

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

Submission date 30/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 30/09/2005	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 19/04/2011	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Study type(s)

Not Specified

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(s)

Serum lactate and potassium levels.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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**

United Kingdom

England

Study participating centre

Birmingham Children's Hospital

Birmingham

United Kingdom

B4 6NH

Sponsor information**Organisation**

Department of Health

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

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	01/04/2007		Yes	No