

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

Submission date
22/02/2011

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
12/10/2011

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
15/10/2014

Condition category
Injury, Occupational Diseases, Poisoning

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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) $\geq 8/10$. 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 $< 150\text{mg/day}$
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

United Kingdom

BH15 2JB

Sponsor information

Organisation

Poole Hospital NHS Foundation Trust (UK)

Sponsor details

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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