

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

<b>Submission date</b> 21/11/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 21/11/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/05/2017	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Gavin Murphy

**Contact details**  
Grobby Road  
Leicester  
United Kingdom  
LE3 9QP  
-  
gjm19@le.ac.uk

## 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/1.72m<sup>2</sup> 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  
University Road  
Leicester  
England  
United Kingdom  
LE1 7RH

## 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?
<a href="#">Protocol article</a>	protocol	07/03/2016		Yes	No
<a href="#">Results article</a>	results	01/05/2017		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No