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

Submission date
22/07/2016

Recruitment status
No longer recruiting

Registration date
26/07/2016

Overall study status
Completed

Last Edited
18/02/2019

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Meibergdreef 9
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Sponsor information

Organisation
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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?
Results article	results	01/02/2020		Yes	No