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Randomised controlled trial to compare the magnitude and incidence of haemodynamic changes during fixation of extracapsular fractures of the neck of femur using the compression hip screw versus the intramedullary hip screw

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/07/2016	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

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

N0227149002

Study information

Scientific Title
Randomised controlled trial to compare the magnitude and incidence of haemodynamic changes during fixation of extracapsular fractures of the neck of femur using the compression hip screw versus the intramedullary hip screw

Study objectives
To determine the magnitude and incidence of haemodynamic changes associated with using a compression hip screw and an intramedullary hip screw to fix extra-capsular fractures of neck of femur.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Extra-capsular fractures of neck of femur

Interventions
Prospective, randomised controlled trial with two limbs. It is a single centred study conducted in the Orthopaedic and Anaesthetic departments at James Cook University Hospital. Patients presenting with extracapsular fractures of the neck of the femur will be asked to participate in the study on the basis of predetermined inclusion criteria.

Randomisation: Computer generated random tables will be used. Delivery of randomisation will be in opaque sealed envelopes to be opened at the time of operation in the operating theatre. Time of 'randomisation (opening the envelope) to delivery of treatment (operation)' will be less than 5 minutes. For this purpose, we propose to have two groups of patients. The patients would be assigned to the groups randomly. One group would be treated using a compression hip screw while the other will be treated using an intramedullary hip screw. All patients will have a preoperative assessment to ensure a stable cardiovascular system. Intraoperative monitoring of the cardiovascular system will be continued through out the operation.

For this purpose, we will place a probe into the oesophagus (gullet) after they have been anaesthetised which would allow us to monitor the heart more effectively. This transoesophageal ultrasound doppler probe has been used in numerous previous studies and in

fact it is often used to monitor high-risk patients. It has a no known complication from its use if the exclusion criteria that have been outlined later are strictly adhered to, and if anything the patients would actually benefit from the higher level of monitoring they receive during the procedure. An independent observer, blinded to the group allocation of the patients, and competent in trans-oesophageal doppler probe insertion will record the readings from the probe monitoring. This would increase the validity of the study.

We propose to compare the two groups of patients with regard to their cardiovascular status during the operation and specifically during insertion of the implant. Intraoperative trans-oesophageal doppler monitoring will observe any significant changes in the incidence and magnitude of cardiovascular status or function.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Per-operative (during placement of fixation implant): stroke volume, cardiac output, mean arterial blood pressure, change in arterial blood gases at specified intervals during the surgical procedure
2. Recovery: oxygen saturation, blood pressure
3. Postoperative: Hospital stay, pulmonary embolism mortality

Key secondary outcome(s))
No secondary outcome measures

Completion date
30/09/2004

Eligibility

Key inclusion criteria
All patients on admission to the trauma ward with an extracapsular fracture of the neck of femur will be given the opportunity to participate in the study. They will be given the patient information sheet and the opportunity to discuss with the research team. They will be given the opportunity to discuss with their friends, family and GP (if they wish so). If they agree to participate they will be placed on the list but not randomised at that stage. The consent to participate in the study will be taken by the researcher.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients unwilling to take part in the study
2. Paediatric cases (unlikely)
3. Patients not suitable for or not wanting general anaesthesia
4. Patients unable to sign the consent form
5. Known history of deep vein thrombosis
6. Previous oesaphageal surgery (as it can make the placement of oesophageal probe technically unpredictable)
7. Oesophageal varices and other oesophageal abnormalities
8. Pregnant women

Date of first enrolment
01/04/2004

Date of final enrolment
30/09/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The James Cook University Hospital
Middlesbrough
United Kingdom
TS4 3BW

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
South Tees Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration