

# The effect of intravenous iron on postoperative transfusion requirements in hip fracture patients - the IVANOF1 Study

<b>Submission date</b> 05/09/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 10/09/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/05/2019	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Iain Moppett

**Contact details**  
University of Nottingham  
Department of Anaesthesia and Intensive Care  
Queens Medical Centre  
Nottingham  
United Kingdom  
NG7 2UH  
-  
iain.moppett@nottingham.ac.uk

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
2011-003233-34

**Protocol serial number**  
11206

# Study information

## Scientific Title

The effect of intravenous iron on postoperative transfusion requirements in hip fracture patients a pilot study

## Acronym

IVANOF1

## Study objectives

Anaemia following hip fracture is common. Approximately 30-45 % of patients have haemoglobin concentrations ([Hb]) below population norms on admission and around 10% are severely anaemic. Anaemia on admission and in the postoperative period is associated with poor outcome with regard to mobility, postoperative mortality and readmission. There is currently no clear consensus on the optimal method to manage peri-operative anaemia in this frail group of patients with frequent comorbidity. Liberal red cell transfusion in the postoperative period does not appear to improve outcome and tranexamic acid appears to reduce transfusion rate at the expense of increased cardiovascular morbidity. There are encouraging results from one centre with the use of agents to stimulate red cell production, including intravenous iron and erythropoietin. UK practice has significant differences to the patients and these studies and it is not clear whether these promising results will translate to the UK population.

More details can be found at <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=11206>

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised interventional trial

## Primary study design

Interventional

## Study type(s)

Treatment

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

Blood, Injuries and Emergencies

## Interventions

Single-centre randomised controlled parallel group trial. Randomisation by website using computer generated concealed tables. Setting: University hospital in UK. Participants: 80 patients with acute hip fracture undergoing operative repair and aged > 70 years.

Intervention: Three daily infusions of 200mg iron sucrose starting within 24 hours of admission. Control group: standard hospital care at the discretion of the clinical team. Red cell transfusions for each group are given in accordance with standard clinical triggers.

Primary outcome: difference in mean reticulocyte count between groups at day 7.  
Secondary outcomes include: haemoglobin concentrations, early and late transfusion rates, infectious and cardiovascular complications, mobility and 30-day mortality.

**Intervention Type**

Procedure/Surgery

**Phase**

Not Applicable

**Primary outcome(s)**

Reticulocyte count measured at day 7

**Key secondary outcome(s)**

1. Infective complications
2. Length of actual hospital stay
3. Minimum haemoglobin
4. Mortality within first 7 days
5. Mortality within first 30 days
5. Safety variables
6. Transfusion requirements
7. Pre-operative transfusion
8. Postoperative transfusion
9. Late transfusion (> day 7)

**Completion date**

12/03/2014

**Eligibility****Key inclusion criteria**

1. Primary hip fracture
2. Aged over 70
3. Able to consent for themselves
4. Male and female participants

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Total final enrolment**

80

## **Key exclusion criteria**

1. Undisplaced intracapsular fractures (very low transfusion requirements)
2. Contraindications to intravenous iron
3. Currently taking antiplatelet drugs other than aspirin

## **Date of first enrolment**

12/06/2012

## **Date of final enrolment**

12/03/2014

## **Locations**

### **Countries of recruitment**

United Kingdom

England

### **Study participating centre**

**University of Nottingham**

Nottingham

United Kingdom

NG7 2UH

## **Sponsor information**

### **Organisation**

University of Nottingham (UK)

### **ROR**

<https://ror.org/01ee9ar58>

## **Funder(s)**

### **Funder type**

Research organisation

### **Funder Name**

National Institute of Academic Anaesthesia [NIAA] (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?
<a href="#">Results article</a>	results	01/09/2019	29/05/2019	Yes	No
<a href="#">Protocol article</a>	protocol	09/09/2013		Yes	No
<a href="#">Basic results</a>		15/11/2018	15/11/2018	No	No