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The FINOF - Femoral nerve-block Intervention in Neck Of Femur fracture study

Submission date
25/10/2012

Recruitment status
No longer recruiting

Registration date
26/10/2012

Overall study status
Completed

Last Edited
26/11/2018

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Hip fracture is one of the most serious injuries that occur in older people. These fractures are very painful and traditionally require potent analgesia (painkillers), which are effective but have side effects including nausea, vomiting, constipation and confusion. The patient may then refuse treatment and remain in pain, or in some cases remain pain-free if they lie in bed, but struggle when walking. Techniques which directly involve numbing the nerves around the hip have been proposed as an alternative and practical method of reducing pain when moving and at rest. However, no study has evaluated numbing of the main nerve in the leg (called femoral nerve block), its effects on overall pain control, and its acceptability to staff and patients compared with standard analgesia. The aim of this study is to find out whether femoral nerve block controls pain more effectively compared to standard analgesia.

Who can participate?
Patients aged 70 and over with an acute hip fracture.

What does the study involve?
Participants are randomly allocated to be treated with either a femoral nerve block or standard analgesia.

What are the possible benefits and risks of participating?
We expect that femoral nerve block will result in fewer side effects, earlier recovery, shorter length of stay in hospital and improved quality of life for patients suffering with an acute hip fracture. The most commonly reported side effects of the drugs used for the femoral nerve block are: low blood pressure, nausea, anaemia, vomiting, dizziness, headache, fever, procedural pain, back pain, and ‘pins and needles’.

Where is the study run from?
Queens Medical Centre, Nottingham University Hospitals NHS Trust, Nottingham, UK.

When is the study starting and how long is it expected to run for?
January 2012 to December 2012.

Who is funding the study?
Nottingham University Hospitals NHS Trust (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2010-023871-25

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10929

Study information

Scientific Title
The FINOF - Femoral nerve-block Intervention in Neck Of Femur fracture study

Acronym
FINOF

Study objectives
Hip fracture is one of the most serious injuries that occur in older people. These fractures are very painful and traditionally require potent opioid/opioid related analgesia, which although effective, has undesired adverse events.

Common side-effects include nausea, vomiting, constipation, and more infrequently, but importantly, delirium. Patient may then refuse treatment and remain in pain or in some cases find if they lie in bed, remain pain-free, but struggle during ambulation. This leads to further complications, impaired rehabilitation and prolonged hospital stay.

Techniques which directly involve numbing the nerves around the hip, have been proposed as an alternative and practical method of alleviating both rest and dynamic pain (important when patients are being transferred or ambulating). However no study has evaluated numbing of the main nerve in the leg (femoral nerve) and the effects on overall pain control, rehabilitation and issues of compliance, acceptability to staff / patients compared to standard analgesic regimes.

We plan to undertake a 12 month randomised controlled study of 150 elderly patients admitted with an acute hip fracture. Subjects on admission, following informed consent will be randomly allocated to a nerve block, followed by a continuous nerve block infusion or standard analgesic care.

We envisage nerve block analgesia compared to conventional analgesia will result in fewer drug related adverse events, earlier recovery, shorter length of stay in hospital and overall, improved quality of life for patients suffering with an acute hip fracture.

Acceptability and implementation will be measured by semi-structured interviews with both staff and patients focusing around pain (patient group) and ease of use (staff group) which will help the implementation of these findings across the country.

More details can be found at: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=10929

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham Research Ethics Committee 2, 28/01/2011, ref: 10/H0408/113

Study design
Randomised controlled 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
Hip fracture

Interventions
1. Standard analgesic care
2. Femoral nerve block followed by insertion of a femoral catheter and continous femoral nerve block

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Cumulative dynamic pain score
2. Cumulative ambulation score

Measured from day 1 to day 3 post operatively

Secondary outcome measures
1. Cumulative dynamic pain score preoperatively (at 30 mins, 60 mins, 12 hours following the initial femoral nerve block)
2. Cumulative side effects (nausea, vomiting, constipation, delirium) (from admission to day three post-operatively)
3. Cumulative calorific and protein intake (from admission to day 3 post-operatively)
4. Health related quality of life, measured using the EUROQOL EQ-5D (14) informing a cost effectiveness analysis
5. Hospital length of stay
6. Rehabilitation outcome, measured by New Mobility Score
7. Participant and staff experience (qualitative study)

Overall study start date
02/01/2012

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Aged 70 years and over
2. Resident in their own home or warden aided flat
3. Patients who are cognitively intact [as defined by a score of seven or more on the Abbreviated 10 point Mental Test Score (AMTS)
4. A prior fracture New Mobility Score of 3 or more (indicating independent indoor ambulation)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 150; UK Sample Size: 150

Key exclusion criteria
1. Prefracture hospitalisation
2. Contraindications to femoral nerve block analgesia
3. Regular prefracture opioid or glucocorticoid therapy
4. Alcohol or substance abuse
5. Morphine intolerance, and postoperative surgical restrictions for ambulation

Date of first enrolment
02/01/2012

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queens Medical Centre
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust (UK)

Sponsor details
MRC Institute of Hearing Research Nottingham Clinical Section
Eye Ear Nose and Throat Centre
Queens Medical Centre
Derby Road

Nottingham
England
United Kingdom
NG7 2UH

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB)

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?
Protocol article	protocol	24/05/2014		Yes	No
Results article	results	10/04/2018		Yes	No
HRA research summary			28/06/2023	No	No