

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

Submission date
23/04/2010

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
23/04/2010

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
24/05/2016

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

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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 analgesia 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 bupivacaine 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 bupivacaine 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 Analogue 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 |