A comparison of pericapsular nerve group block, fascia-iliaca compartment block and femoral nerve block for pain management in patients with hip fracture in the emergency department - A randomized controlled trial

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The aim of this study is to compare the efficacy and safety of preoperatively placed Pericapsular Nerve Group block (PENG), Fascia-Iliaca Compartment Block (FICB) and Femoral Nerve Block (FNB) for patients with hip fractures in the ED.

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON57433

Source
ToetsingOnline

Brief title
CPFF-ED

Condition

- Bone and joint injuries

Synonym
hip fracture - broken hip

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Medisch Centrum Leeuwarden

Intervention

Keyword: Emergency department, Hip fracture, Nerve block, Regional anaesthesia

Outcome measures

Primary outcome

Score on the patient-reported QoR-15 questionnaire.

Secondary outcome

o Pre-operative pain scores at 15 min-, 30 min-, and 1 hour post-block

placement.

o The amount of rescue medication calculated as mg/hour given IV in the ED

after block placement or SC/IO in the ward during the first 12 hours after

block placement or until operation.

o Number and type of adverse and serious adverse events.

Study description

Background summary

An aging population will result in a growing prevalence of hip fractures. Hip fractures pose an increased risk of mortality, morbidity, and functional impairment.

Adequate perioperative pain reduction is of utmost importance as pain is an important factor influencing complication rates, posing a significant risk for decreased functional outcomes. Systemic analgesia is commonly used in the pain management of patients with hip fractures, including opioids (e.g. morphine or fentanyl). However, opioids are associated with adverse events. An alternative

method to obtain adequate analgesia is the use of regional nerve blocks. Nerve blocks have several advantages over systemic analgesia. First, they may provide superior analgesia. Second, they contribute to a reduction in opioid use and opioid-related adverse events. Recent guidelines therefore advise to use regional anaesthetic techniques for pain management in hip fractures.

Currently, there are three different types of nerve blocks for pain management for hip fractures: Femoral Nerve Block, Fascia-Iliaca Compartment Block en Pericapsular Nerve Group Block. So far, literature directly comparing the different options to provide regional anaesthesia after a hip fracture is scarce, and not focussed on early administration of nerve blocks in the emergency department (ED).

Study objective

The aim of this study is to compare the efficacy and safety of preoperatively placed Pericapsular Nerve Group block (PENG), Fascia-Iliaca Compartment Block (FICB) and Femoral Nerve Block (FNB) for patients with hip fractures in the ED.

Study design

This study is a Randomized Controlled Trial (RCT).

Intervention

Participants will receive either FNB, FICB or PENG block.

Study burden and risks

Although PENG, FICB and FNB are overall safe when performed correctly, there are some risks associated with these procedures. These risks include: bleeding (1-2% chance), infection, damage to surrounding structures, (permanent) nerve injury, and intravascular uptake of local anesthetic resulting in systemic toxicity (LAST). In addition, there is a 5-10% chance that the block provides suboptimal analgesia with the need for additional analgesics. Important to note is that PENG, FICB and FNB are all standard care in the ED. However, since all included types of regional anesthesia in the setting of traumatic femur fractures are part of well-established clinical practice, there is no additional risk for the patients participating in this study.

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

- 18 years or older.
- proximal- or neck of femur fracture requiring surgical intervention.
- Able and willing to provide informed consent and reliably report symptoms to the research team.

Exclusion criteria

- Known allergy to local anaesthetics.
- Infection at the injection-site.
- Periprosthetic fracture.
- Skin injury, local infection or recent burns hindering the use of ultrasound for ultrasound guided nerve block placement.
- Multiple fractures simultaneously.
- Pain score of < 2 (range 0 - 10) or < 20 (range 0 - 100) in rest or when

moving in bed, when presented to the ED.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2025
Enrollment:	198
Type:	Anticipated

Ethics review

Approved WMO

Date:	30-01-2025
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
CCMO	NL87859.099.24