

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/10/2017	Condition category Surgery	<input type="checkbox"/> Individual participant data

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

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 haemoglobin above 10 g/dl.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome measure

Mortality

Secondary outcome measures

Length of hospital stay, complications

Overall study start date

01/08/2002

Completion date

01/05/2012

Eligibility**Key inclusion criteria**

Haemoglobin between 8 to 9.5 g/dl after hip fracture surgery.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

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**

England

United Kingdom

Study participating centre

Peterborough District Hospital
Peterborough
United Kingdom
PE3 6DA

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

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