

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 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/07/2016	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr M Ahmad

Contact details

The James Cook University Hospital
Orthopaedics Department
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

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mubashshar72@hotmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/04/2004

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

Age group

Adult

Sex

Both

Target number of participants

42

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 oesophageal 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**

England

United Kingdom

Study participating centre

The James Cook University Hospital

Middlesbrough

United Kingdom

TS4 3BW

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

South Tees 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