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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

Submission date	Recruitment status	[ ] Prospectively registered
14/08/2009	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/10/2009	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/06/2014	Injury, Occupational Diseases, Poisoning	[ ] 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
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