# 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	Recruitment status	<ul><li>Prospectively registered</li></ul>
30/09/2009	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
14/10/2009	Completed	Results
Last Edited	Condition category	Individual participant data
07/03/2017	Surgery	<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Not provided at time of registration

# **Contact information**

# Type(s)

Scientific

### Contact name

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### Contact details

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# Additional identifiers

# Protocol serial number

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

# Study type(s)

Treatment

# 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(s)

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.

# Key secondary outcome(s))

- 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

# 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

# Healthy volunteers allowed

No

# Age group

Adult

# Lower age limit

18 years

### Sex

Αll

### 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

**United Kingdom** 

Northern Ireland

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

# Sponsor information

# Organisation

Belfast Health and Social Care Trust (UK)

### **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**

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?

Participant information sheet 11/11/2025 No Yes