Ultrasound guided fascia iliaca block: a comparison with the landmark method

Published: 26-09-2017
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Percentage of accurate guessed blocks

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45479

Source
ToetsingOnline

Brief title
Ultrasound guided fascia iliaca block versus landmark method

Condition

- Other condition

Synonym
pain management

Health condition

analgesie

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: onderzoekers

Intervention

Keyword: FICB, hipfracture, landmark methode, ultrasound

Outcome measures

Primary outcome

Reduction in pain during immobilisation by using the visual analogue scale 60 minutes after block placement.

Secondary outcome

- Accordance between preceived block and guessed block by the patient
- Time of maximum pain reduction after block placement
- De difference in VAS reduction during dynamic and static exam after block placement
- Side effects of the fascia iliaca compartment block (infection, hematoma, sensibility disorder, allergic reactions)

Study description

Background summary

Hip and femur fractures are common. These patients experience a lot of pain. Sufficient analgesia may be given by systemic administered paracetamol, NSAIDS, opiates and regional nervous blockade. A fascia iliaca compartment block, a FICB, is a form of regional anesthesia that can reduce the femoral nerve, lateral cutaneous nerve and (possible) obturator nerve. Onset after successful placement of the block with levobupivacaine is 15-30 minutes and last up to 12 hours. The advantage of a block is that no or lower amounts of systemic opiates need to be given. An FICB can be placed ultrasound guided or according to the landmark method. The literature states that a FICB can be used safely and efficiently, and there are almost no complications registered with only minor local side effects. It is also a technique that can be easily learned.
However, in the current investigations, various methods, times after FICB placement and outcomes are described, making this research difficult to generalize, and difficult to use for calculating power for a new study. In

addition, blindering of patients and outcome assessors did not take place in earlier studies. This may have led to distorted outcomes of those studies. Both the landmark method and the echo-guided method are applied within the Isala. These two methods have not previously been investigated side by side with respect to reduction in pain score expressed from 0 to 100 mm on a visual analog scale (VAS). We want to investigate with this pilot study the ability to test these methods double-blind, to also see which moment after the block can be used (both methods) for the primary pain reduction (pre and post block) and a better estimation of the reduction in pain between both methods, so that an RCT could possibly be done in the future to compare the efficiency between the two methods.

Study objective

Percentage of accurate guessed blocks

Study design

Randomised double blinded pilot study

Intervention

Group 1: Fascia iliaca compartment block with landmark methode
Group 2: Ultrasound guided fascia iliaca compartment block

Study burden and risks

There is no added burden. Possible risks are infection, hematoma and allergic reactions.

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

- Adults
- Hip fracture

Exclusion criteria

- Allergy for levobupivacaïne
- Infection at injection site
- INR > 1,5
- Previous femoral vascular surgery at fracture site
- Non-cooperative patient and reduced level of consciousness

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	26-09-2017
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	EUCTR 2016-003605-3-NL
CCMO	NL59101.075.16