MORphine use in the Fascia Iliaca Compartment block with UltraSound

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47062

Source
ToetsingOnline

Brief title
MORFICUS

Condition

- Other condition
- Bone and joint injuries

Synonym
Injection with painmedication to obtain anesthesia of the hip

Health condition

Regionale Pijnstilling

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Fresenius Medical Care,Medicatie en materialen worden uit onderzoeksbudget van het ziekenhuis gefinancierd. 5000 via het SGO fonds.

Intervention

Keyword: femur fracture, FICB, hip fracture, Levobupivacaine, PCA, Ultrasound

Outcome measures

Primary outcome

The main study endpoint will be the mean preoperative morphine use between the

groups.

Secondary outcome

Secondary parameters will include the pain scores reported by the numerical

rating scale both at rest and during transport to another bed and side effects

from morfine are compared.

Study description

Background summary

Appropriate management of analgesia for proximal femur fracture is a common problem in the emergency department (ED). Side effects are especially pronounced in elderly. Fascia Iliaca Compartment Block (FICB) holds promise as a simple and safe, and effective method to reduce pain. Local anesthetic injected in the anatomic space underlying the fascia iliaca, spreads to block the nerves traversing it. This regional anesthesia includes the femoral nerve. Previous studies showed promise but lacked blinding, involved low numbers of subjects, or did not use ultrasound localisation of the injection site. The latter is becoming common practice. In this randomised placebo controlled trial the FICB with ultrasound localisation of injection of levobupivacaïne will be compared to the FICB with placebo. It aims to prove that less morphine is used in the intervention group. Other research parameters are pain scores, length of hospital stay and minor adverse events related to morphine use. Major adverse

events will be reported separately.

Study objective

The main study endpoint will be the mean preoperative morphine use per hour in patients with and without FICB with levobupivacaine, guided by ultrasound. Secondary parameters will include the pain scores reported by the numerical rating scale both at rest and during transport to another bed, and minor adverse events are compared.

Study design

The study is designed as a double-blinded randomized placebo-controlled trial. Study medication will be prepared and blinded by the hospital pharmacy.

Intervention

Ultrasound guided FICB will be performed after radiological diagnosis. Two groups will be assigned randomly to injection of weight based volume and dosage of levobupivacaïne or weight based volume of sodium chloride which is used as placebo. Escape medication will consist of morphine, which will be administered by intravenous patient controlled analgesia (PCA).

Study burden and risks

After the diagnosis patients will be informed of the study and will be asked for written consent. The FICB will be performed as a single injection. All patients will receive adequate additional pain management. Simultaneous pain, nausea and delirium assessments will be carried out preoperatively, according to standard hospital procedures for pain management. No severe adverse events have been reported on the FICB in previous literature. Nevertheless necessary preventative measures and safety precautions will be made.

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

Adult patient diagnosed with a proximal femur fracture upon arrival at the ED.

Exclusion criteria

No informed consent patient;Skin infection at injection site(s);Morphine allergy;Levobupivacaine allergy;Operation within an hour after admission;Inability to understand and quantify pain on a NRS;Dementia;Neurological deficit of fractured leg upon arrival at the ED;Trauma with multiple fractures (more than 1);Risk of compartment syndrome of ipsilateral lower leg.;Proximal femur fracture with other definitive treatment than operation;Transfer to another hospital;Actual morphine use;Distracting pain in other location than hip;Pregnancy;No physician/nurse available for procedure.;BMI > 40;Saturation < 90%

Study design

Design

Study phase:	4
Study type:	Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2019
Enrollment:	120
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Chirocaïne
Generic name:	Levobupivacaïne
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	04-01-2017
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	29-05-2017
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	30-10-2018
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	EUCTR2016-004698-42-NL
CCMO	NL60104.096.16