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Effect of two different volumes of blood transfusion on cardiac function, cerebral and gut hemodynamics in neonates: a randomised controlled trial

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/09/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/08/2015	**Condition category** Neonatal Diseases	[_] Individual participant data [_] Record updated in last year

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

N0227163238

Study information

Scientific Title
Effect of two different volumes of blood transfusion on cardiac function, cerebral and gut hemodynamics in neonates: a randomised controlled trial

Study objectives
What are the hemodynamic effects of different volumes of blood transfusion in newborn babies: effects on cardiac output, gut and cerebral flow?

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)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Neonatal Diseases

Interventions
After taking informed consent the Ultrasonographic and Doppler assessment of cerebral flow, gut flow and cardiac function, would be done 4 hours before, and 4 and 24-30 hours after transfusion. Block randomisation with stratification as per the gestation (less than and equal to and more than 30 weeks gestation) will be done.

Once eligible baby will be randomised into one of the 2 groups:
1. Volume of transfusion 20 ml per kg given over 4 hours
2. Volume of transfusion 10 ml per kg given over 2 hours and repeated with 10 ml per kg transfused over two hours from same donor, 24 hours apart

Each baby will act as control pre transfusion and case post transfusion. Each consented transfusion event will be enrolled as a subject.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Effect of blood transfusion
2. Change in cardiac output post transfusion

Secondary outcome measures
1. Change in gut flow
2. Change in cerebral flow
3. Effect on Hemoglobin concentration

Overall study start date
01/10/2004

Completion date
28/02/2007

Eligibility

Key inclusion criteria
Babies admitted to the neonatal intensive care unit and requiring blood transfusion (packed cells) as per the unit protocol and guidelines will be eligible for the study.

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
70, 57 recruited as of September 2006

Key exclusion criteria
1. Babies with pneumothorax, pneumomediastinum or pneumoperitoneum during study
2. Hypotension requiring changing ionotropic support at time of transfusion
3. Terminally ill babies
4. Complex congenital heart disease
5. Major congenital anomalies

Date of first enrolment
01/10/2004

Date of final enrolment

28/02/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
South Tees Hospital Trust
Cleveland
United Kingdom
TS4 3BW

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, 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
South Tees Hospitals NHS Trust (UK), NHS R&D Support Funding

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