

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

Contact name

Dr Samir Gupta

Contact details

South Tees Hospital Trust
The James Cook University Hospital
Marton Road
Cleveland
United Kingdom
TS4 3BW

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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

United Kingdom

England

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

Funder(s)

Funder type

Government

Funder Name

South Tees Hospitals NHS Trust (UK), NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration