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Randomised controlled trial of Femoral Nerve Blockade for fractured femurs

Submission date	Recruitment status	[ ] Prospectively registered
04/07/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/08/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/01/2012	Musculoskeletal Diseases	

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
SDHCT03/02/002; NRR Pub. ID: N0224122747

Study information

Scientific Title

Acronym
FNB study

Study objectives
To determine whether local anaesthetic blockade of the femoral nerve reduces pain from fractured proximal femurs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Devon Research Ethics Committee (formerly Torbay REC) approval gained on 14th February 2003 (reference number: 36/08/02).

Study design
Randomised, double blind, placebo controlled 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 proximal femurs

Interventions
Local anaesthetic blockade of the femoral nerve (0.5% bupivacaine) versus placebo (0.9% sterile saline) in patients with fractured proximal femurs.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Bupivacaine

Primary outcome measure
To assess the quality of anaesthesia provided by systemic opioids alone or combined with femoral nerve blockade in two otherwise equivalent groups by measuring pain scores and levels of systemic opioid administration required.

Secondary outcome measures
1. To assess mental function using a standard ten point scale (Abbreviated Mental Test Score [AMTS]) and a 30 point scale (Mini Mental State Examination [MMSE]) before and after the operation, comparing the two groups
2. To assess mobility and function, using a modified Physiotherapy Functional Mobility Profile (PFMP) and achievement of activities for daily living score (MIMS), before and after the operation, comparing the two groups
3. To monitor the lengths of stay in the two groups
4. To monitor the incidence of death in the two groups at 30 days and 90 days
5. To monitor the levels and incidence of infections to the wound, prosthesis and/or catheter post operatively

Overall study start date
20/02/2004

Completion date
30/10/2008

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Fractured proximal femur
3. Capable of informed consent
4. Written informed consent obtained

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
268

Key exclusion criteria

1. Documented allergy to bupivacaine
2. Infection at the site of catheter placement
3. Aged under 18 years
4. Unable to give informed consent
5. Refusal to give informed consent

Date of first enrolment
20/02/2004

Date of final enrolment
30/10/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Anaesthetics Department
Torquay
United Kingdom
TQ2 7AA

Sponsor information

Organisation
South Devon Healthcare NHS Trust (UK)

Sponsor details
Torbay Hospital
Lawes Bridge
Torquay
England
United Kingdom
TQ2 7AA

Sponsor type
Hospital/treatment centre

Website
http://www.sdhct.nhs.uk/

ROR
https://ror.org/05374b979

Funder(s)

Funder type
Charity

Funder Name
Torbay Medical Research Fund

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	01/12/2007		Yes	No