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

Submission date 05/09/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/09/2012	**Overall study status** Completed	
Last Edited 29/05/2019	**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

EudraCT/CTIS number
2011-003233-34

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Reticulocyte count measured at day 7

Secondary outcome measures
1. Infective complications
2. Length of actue 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)

Overall study start date
12/06/2012

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

Age group
Senior

Sex
Both

Target number of participants
UK Sample Size: 80

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
England

United Kingdom

Study participating centre
University of Nottingham
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
University Park
Nottingham
England
United Kingdom
NG7 2RD

Sponsor type
University/education

Website
http://www.nottingham.ac.uk/

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Research organisation

Funder Name
National Institute of Academic Anaesthesia [NIAA] (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?
Protocol article	protocol	09/09/2013		Yes	No

Basic results	results	15/11/2018	15/11/2018	No	No
Results article		01/09/2019	29/05/2019	Yes	No