

# The effect of red cell washing on serum biochemistry in neonates and infants undergoing surgery for complex congenital heart disease with cardiopulmonary bypass

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|--|---|--|
| <b>Submission date</b><br>30/09/2005   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered    |
|  |   | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>30/09/2005 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>19/04/2011       | <b>Condition category</b><br>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

Miss Christine Swindell

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N0045158194

# Study information

## Scientific Title

### Study objectives

To determine whether pre-washing red cells affects the serum potassium and lactate levels in young children (<1 year old) who require an irradiated red cell transfusion as part of their open heart surgery.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

## Participant information sheet

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

Congenital heart disease

### Interventions

A prospective, open label study with each patient randomly assigned to a group. One group will receive unwashed irradiated red cells and the other will receive washed irradiated red cells in the cardiopulmonary bypass circuit prime.

### Intervention Type

Other

### Phase

Not Specified

**Primary outcome measure**

Serum lactate and potassium levels.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/11/2004

**Completion date**

31/01/2005

## Eligibility

**Key inclusion criteria**

Children <1 year of age with complex congenital heart defects limited to those undergoing elective or urgent cardiac surgery with cardiopulmonary bypass.

**Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

40

**Key exclusion criteria**

Children undergoing emergency surgery as it will not be possible to pre-wash the irradiated red cells.

**Date of first enrolment**

01/11/2004

**Date of final enrolment**

31/01/2005

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Birmingham Children's Hospital**  
Birmingham  
United Kingdom  
B4 6NH

## **Sponsor information**

### **Organisation**

Department of Health

### **Sponsor details**

Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL  
+44 (0)20 7307 2622  
dhmail@doh.gsi.org.uk

### **Sponsor type**

Government

### **Website**

<http://www.dh.gov.uk/Home/fs/en>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

Birmingham Children's Hospital NHS Trust (UK)

### **Funder Name**

NHS R&D Support Funding (UK)

## **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 | 01/04/2007   |            | Yes            | No              |