

Comparison of the post-operative pain relief provided by the administration of either a femoral nerve block or fascia iliaca compartment block at one of two different doses in patients undergoing surgery for hip fracture

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| Submission date 14/08/2009 | Recruitment status Stopped | <input type="checkbox"/> Prospectively registered |
| Registration date 01/10/2009 | Overall study status Stopped | <input type="checkbox"/> Protocol |
| Last Edited 12/06/2014 | 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

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RGHT 000675

Study information

Scientific Title

Comparison of fascia iliaca compartment block or femoral nerve block using levobupivacaine for post-operative analgesia after operative repair of femoral neck fracture - dose response study: a randomised controlled double-blind trial

Study objectives

Is there a significant difference in post-operative pain scores in patients who have received either a femoral nerve block or fascia iliaca compartment block at one of two different doses after operative repair of hip fracture?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Health and Social Care Research Ethics Committee (HSC REC 2) (Northern Ireland) approved on the 28th July 2009 (ref: 09/NIR02/39)

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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Fractured neck of femur

Interventions

Patients will be randomised to four groups - all blocks will be performed under ultrasound guidance:

Group I: Fascia iliaca compartment block at a dose of 1 mg/kg levobupivacaine

Group II: Fascia iliaca compartment block at a dose of 1.5 mg/kg levobupivacaine

Group III: Femoral nerve block at a dose of 1 mg/kg levobupivacaine

Group IV: Femoral nerve block at a dose of 1.5 mg/kg levobupivacaine

After administration of the nerve block, all patients will receive spinal anaesthesia with surgery then continuing as normal.

Added 09/08/2011: Trial closed early due to low recruitment - 60 patients recruited in total.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Levobupivacaine

Primary outcome measure

Comparison of post-operative pain scores after one of two nerve blocks using one of two doses of the local anaesthetic following operative repair of fractured neck of femur. A post-operative assessment will be performed in the recovery room and at 4, 24 and 48 hours post-procedure. Pain scores will also be recorded by nursing staff whilst assessing routine observations.

Secondary outcome measures

Assessed at 4, 24 and 48 hours post-operatively:

1. Incidence of motor blockade
2. Post-operative analgesia requirements and time to first request of post-operative analgesia
3. Ability to mobilise on the first post-operative day
4. Incidence of any adverse events
5. One and three month mortality

Overall study start date

31/08/2009

Completion date

05/02/2010

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

1. American Society of Anaesthesiologists (ASA) class I - III
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

120 - 30 in each group (Only 60 actually recruited)

Key exclusion criteria

1. History of allergy to any of the medications used in the study
2. Patients with a history of dementia or difficulty in providing informed consent
3. Patients with a history of significant neurological impairment of one or both of the lower limbs
4. Patients with a pathological fracture of the neck of femur
5. Patients suffering from severe hypotension such as cardiogenic or hypovolaemic shock or with a serious cardiac arrhythmia

Date of first enrolment

31/08/2009

Date of final enrolment

05/02/2010

Locations**Countries of recruitment**

Northern Ireland

United Kingdom

Study participating centre

Department of Anaesthetics and Intensive Care Medicine

Belfast

United Kingdom

BT12 6BA

Sponsor information

Organisation

Belfast Health and Social Care Trust (UK)

Sponsor details

Grosvenor Road
Belfast
Northern Ireland
United Kingdom
BT12 6BA

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 000675)

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

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| HRA research summary | | | 28/06/2023 | No | No |