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Efficacy of Femoral Nerve Block vs Fascia Iliaca Block for preoperative analgesia in fracture neck of femur

Submission date	Recruitment status
22/02/2011	No longer recruiting
Registration date	**Overall study status**
12/10/2011	Completed
Last Edited	**Condition category**
15/10/2014	Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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

Study information

Scientific Title
Efficacy of Femoral Nerve Block vs Fascia Iliaca Block for preoperative analgesia in fracture neck of femur: a randomised unblinded comparison study

Acronym
FNB-v-FIB

Study objectives
To determine whether one of the two standard techniques of local anaesthetic block of the femoral nerve is superior in terms of analgesia provided for elderly patients with fractured hip.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Isle of Wight, Portsmouth & South East Hampshire Local Research Ethics Committee, 09/11/2011, ref: REC10/H0501/25

Study design
Randomised unblinded comparison study

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
Fracture of femur

Interventions
Femoral Nerve Block versus Femoral Iliaca Block

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Differences in pain scores using the Linear Analogue Pain score immediately before and 2 hours after performing the block

Secondary outcome measures
Statistical difference between the consumption of analgesics in the 12 hours after the block

Overall study start date
01/03/2011

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Patients male or female, admitted with diagnosis of fracture neck of femur
2. Patients with capability to give informed consent with Mini Mental Score Examination (MMSE) ≥ 8/10. MMSE is routinely performed on initial assessment of these patients.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Respiratory rate less than 10 beats per minute (bpm)
2. Systolic Blood Pressure less than 100 mm Hg
3. Glasgow Coma Scale (GCS) less than 12/15
4. Anticoagulant therapy (warfarin / heparin infusion). Not contraindicated in patients taking low dose aspirin < 150mg/day
5. Clotting disorders [international normalised ratio (INR) or activated partial thromboplastin time ratio (APTR)] > 1.5, Platelets < 80,000
6. Previous femoral vascular surgery
7. Hepatic Impairment
8. Debilitated or acutely ill patients
9. Patient refusal
10. Known hypersensitivity to local anaesthetic agents of amide type
11. MMSE < 8/10. Standard exclusion criteria for the local anaesthetic nerve block as per local protocol

Date of first enrolment
01/03/2011

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Anaesthesia
Poole
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Sponsor information

Organisation
Poole Hospital NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03kdm3q80

Funder(s)

Funder type
Government

Funder Name
Poole Hospital NHS Foundation Trust (UK)

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?
Results article	results	01/09/2013		Yes	No