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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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

## 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
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 measure
48-hour post transfusion haemoglobin (Hb) increment.

### Secondary outcome measures
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

### Overall study start date
31/08/2000

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Not Specified

### Target number of participants
20 patients from three centres (2 - 4 from QEH)

### 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
England

United Kingdom

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

# Sponsor information

### Organisation
Department of Health (UK)

### Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

### Sponsor type
Government

### Website
http://www.doh.gov.uk

# Funder(s)

### Funder type
Government

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