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Study of monitoring blood concentration of local anaesthetic after a nerve block in elderly patients with hip fracture

Submission date
19/12/2016

Recruitment status
No longer recruiting

Registration date
21/12/2016

Overall study status
Completed

Last Edited
11/10/2019

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
A commonly used technique to help provide pain relief is performing a nerve block. This technique involves a local anaesthetic (numbing) fluid being injected into the area that is painful in order to relieve pain by blocking pain signals sent by nerves. Elderly patients with hip fractures admitted to East Surrey Hospital (ESH) routinely receive a type of nerve block called a Fascia Iliaca Compartment Block (FICB). The nerve block is performed shortly after admission and involves injecting a local anaesthetic called levobupivicaine into an area at the top of the thigh to provide pain relief. Over time local anaesthetic is absorbed from the site of injection into the blood. Currently there is very little research describing how long it takes for the local anaesthetic to reach the best concentration levels in the plasma (fluid part of blood), and even fewer studies focusing on an elderly population. The aim of this study is to identify a technique for monitoring plasma local anaesthetic concentration after FICB in elderly patients with hip fractures.

Who can participate?
Patients over the age of 80 years with confirmed hip fractures who receive FICB as part of routine care.

What does the study involve?
All participants receive a FICB are per the standard care protocol at East Surrey Hospital. This involves injection of 30ml of local anaesthetic (0.25% levobupivacaine) into a specific point in the groin on the same side as the hip fracture. The local anaesthetic spreads to affect multiple nerves supplying sensation to the hip and leg, thereby providing effective pain relief. Participants have an intravenous catheter (thin tube inserted into a vein) put in place which is used to take samples of blood 10, 20, 30, 45, 60, 75, 90, 105, 120, 240 minutes after the FICB. Pain levels are assessed at the same time as blood samples are taken using a scale from 0-10 when at rest and when raising the affective hip slightly. After the 4 hour study period is complete and the final blood sample has been taken, there are no further requirements for participants. The intravenous catheter is then removed and usual care continues.

What are the possible benefits and risks of participating?
There are no direct potential benefits to participants for participating in this study however routine care will not be disadvantaged in any way. There is a minor risk of temporary and mild discomfort on insertion of the catheter, bruising and phebilitis (inflammation around the vein) from the intravenous catheter. In addition, a number of rare complications may occur. These complications only tend to occur when catheters remain in situ for several days or weeks. In this study the catheter will only be in place for 4 hours, therefore it would be extremely unlikely that a participant will encounter any of the following, but they still remain as potential risks: catheter blockage or blood clots, damage to the catheter, infection at the catheter insertion site or air embolism (blockage in the vein caused by an air bubble).

Where is the study run from?
East Surrey Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2015 to November 2017

Who is funding the study?
Regional Anaesthesia - UK (UK)

Who is the main contact?
Dr Peter Odor
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32449

Study information

Scientific Title
Pilot study of a plasma local anaesthetic monitoring regime after fascia iliaca block in elderly patients

Study objectives
The aim of this study is to identify an optimised sampling strategy for monitoring plasma local anaesthetic concentration after Fascia Iliaca Compartment Block (FICB) in elderly patients with hip fractures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Central Research Ethics Committee, 31/09/2016, ref: 16/LO/1321

Study design
Non-randomised; Interventional; Design type: Process of Care, Management of Care

Primary study design
Interventional

Secondary study design
Non randomised study

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
Specialty: Anaesthesia, perioperative medicine and pain management, Primary sub-specialty: Anaesthesia, Perioperative Medicine and Pain Management; UKCRC code/ Disease: Injuries and Accidents/ Injuries to the hip and thigh

Interventions
All patients recruited into the study are admitted to hospital with a fractured neck of femur and will receive an analgesic nerve block, called a fascia iliaca compartment block (FICB) prior to surgery. The intervention in the study is to place an intravenous catheter for sampling blood

following injection of local anaesthetic during the nerve block. Blood sampling involves removal of less than 5ml of blood on each occasion and occurs at the following time intervals following FICB: 10, 20, 30, 45, 60, 75, 90, 105, 120, 240 minutes. Pain scores at rest and on 15 degree passive straight leg raise will be recorded using the Numerical Rating Scale (NRS-11) system.

Blood samples will be tested using a validated GC-MS and ELISA assays to produce data on plasma levobupivacaine and alpha-1 glycoprotein concentration.

Investigators will review patient records to obtain relevant data on patient age, weight, height, gender, renal function, albumin and concurrent medication, intravenous fluid administration and supplemental analgesia provided.

Intervention Type
Other

Primary outcome measure
Pharmacokinetic profile of levobupivacaine is measured through blood testing on samples taken at baseline and 10, 20, 30, 45, 60, 75, 90, 105, 120, 240 minutes after the FICB.

Secondary outcome measures
1. Relationship between time and pain after fascia iliaca compartment block is measured through blood testing and visual analogue scale (VAS) on samples taken at baseline and 10, 20, 30, 45, 60, 75, 90, 105, 120, 240 minutes after the FICB
2. Range of alpha-1 glycoprotein plasma concentration in elderly patients with hip fracture is measured through blood testing on samples taken at baseline and 10, 20, 30, 45, 60, 75, 90, 105, 120, 240 minutes after the FICB
3. Patient demographics, renal function, intravenous fluid administration, supplemental analgesia requirements are measured using medical record review at baseline

Overall study start date
01/08/2015

Completion date
01/11/2017

Eligibility

Key inclusion criteria
1. Informed consent: signed written informed consent before inclusion in the study
2. Radiologically-confirmed fractured neck of femur
3. Age 80 years and over
4. Scheduled to receive fascia iliaca compartment block (to be done by anaesthetic team, as per standard local care protocol)

Participant type(s)
Patient

Age group
Senior

Sex

Both

Target number of participants
Planned Sample Size: 8; UK Sample Size: 8

Total final enrolment
12

Key exclusion criteria
1. Patient refusal or incapacity
2. Patient on anticoagulation medication
3. INR > 3.0
4. Platelets < 50
5. Allergy or contraindication to local anaesthetics
6. Local infection to site of FICB injection or blood sampling
7. Creatinine >300 or receiving renal replacement therapy or dialysis
8. Patients requiring Level 2 or 3 care
9. Estimated weight < 40kg or > 120kg

Date of first enrolment
14/11/2016

Date of final enrolment
15/05/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
East Surrey Hospital
Canada Avenue
Redhill
United Kingdom
RH1 5RH

Sponsor information

Organisation
Surrey and Sussex Healthcare NHS Trust

Sponsor details

East Surrey Hospital
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0480vrj36

Funder(s)

Funder type
Research organisation

Funder Name
Regional Anaesthesia - UK (RA-UK)

Results and Publications

Publication and dissemination plan
Planned presentation at the European Society of Regional Anaesthesia Meeting 2018.
Publication in high-impact, peer reviewed journal within one year of the overall trial end date.

Intention to publish date
01/11/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the chief investigator.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2019	03/05/2019	Yes	No
HRA research summary			28/06/2023	No	No