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FIB trial: Fascia-iliaca block versus 'three-in-one' block for femoral neck fractures

Submission date	Recruitment status	[_] Prospectively registered
23/04/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/05/2016	Injury, Occupational Diseases, Poisoning	

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
7820

Study information

Scientific Title
Randomised trial of the fascia-iliaca block versus the 'three-in-one' block for femoral neck fractures in the emergency department

Acronym
FIB trial

Study objectives
The FIB trial is a two group randomised equivalence trial investigating the effects of the fascia-iliaca block versus the "three-in-one" block on pain scores and analgesia requirement in the subsequent 24 hour period, in patients with radiologically confirmed fractured neck of femur presenting to the emergency department. The primary null hypothesis is that the fascia-iliaca block will be as effective as the "three-in-one" block in reducing pain and anlagesia requirement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Frenchay Ethics Committee approved on the 14th February 2008 (ref: 07/H0107/65)

Study design
Randomised interventional process of care trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Topic: Injuries and Accidents; Subtopic: Injuries and Accidents (all Subtopics); Disease: Injuries & Accidents

Interventions
Intervention arm:
Fascia-iliaca block (FIB): At the point 1 cm beneath the junction of the outer and middle thirds of a line drawn between the superior anterior iliac crest and the pubic tubercle a 18G tuohy needle is inserted at 90 degrees until two distinct pops are felt as it penetrates the fascia lata and then

fascia iliaca. The needle is aspirated to exclude intra-vascular placement and the sub-fascial compartment is then filled with 2 mg/kg (max 150 mg) of bupivicaine solution diluted to a volume of 30 ml if required.

Control arm:
3 in 1 Femoral Nerve Block: At the femoral crease immediately lateral to the femoral arterial pulse a stimuplex needle will be guided to within the femoral sheath using a nerve stimulator. When the needle is appropriately placed linear patellar movement will be seen at 30 mV but not less than 30 mV. At this time the needle will be aspirated to exclude intra-vascular placement and femoral sheath is injected with 2 mg/kg (max 150 mg) of bupivicaine solution diluted to a volume of 30 ml if required whilst occluding the femoral sheath to prevent distal LA spread.

Follow up period: 24 hours

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain as measured by the Visual Anologue Scale (VAS) score (0 = no pain, 10 = unbearable pain), at 0 minutes, 30 minutes and 60 minutes

Secondary outcome measures
1. Analgesia consumption: sum quantity of analgesia given within 24 hours of the block, measured at 24 hours post-nerve block
2. Hospital length of stay

Overall study start date
01/12/2008

Completion date
01/12/2010

Eligibility

Key inclusion criteria
1. Patients with radiologically confirmed unilateral fractured neck of femur presenting to emergency department
2. Capacity to consent to participate in study
3. Aged greater than or equal to 18 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
Planned Sample Size: 190

Key exclusion criteria
1. Patients unable to consent due to delirium, dementia or incapacity
2. Patients with other distracting painful pathology; patients with reduced level of consciousness
3. Patients who present greater than 24 hours post-injury
4. Patients for whom use of local anaesthesia agents is contraindicated
5. Patients who decline to take part in the study
6. Patients who are unable to speak or understand English

Date of first enrolment
01/12/2008

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Royal Infirmary
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
Bristol Royal Infirmary (UK)

Sponsor details
Gastroenterology Research Group, Research Floor Level 7
Bristol Royal Infirmary
Marlborough Street
Bristol
England
United Kingdom
BS2 8HW

Sponsor type
Hospital/treatment centre

Website
http://www.uhbristol.nhs.uk/your-hospitals/bristol-royal-infirmary.html

ROR
https://ror.org/031p4kj21

Funder(s)

Funder type
University/education

Funder Name
The College of Emergency Medicine (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	01/09/2015		Yes	No