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

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		
04/10/2017	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

Study design

Randomised controlled trial

Primary study design

Interventional

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