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Intra- and post-operative analgesia for patients undergoing surgery for hip fracture - role of Fascia Illiaca Compartment Block

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Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 12/10/2017	**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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0265178818

Study information

Scientific Title
Intra- and post-operative analgesia for patients undergoing surgery for hip fracture - role of Fascia Illiaca Compartment Block

Study objectives
1. Analgesia technique for patients undergoing surgery for hip fracture?
2. Is better pain relief associated with any other clinical benefit?

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

Health condition(s) or problem(s) studied
Surgery: Analgesia

Interventions
Purpose:
To see whether analgesic efficacy of Fascia Iliaca Compartment Block (FICB) is better than that of Morphine during and post hip fracture surgery

Theoretical framework:
The commonly used nerve blocks for patients undergoing hip fracture surgery are:
1. Lumbar plexus block
2. Psoas compartment block
3. 3-in-1 block
1 and 2 require change in patient position and the potential for complications is greater. They have not been shown to be more effective than 3-in-1 block which does not need change in

position and has lesser potential for complications. FICB is a simpler technique of blocking the same nerves as the 3-in-1 block was first described in 1989 and is commonly used in children undergoing hip or thigh surgery. Lt has been studied in adults also and shown to have analgesic efficacy similar to that of 3-in-1 block in hip, thigh and knee surgeries but the number of patients undergoing hip surgery was small and the type of hip surgery was different. FICB has been shown to have good analgesic efficacy in the pre-operative care of patients with hip fracture. For two specific kinds of hip surgery namely Dynamic f-tip Compression Screw and Cannulated Screw fixation FIGB may be more suitable than 3-in-1 block as it blocks one of the nerves (lateral cutaneous nerve of thigh) responsible for pain from this surgery more reliably FICB is quicker, easier and cheaper than 3-in-1 block and could be repeated on the ward it necessary The potential for complications is lower than that of 3-in-1 block. To our knowledge there are no ACTS assessing the efficacy of FICB compared to Morphine in this group of patients.
It is not clear from previous studies whether nerve blocks provide any additional clinical benefit over conventional pain killers apart from reducing their requirements. Our choice of secondary outcome measures is based on conclusions made in a systematic review on nerve blocks in hip fractures (Cochrane review) and a recent study which performed mortality analysis in hip fracture and discussed its implications on design of future trials. We hope to make a small contribution to significant work being done in this field by providing full reporting of outcome measures.

Design and Methodology:
Randomised Controlled Trial - Study group will have FICB for analgesia and the control group will have Morphine. The control arm is essential because Morphine is the most common analgesic used in these patients perioperatively.
Blinding - Patients and staff responsible for assessing analgesic efficacy will be blind to the choice of technique. This is to eliminate placebo effect and observer bias.
Organisation - 40 adult patients of ASA grades 1, 2 & 3 admitted to Selly Oak Hospital with hip fracture and scheduled for DHS or Compression screw fixation will be recruited after obtaining consent. They will then be randomly allocated to two groups of 20 each. To detect differences in analgesic requirements during the first 24 hours after surgery at the 5% significance level with 80% power, 18 patients will be required in each group. This calculation was based on previous studies assessing efficacy of nerve blocks post hip fracture surgery. We decided to recruit 20 in each group to make some allowance for dropouts if any.

Each patient will have a standard pre-operative assessment, standard monitoring and recovery care and will have assessments at 1,3,6 and 24 hours post-op. Thereafter data collection will be on a daily basis until 30 days post-op./discharge/death whichever is earlier-Our hospital already has a framework for data collection (Integrated Care Pathway). For our study we will be using the same data.

Statistical analysis:
Test Null Hypothesis
SPSS software will be used to perform statistical analysis. The following tests will be used to analyse data for significance:
't' test or Mann Whitney test for continuous data depending on distribution.
Kendalls tau-b test for ordinal data
Fishers exact test for nominal data
McNemars test for intra-group analysis for ordinal data at various time points
Kendalls tau-b test for inter-group analysis for ordinal data at various time points

P value <0.05 will be considered significant.

Inconvenience:
Interview for recruitment. All assessments are standard and no different from other patients.

Benefits:
A tow risk alternative analgesic technique which may result in reduction of conventional analgesic use and also their side effects.

The study is expected to lasts to 6 months to get the required no, of patients and a further month to complete follow-up.
Data analysis and reporting will take one more month.
There will not be any interim analyses.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Morphine

Primary outcome measure
Total dose of morphine required during first 24 hours post-op

Secondary outcome measures
1. Time to first dose of morphine post-op
2. Pain scores in recovery room and at 13, 16 and 24 hours post-op, intra- and inter-group analysis
3. Time to first appropriate response to verbal commands post-op
4. Time to discharge from recovery room
5. Occurrence of nausea and vomiting in recovery and no. of episodes during the first 24 hours post-op
6. Total dose of Cyclizine required in the first 24 hours post-op.
7. Need for Granisetron during the first 24 hours post-op.
8. Sedation Scores at 1,3,6 and 24 hours post-op.
9. Mental Test Scores at 1,3,6 and 24 hours post-op. compared to pre-op score, intra- and inter-group analysis.
10. Other: unlikely to find significant difference because of sample size but full reporting of morbidity, complications, rehabilitation outcomes and mortality will be useful. There has been no involvement of patient groups, research participants or communities in the design of this study.

Overall study start date
04/04/2006

Completion date
04/04/2007

Eligibility

Key inclusion criteria

All adult ASA physical status 1, 2 and 3 patients with hip fracture posted for DHS or cannulated screw fixation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Dementia/confusion as it is difficult to assess pain relief
2. Pre-operative chest infection and/or poor respiratory function - Temperature 380C or more, white cell count> 11000 mm3, Respiratory rate > 25 per minute, auscultation and or chest x-ray evidence, Sp02 < 90 % on air
3. Congestive Cardiac Failure (CCF)
4. Bed bound or use of 2 or more aids for mobilisation pre-fracture
5. Malignancy
6. Coagulopathy
7. Known or suspected allergy to Ropivacaine and/or Morphine
8. Local infection at the site where the block is to be performed
9. Refusal of permission to approach General Practitioner

Justification for these exclusion criteria:
Pre-fracture poor mental status, poor mobility, CCF, poor respiratory function and malignancy are independent risk factors for poor outcome following hip fracture The morbidity and mortality in this group is high and unlikely to be influenced by choice of technique. The others are standard contra-indications for any nerve block technique.

Date of first enrolment
04/04/2006

Date of final enrolment
04/04/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Selly Oak Hospital
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

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Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK), NHS R&D Support Funding

Results and Publications

Publication and dissemination plan
The aim is to present the findings in the hospital and in the region and also to publish the results in a peer reviewed journal. The trialists will also aim to provide feedback to research participants in the form of letters.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration