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Randomised trial of a blood transfusion policy after fracture of the proximal femur (hip fracture)

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 04/10/2017	**Condition category** Surgery	

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
N0181115109

Study information

Scientific Title
Randomised trial of a blood transfusion policy after fracture of the proximal femur (hip fracture)

Study objectives
The threshold at which blood transfusion should be given after surgery is the subject of controversy. This study aims to address this question of transfusion after hip fracture surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Peterborough and Fenland LREC, ref: PO1/154

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Surgery: Blood transfusion

Interventions
Patients are then randomised (if willing) to either no transfusion and to receive oral iron supplements or have a blood transfusion to raise the haemaglobin above 10 g/dl.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
Mortality

Key secondary outcome(s)
Length of hospital stay, complications

Completion date
01/05/2012

Eligibility

Key inclusion criteria
Haemaglobin between 8 to 9.5 g/dl after hip fracture surgery.

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Patients unwilling to give written informed consent
2. Post-operative haemoglobin on day 1 or 2 after surgery of below 8g/dl or above 10g/dl
3. Multiple trauma. (defined as either more than two other fractures or any other fracture requiring surgery other than simple manipulation alone)
4. Patients who refuse transfusion due to religious reasons
5. Patients aged less than 60 years

Date of first enrolment
01/08/2002

Date of final enrolment
01/05/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Peterborough District Hospital
Peterborough
United Kingdom
PE3 6DA

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Peterborough Hospitals 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?
Results article	results	01/12/2013		Yes	No