

# A comparison of ultrasound-guided fascia iliaca compartment block versus parenteral opioids for analgesia in emergency department patients with hip fractures: a single centre randomised controlled study

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The primary objective of this study is to compare the efficacy of ultrasound-guided fascia iliaca block (FICB) to standard treatment with parenteral opioids for pain control in patients with hip fractures in the emergency department. Is there a...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON40710

### Source

ToetsingOnline

### Brief title

Analgesia for emergency department patients with hip fractures

### Condition

- Other condition
- Bone and joint therapeutic procedures

### Synonym

collum fracture, hip fracture

## Health condition

pijnstillend

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Sint Franciscus Gasthuis

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** emergency department, hip fractures, systemic opioids, ultrasound-guided fascia iliaca block

## Outcome measures

### Primary outcome

Primary outcome of the study:

patient reported pain scores, ranging from 0 (no pain) to 10 (worst pain imaginable)

### Secondary outcome

Secondary outcome of the study:

- side effects/complications
- period of time spending at the emergency department until adequate pain reduction (pain score  $\leq 4$ )
- proportion successful FICB
- patients experience

## Study description

### Background summary

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Annual, about 350 patients present at the emergency department of the Sint Franciscus Gasthuis with a painful hip fracture.

Patients who experience pain from hip fracture are often treated with intravenous opiates, which may cause deleterious side effects, particularly in elderly patients.

An alternative to systemic opioid analgesia involves peripheral nerve blockade. Multiple studies concluded that the fascia iliaca compartment block (FICB) is a fast, safe and effective method of providing pain relief to patients with fracture of the femur. After a successful block, the subsequent requirement of opioids is reduced which avoids potential side effects such as nausea, vomiting, delirium and respiratory depression, especially in elderly patients. This approach may be ideally suited for the ED environment, where one injection could control pain for many hours.

In Sint Franciscus Gasthuis the current practice for pain relief in patients with fracture of the femur is still opioids.

## **Study objective**

The primary objective of this study is to compare the efficacy of ultrasound-guided fascia iliaca block (FICB) to standard treatment with parenteral opioids for pain control in patients with hip fractures in the emergency department.

Is there a significant reduction in pain between arrival and departure of the emergency department in patients with femur fracture that were treated by ultrasound-guided femoral nerve block? Is there a significant reduction in pain when patients received parenteral opioids?

Secondary objectives:

1. incidence of side effects in parenteral opioids vs FICB
2. percentage successful FICB
3. duration of adequate pain relief in FICB vs parenteral opioids
4. patients experience of FICB vs parenteral opioids
5. effectiveness of FICB given by an ED doctor vs resident emergency medicine

## **Study design**

single center randomized controlled trial

## **Intervention**

intervention: ultrasound-guided fascia iliaca compartment block using bupivacaine as an anesthetic. Control strategy: parenteral opioids.

Patients who are not able to consent and patients who do not meet all inclusion

criteria (or meet one of the exclusion criteria) received standard care: parenteral opioids.

### **Study burden and risks**

Overall a FICB has a very low risk profile, besides local hematoma and redness around the injection side.

The location of the FICB injection means the risk of intravascular injection, local anaesthetic toxicity, and mechanical nerve damage is extremely low. The technique will be performed under ultrasound-guidance, mimimalising the risk even further.

There is a antidote protocol available at the emergency department.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

- (1) patients presenting at the emergency department between 08:00 and 23:00 hr.
- (2) patients with a radiographically proven hip fracture
- (3) patients aged 18 years and older
- (4) informed consent

## Exclusion criteria

- (1) open fractures
- (2) femoral nerve injury
- (3) Inflammation or infection over injection site
- (4) known international normalized ratio > 4.5
- (5) prior femoral artery vascular surgery on the same side as the fracture
- (6) known hypersensitivity to local anesthetics or morphine

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	11-11-2014
Enrollment:	70
Type:	Actual

## Ethics review

Approved WMO

Date: 21-05-2014

Application type: First submission

Review commission: TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

## 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	NL47789.101.14