ISRCTN46653818 https://doi.org/10.1186/ISRCTN46653818

Femoral nerve blockade in hip fracture patients

Submission date	Recruitment status	[ ] Prospectively registered
30/03/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/05/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/05/2009	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

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
N/A

Study information

Scientific Title
Femoral nerve blockade in hip fracture patients: a randomised controlled trial

Study objectives
Femoral nerve blockade reduces pain and the need of opioids and therefore also post-operative delirium and complications in hip fracture patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the Faculty of Medicine at Umea University approved on the 7th October 2008 (ref: 08-121M)

Study design
Randomised controlled trial

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
Patients are randomised to femoral nerve blockade or the regular use of opioids. Both groups will receive 1 g of paracetamol 4 times/day. The patients in the intervention group will receive a femoral nerve blockade as soon as they arrive at the Orthopaedic Department. If the patients in the intervention group assess pain according to Visual Analogue Scale (VAS) more than 4 then they will be given morphine intravenously (iv) according to the standard protocol (morphine 10 mg/ml, 1 - 5 mg when necessary). Patients in the control group will be given morphine iv according to the standard protocol when they assess pain according to VAS more than 4 but no blockade (morphine 10 mg/ml, 1 - 5 mg when necessary). Post-operative pain treatment will be given according to the standard protocol in both arms of the study. The total follow-up of the trial for both arms will end at the time of discharge.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Post-operative delirium, assessed three times a day at the Orthopaedic Department
2. Post-operative complications, such as decubital ulcers, infections, thrombosis, heart failure, assessed three times a day at the Orthopaedic Department
3. Pain, assessed three times a day at the Orthopaedic Department

A cognitive test will be assessed in the ambulance pre-hospitally and at 24 +/- 6 hours post-operatively. At days three to five a more thorough assessment will be done including delirium, depression, cognitive status, quality of life and more.

Secondary outcome measures
1. Mortality
2. Orthopaedic recovery, recorded at the time of discharge from the hospital
3. EQ-5D
4. Economics

A cognitive test will be assessed in the ambulance pre-hospitally and at 24 +/- 6 hours post-operatively. At days three to five a more thorough assessment will be done including delirium, depression, cognitive status, quality of life and more.

Overall study start date
30/03/2009

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Both males and females, aged 70 years and above
2. All hip fracture patients admitted to the Orthopaedic Department

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
250

Key exclusion criteria
1. Local infection
2. Allergic to local anaesthesia
3. Dying patients
4. Pathologic hip fractures

Date of first enrolment
30/03/2009

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Sweden

Study participating centre
Operationscentrum
Umea
Sweden
SE-901 85

Sponsor information

Organisation
Umeå University (Sweden)

Sponsor details
-
Umea
Sweden
SE-901 87

Sponsor type
University/education

Website
http://www.umu.se/umu/index_eng.html

ROR
https://ror.org/05kb8h459

Funder(s)

Funder type
Government

Funder Name
County Council of Västerbotten (Västerbottens läns landsting [VLL]) (Sweden)

Funder Name
Umeå University (Sweden)

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