

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

Submission date 25/10/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/10/2012	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 26/11/2018	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Clinical Trials Information System (CTIS)
2010-023871-25

Protocol serial number
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

Study type(s)

Treatment

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 continuous femoral nerve block

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Cumulative dynamic pain score
2. Cumulative ambulation score

Measured from day 1 to day 3 post operatively

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre**Queens Medical Centre**

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

Nottingham University Hospitals NHS Trust (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

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