. Pregnancy
9. Patients who are participating in another interventional clinical study

Date of first enrolment
01/03/2013

Date of final enrolment
31/05/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leicester
Leicester
United Kingdom
LE1 7RH

Sponsor information

Organisation
University of Leicester (UK)

Sponsor details
Department of Genetics
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Sponsor type
University/education

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility; Grant Codes: RP-PG-0407-10384

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?
Protocol article	protocol	07/03/2016		Yes	No
Results article	results	01/05/2017		Yes	No
HRA research summary			28/06/2023	No	No