Femoral Nerve Blockage in Proximal Femoral Fractures in patients of 65 years of age or older, a Randomised Controlled Trial

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON45916

Source
ToetsingOnline

Brief title
Femoral Nerve Blockage in Proximal Femoral Fractures

Condition

- Bone and joint injuries
- Bone and joint therapeutic procedures

Synonym
Hip fracture / Proximal femoral fracture

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: vakgroep orthopedie

Intervention

Keyword: Hip fracture, Nerve blockage

Outcome measures

Primary outcome

Raw pain intensity difference (PID) up to 4 hours after femoral nerve blockage.

The raw PID was calculated as the change from baseline NRS for each measurement in time. The PID will be calculated from the first measured Numeric Rating Scale (NRS) (worst pain in the hour before the femoral nerve blockage).

NRS for pain will be measured using a 11-point scale ranging from 0 (no pain) to 10 (worst pain imaginable) at admission (before randomization), 1 hour, 2 hours and 4 hours after femoral nerve blockage.

The percentage of patiënts with and without complications will be recorded.

Next we will record every individual complication.

Secondary outcome

For the amount of opioid use, the electronic dossier of the patient will be reviewed. NRS for pain will be measured at 1, 2, 6 and every 6 hours after the nerve blockage until the operation.

After surgery, NRS for pain will be monitored twice daily. Post-operative mobility score will be scored daily using the Cumulated Ambulation Score (CAS) for first three postoperative days.

Study description

Background summary

With an average age of 81 years fractures of the hip are frequently seen in the elderly (Court-Brown and Caesar, 2006). In this elder population three out of four hip fractures occur in women and show an annual incidence of 793.5 per 100,000 in women and 368.0 in men (Holt et al., 2008; Wiles et al., 2011) Hip fractures show high mortality rates up to 30% after 1 year (Wiles et al., 2011). Moreover 4.5-14.3% of these vulnerable patients die during their admission (Bottel and Aylin, 2006; Belmont et al. 2014).
Pain reduction is one of the main treatment goals in hip fractures. Primarily for the patient*s comfort, but also to reduce complications and improve rehabilitation. Patients with severe pain have a higher chance to develop a delirium (morrisson et al.). Furthermore, pain is related with longer hospital stays, delayed ambulation and persistent disabilities (Morrison et al., 2003; Morrison et al., 2003). Controversially these frail patients are less likely to receive pain medication in comparison to younger patients (Jones et al., 1996; Platts-Mills et al., 1996).
Many different analgesics can nowadays be used to reduce pain. In many institutes analgesics in trauma patients are chosen according to the WHO pain ladder that was originally developed for cancer pain control (Vargas-Schaffer, 2010). According to this ladder mild pain is best treated with paracetamol and shows little adverse events. The use of NSAIDs is frequently contraindicated in the elder population due to gastrointestinal and renal complications, therefore this step is skipped in most cases and opioids are prescribed (Holdgate et al. 2010). However, these opioids have several possible side effects. It is therefore recommended to monitor patients on opioids for side-effects like nausea, constipation and respiratory depression (Chau et al., 2008; Cepeda et al., 2003).
Local anaesthetics can be a good additive or substitute for systemic analgesia in trauma patients with a hip fracture (De Buck et al., 2012). At this moment two different techniques are potentially suitable in hip fractures; fascia iliaca compartment block (FICB) and femoral nerve blockage (FNB). However, current literature for nerve blockage in hip fractures is scarce and inconclusive. Furthermore, there is discussion on the best way to improve the duration of the analgesia since single injection on admission might not be adequate as they only provide analgesia for up to 24 hours. Therefore, it is proposed to use a perineural catheter which allows prolonged delivery of local anaesthetic (Sahota et al., 2014). However, these catheters are not used by emergency physicians (EPs) and its usefulness might therefore be questionable.
We therefore propose to study the effect of a FNB after a hip fracture at admission compared to a placebo injection regarding pain, complications and functional outcome. If necessary, the FNB can be repeated to prolong the duration of the analgesia.

Study objective

The objective of this study is to determine the clinical outcomes of ultrasound guided femoral nerve blockage using intermitting shots of levobupivacaine, in patients with hip fractures and to compare these results with placebo injections.
The primary objective is to investigate if femoral nerve blockage leads to a decrease in pain and a decrease in complications (delirium, nausea, vomiting, obstipation, hypotension, urinary retention, and respiratory depression). This will be measured with the raw pain intensity difference up to 4 hours after the femoral block. The percentage of patiënts with and without complications will be recorded. Next we will record every individual complication.
The secondary objectives of this study include the pain measured with NRS on multiple moments before and after surgery, the amount of analgesics used (paracetamol, non-steroid anti-inflammatory drugs and opioids), length of hospital stay, post-operative mobility status and subsequent discharge location.

Study design

This is a double-blind randomized controlled trial. Participants will be randomized into one of two arms: femoral nerve block with 0,25% Levobupivacaine 20ml or femoral nerve block with saline 20ml. Patient will be included into the study immediately after radiographic confirmation of the hip fracture. Before start of the study, the hospital pharmacy will perform randomization. Since the study is double blind the hospital pharmacy will pack and blind the femoral nerve blockage syringes supplied with a randomization number by a person not affiliated with the project.

Intervention

The emergency physician will perform the ultrasound guided femoral nerve block with either Levobupivacaïne or plcebo sham injection.
If the patient is transferred to the nursing room, the nurse of the department will measure NRS for pain. If necessary, the emergency physician will perform a second femoral nerve block (with the blinded syringe containing the same content as the first syringe). The second femoral nerve block will not be performed before 6 hours after the first block.

Study burden and risks

The burden is highest during the femoral nerve blockage. This will comprise a echo guided injection and will take a maximum of 15 minutes.
Asking NRS for pain is standard care. Physiotherapy in the first postoperative days is standard care as well.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Proven proximal femoral fracture (trochanteric, head and neck fractures)
- Normal lower extremity anatomy and neurovascular examination
- NRS pain score of *4 at admission
- Aged 65 or older

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Cognitive impairment; previous diagnosed with dementia or MMSE * 22
- Delirium at inclusion
- No good understanding of the Dutch language
- Known hypersensitivity to local anaesthetics or morphine
- Multi-trauma patients
- Pre injury use of opioids
- Pre injury bedridden or wheelchair bound patients

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	84
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Chirocaine
Generic name:	Levobupivacaine
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	22-02-2016

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	25-04-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	03-05-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2005-004119-19-NL
CCMO	NL54756.098.16