

# An alternative approach to a frequently used nerve block in patients with a broken hip in the emergency department

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<b>Registration date</b> 26/07/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/02/2019	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

A hip fracture is where there is a break in the upper thigh bone (femur). They are very common, particularly in older adults, and are extremely painful. A nerve block is a type of treatment in which a local anaesthetic (numbing) fluid is injected into the area that is painful in order to relieve pain. A Fascia Iliaca Compartment Block (FICB) is a type of nerve block in which the anaesthetic is injected into the space below the layer of muscle at the top of the leg. This study evaluates whether the use of a relative new way of administering this injection called a supra-inguinal FICB. This is where the anaesthetic is injected above the inguinal ligament (band of tissue in the groin) in order to decrease the need for morphine-like pain medications.

### Who can participate?

Adults with a broken hip.

### What does the study involve?

All participants receive pain management treatment with a supra-inguinal FICB. Each participant is asked to rate their pain with a number on a scale of 0 (no pain) to 10 (most severe pain imaginable) before the injection and then 30, 60 and 120 minutes afterwards. Participants are assessed and reviewed by the medical staff so that their need for other pain medication (and what they had already been given), side effects and type of hip fracture can be recorded. Data from these patients is compared with data from the hip fracture patients who do not receive this nerve block, during the same study period.

### What are the possible benefits and risks of participating?

There are no direct benefits or risks involved with participating, as the study does not change the treatment participants receive as part of their standard care.

### Where is the study run from?

Academic Medical Center (Netherlands)

When is the study starting and how long is it expected to run for?  
January 2014 to July 2015

Who is funding the study?  
Academic Medical Center (Netherlands)

Who is the main contact?  
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## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
SuprainguinalFICB14

## Study information

**Scientific Title**  
Opioid consumption in a supra-inguinal fascia iliaca compartment block compared to systemic analgesia in Emergency Department hip fracture patients, a cohort study

**Study objectives**

Hypothesis as of 03/04/2017:

Administration of a supra-inguinal FICB would lead to a significant decrease in usage of opioid analgesics in elderly hip fracture patients, compared to systemic analgesia.

Original hypothesis:

Administration of the supra-inguinal FICB would cause a significant reduction in NRS pain scores.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

The Institutional Review Board (IRB) of the AMC waived the need for official ethics approval as the Medical Research Involving Human Subjects Act (WMO) does not apply to the study.

### **Study design**

Prospective observational cohort study

### **Primary study design**

Observational

### **Secondary study design**

Cohort study

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

No participant information sheet available

### **Health condition(s) or problem(s) studied**

Hip fracture

### **Interventions**

Each patient will receive care as usual, which is pain treatment using a (supra-inguinal) FICB. NRS pain scores will be followed-up strictly and asked for at baseline, as well as 30, 60 and 120 in minutes after administration of the FICB while in rest and with careful movement of the injured extremity. Patients will be questioned whether they experience any adverse events, while continuous three-lead monitoring and pulsoxymetry is continued. Patients will be asked at each NRS-pain question whether they would like additional analgesia as well. Observation and follow-up ends at the moment of discharge from the Emergency Department. Patients will receive hip fracture care as usual (admittance and surgery).

Added 03/04/2017:

Data from the remaining hip fracture patients will be collected retrospectively from the electronic patient charts.

### **Intervention Type**

Procedure/Surgery

**Primary outcome measure**

Number of participants with a three-point decrease in Numerical Rating Scale (NRS) pain scores is measured prospectively for the FICB group at 30, 60 and 120 minutes after performing the nerve block and retrospectively from patient charts for those in the control group.

**Secondary outcome measures**

1. Decrease in Numerical Rating Scale (NRS) pain scores for different fracture types is measured at 30, 60 and 120 minutes after administration of the FICB for the FICB group and retrospectively from patient charts for those in the control group
2. Need for additional opioid analgesics is measured by emergency department and anesthesiology staff members, as well as members of the research team at 30, 60 and 120 minutes for the FICB group and retrospectively from patient charts for those in the control group
3. . Occurrence of side effects is measured by emergency department and anesthesiology staff members, as well as members of the research team at 30, 60 and 120 minutes for the FICB group and retrospectively from patient charts for those in the control group

**Overall study start date**

01/01/2014

**Completion date**

31/07/2015

**Eligibility****Key inclusion criteria**

1. Adult (18 years or older) patients
2. Radiologically confirmed hip fracture

Removed 03/04/2017:

3. Will be treated with a supra-inguinal FICB in the ED

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

At least 17 patients in order to detect a difference of 5 versus 9 mg of opioid usage.

**Key exclusion criteria**

1. Allergies for local anesthetics
2. Polytrauma patients
3. Not receiving a supra-inguinal FICB

**Date of first enrolment**

01/05/2014

**Date of final enrolment**

30/03/2015

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre****Academic Medical Center**

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## **Sponsor information**

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**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/03t4gr691>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Academic Medical Center

## Results and Publications

**Publication and dissemination plan**

A manuscript with the results will be submitted for publication in a peer-reviewed medical journal.

**Intention to publish date**

01/06/2016

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/02/2020		Yes	No