Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The comparison of pericapsular nerve group block (PENG block) with fascia iliaca block on opioid intra-operative consumption and post-operative analgesic effects in extra-capsular and intra-capsular hip fracture

Protocol summary

Study aim
- The Comparison of pericapsular nerve group block (PENG block) with Fasia iliac block on opioid intraoperative consumption and post-operative analgesic effects in extra capsular and intracapsular hip fracture

Design
A randomized controlled clinical trial with parallel groups, Double blinded

Settings and conduct
After approval by the ethics committee of Shahid Beheshti University of Medical Sciences and obtaining patient satisfaction, 36 patients aged between 50-75 years and ASA class I and II, who are candidates for femoral neck fracture or intertrochanteric fracture surgery, will be randomly assigned to 2 groups according to the table of random numbers.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Patients with hip fractures (femoral neck and intertrochanteric fractures) aged 50-75 years and ASA Class I and II - Elective surgery - Hemoglobin levels above 9 mg / dl Exclusion criteria: - Other fractures or other lesions require surgery - History of drug or psychotropic addiction - Presence of psychiatric illnesses - Existence of coagulation disorder or contraindication to spinal anesthesia - Sensitivity to local anesthetics - Nervous disorders in the nerves of the lower extremities

Intervention groups
First intervention group: After prep , with a 2 cc syringe with a 1% Lidocaine injection, with the help of a high-frequency linear transducer, an in-plane ultrasound machine with a B Brain needle of 3 ml / kg and a maximum of 40 cc Rupivacaine is injected directly between the fascia iliac and the iliopsoas muscle. Second intervention group: Patient group with pericapsular nerve block: PENG is given to each patient under the guidence of low frequency, Curvilinear probe that is Horizontally placed over Anterior inferior iliac spine.

Main outcome variables
intra-operative opioid consumption; Pain

General information

Reason for update

Acronym
PENG

IRCT registration information
IRCT registration number: **IRCT20200314046763N1**
Registration date: **2020-05-11, 1399/02/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-11, 1399/02/22**
Update count: **0**

Registration date
2020-05-11, 1399/02/22

Registrant information

Name
Hamidreza Samadpour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4460 4203

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-20, 1399/01/01

Expected recruitment end date

2021-07-28, 1400/05/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of pericapsular nerve group block (PENG block) with fascia iliaca block on opioid intra-operative consumption and post-operative analgesic effects in extra-capsular and intra-capsular hip fracture

Public title

Evaluation of the effect of pre-capsular nerve group block on opoid intra-operative consumption and analgesic effects after hip fracture surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with hip fractures Elective surgery Hemoglobin levels above 9 mg / dl Age 50 to 75 years ASA class I and II patients

Exclusion criteria:

Other fractures or other lesions require surgery History of drug or psychotropic addiction Presence of psychiatric illnesses Existence of coagulation disorder Sensitivity to local anesthetics Nervous disorders in the nerves of the lower extremities

Age

From **50 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Accidentalization was performed using block randomization method with 9 blocks and 2, 4, 6, 8 in blocks using blockrand package in R software.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the first step, the first and second intervention groups will be placed in the envelope. The study is double blind in that the patient will not be aware of the type of treatment, the evaluator will be different from the therapist, and the evaluator will be uninformed, but the therapist will be aware of the treatment. The evaluator will examine the patients at the beginning of their visit and refer them to a therapist if they have the conditions to study, and the therapist will select the treatment envelope according to the random block method. In the next step, the evaluator will perform the evaluation without knowing the assigned method.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran national committee for Ethics in biomedical research

Street address

Tehran - Qods Township (West) - 13th Floor Between South Flamak and Zarafshan, Iran Sime St. - Headquarters of Ministry of Health and Medical Education, Block A

City

Tehran

Province

Tehran

Postal code

11111111

Approval date

2019-05-14, 1398/02/24

Ethics committee reference number

IR.SBMU.MSP.REC.1398.133

Health conditions studied

1

Description of health condition studied

Pericapsular Nerve Group (PENG) block

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain

Timepoint

6, 12 and 24 hours after surgery

Method of measurement

Visual Analog Scale(VAS)

2

Description
opioid intra-operative consumption
Timepoint
At the beginning of the surgery and then every 15 minutes
Method of measurement
Numeric rating scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: PENG nerve block in intraoperative drug use and postoperative analgesic effects in intra-capsular and extracapsular hip fracture groups.After sterilizing the site and performing a skin anesthesia, the curve linear, low-frequency (2-5 MHz) is taken transversely on the Anterior Inferior iliac Spine, by rotating 45 degrees counterclockwise. The femoral artery and pectinus muscle are seen. The nidel is like the nidel of the control group and is inserted from the lateral to the medial in an in-plane so that its tip is located in the fascial muscle between the posterior psoas tendon and the posterior Ramus pubis after aspiration. Negative 0.5% vacuum solution is injected at 3 ml / kg with aspiration every 5 cc.
Category
Rehabilitation

2

Description
Control group: Patients with Fascia Iliaca Neural Block: Patients who undergo vital signs and appropriate intravenous lineage after receiving transfer to the operating room and monitoring with normal saline intake of 5-5 cc / kg, will undergo the following Fascia Iliaca nerve block as follows: Sterilize the block site and perform a skin anesthesia with a 2 cc Needle syringe with 1% lidocaine injection, with the help of a high-frequency linear transducer (10-25 MHz ultrasound device (S-Nerve Sonosite)) that is placed horizontally in the inguinal area. In-plan and with needle (B Brain (22 G, 80 mm, Stimuplex Ultra 360 in the amount of 3 ml / kg and a maximum of 40 ml of Rupivacaine 0.5% (Multeni) with direct view between the fascia The iliac and iliopsoas muscles are injected.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Medical Center Hospital Imam Hussein
Full name of responsible person
Alireza mirkhesti
Street address
Tehran, Martyr Madani Ave., lower than Martyr Madani Metro, Imam Hussein Medical, Educational, Research and Medical Center.
City
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1617763141
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+98 21 7343 0000
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info@ehmc.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Afshin Zarghi
Street address
Tehran - Yemen St. Martyr Chamran Highway - Shahid Arababi Street Next to Ayatollah Taleghani Hospital
City
Tehran
Province
Tehran
Postal code
1983963113
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+98 21 23871
Fax
+98 21 2243 9981
Email
Mpajouhesh@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Hamidreza Samadpour

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
All potential data can be shared after unidentifiable people

When the data will become available and for how long
Start of access period 6 months after printing results

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
1. Respecting the ethics and religion of the patients who participate in these studies. 2-To help improve the validity of the data produced. 3. Assist physicians in interpreting and minimizing disruption to clinical trials. 4. Prevent the recruitment of volunteers who are exposed to the dangers of high-risk trials. 5. Mass media information on the effects of trials that do not conform to

the interests of pharmaceutical companies.

From where data/document is obtainable

drhamidrezasamadpour@gmail 00989125395847

What processes are involved for a request to access data/document

After logging into the system to provide results, three methods are envisaged in which the results can be accessed in different formats. Please click on "Search Output" to make the options visible in the menu.

Comments