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The effect of the use of fasica iliaca nerve blockade on patient positioning for spinal anaesthesia and the effect of continuous nerve blockade on post-operative pain and mobility outcomes in patients with hip fractures

Submission date 30/09/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 14/10/2009	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/03/2017	**Condition category** Surgery	[_] Individual participant data [_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RGHT000559

Study information

Scientific Title
Comparison of fascia iliac compartment block with conventional sedation to facilitate the positioning of patients with fractured neck of femur for spinal anaesthesia and the effect of nerve blockade on post-operative pain and mobility: a randomised double-blind controlled study

Study objectives
Part 1: Does the use of single shot fascia iliaca blockade reduce pain on patient positioning for spinal anaesthesia when compared with a standard sedation regime?
Part 2: Does the use of post-operative bolus dose fascia iliaca blockade improve pain and mobility outcomes in patients undergoing operative repair of fractured neck of femur?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health and Social Care Research Ethics Committee (HSC REC 1) (Northern Ireland), 18/04/2008, ref: 08/NIR01/20

Study design
Randomised controlled double-blind 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Operative repair of fractured neck of femur

Interventions
Part 1:
Patients randomised to receive either fascia iliaca compartment block (FICB) with 2 mg/kg 1%

lignocaine or conventional sedation with 0.2 mg/kg intravenous (iv) ketamine and 0.025 mg/kg iv midazolam. At the end of surgery, a FICB using 1 mg/kg 0.25% levobupivacaine will be performed in all patients.

Part 2:
Patients randomised to receive a pre-operative FICB using either 1 mg/kg 0.25% levobupivacaine or 2 mg/kg 1% lignocaine. After administration of FICB a catheter will be inserted below the fascia iliaca and secured in place. Patients will be reviewed in the post-operative period and bolus doses of 0.125% levobupivacaine administered through the FICB catheter if Visual Analogue Scale (VAS) is greater than 4. The catheter will be removed no longer than 24 hours after surgery.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Part 1: Comparison of VAS score on rest and positioning for spinal anaesthesia in patients who have received either a fascia iliaca compartment block or convention sedation.
Part 2: Comparision between post-operative VAS scores in patients receiving fascia iliaca blockade with either lignocaine or levobupivacaine and the effect of bolus top-up doses of low dose levobupivacaine on VAS scores.

Secondary outcome measures
1. Length of time to first request of additional analgesia
2. The level of assistance required for transfer from the sitting to the standing position
3. Incidence and severity of motor blockade
4. Time taken to mobilisation with walking aid
5. Measurement of oxygen saturations without supplemental oxygen in both groups
6. Incidence of all complications associated with the analgesic techniques in both groups
7. Incidence of nausea and/or vomiting within the first 48 hours after surgery in both groups
8. Use of blood products in all groups

Overall study start date
01/07/2009

Completion date
01/09/2009

Eligibility

Key inclusion criteria
1. American Society of Anaesthesiologists (ASA) class I - IV
2. Patients able to give written informed consent
3. Patients requiring operative repair of fractured neck of femur
4. Patients aged 18 years and over, either sex

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100 patients - 40 in first part of study and 60 in second part of study.

Key exclusion criteria
1. History of dementia or difficulty in obtaining consent
2. History of allergy to any of the medications used in the study

Date of first enrolment
01/07/2009

Date of final enrolment
01/09/2009

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Queen's University Belfast
Belfast
United Kingdom
BT12 6BJ

Sponsor information

Organisation
Belfast Health and Social Care Trust (UK)

Sponsor details
Royal Group of Hospitals
Grosvenor Road

Belfast
Northern Ireland
United Kingdom
BT12 6BJ

Sponsor type
Hospital/treatment centre

Website
http://www.belfasttrust.hscni.net

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
Government

Funder Name
Belfast Health and Social Care Trust (UK) (ref: RGHT 000559)

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