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The clinical effect of length of pre-transfusion storage of blood

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/01/2009	Haematological Disorders	

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
N0009094224

Study information

Scientific Title

Study objectives
That the management of patients requiring regular blood transfusions for anaemia may be enhanced by using fresh blood rather than blood stored for prolonged periods. This may improve patients' quality of life, reduce the risks of infection and iron overload and conserve scare blood resources.

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)
Not Specified

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

Interventions
Stable patients requiring blood transfusions for anaemia more often than every 6 weeks will be recruited. They will be randomised to receive two transfusions of four units of "fresh" blood (less than 10 days old) or two transfusions of "old" blood (24-35 days old). There will then be a crossover in which patients receive two further transfusions of four units of the opposite type of blood.

The following will be measured pre-transfusion and at completion of transfusion, 48 h post-transfusion and 14 days after transfusion: Full blood count (FBC), retics, 2,3-diphosphoglycerate (2-3-DPG), P50, haptoglobin. Pre-transfusion, serum ferritin will also be measured and QOL assessed. QOL assessment will be repeated at 14 days post transfusion.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
48-hour post transfusion haemoglobin (Hb) increment.

Key secondary outcome(s)
1. Changes in red cell 2,3-DPG concentration and Hb-oxygen affinity (P50)
2. Subsequent changes in Hb at 14 days and before next transfusion
3. Changes in patients' quality of life (QOL) as measured by SF-36 health survey and a visual analogue scale

Completion date
31/08/2003

Eligibility

Key inclusion criteria
1. Patients 18 and over with a haematological disorder requiring regular red cell transfusion (eg myelodysplastic syndrome, aplastic anaemia, etc)
2. Able to give informed consent
3. Serum creatinine <200 umol/l within past 2 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
31/08/2000

Date of final enrolment
31/08/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Gateshead Health NHS Trust
Gateshead
United Kingdom
NE9 6SX

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Gateshead Health NHS Trust (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?
Abstract results	abstract page 1	01/04/2005		No	No