ISRCTN54081245 https://doi.org/10.1186/ISRCTN54081245

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 19/04/2011	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Miss Christine Swindell

Contact details
Birmingham Children's Hospital
Main Theatre
Steelhouse Lane
Birmingham
Birmingham
United Kingdom
B4 6NH

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?
Results article	results	01/04/2007		Yes	No