

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison between ultrasound guided supra inguinal fascia iliaca block with infra inguinal fascia iliaca block for post operative pain management in intertrochanteric femour fracture

Protocol summary

Study aim

Comparison between ultrasound guided supra inguinal fascia iliaca block with infra inguinal fascia iliaca block for post operative pain management in intertrochanteric femour fracture

Design

Clinical trial with control group, with parallel groups, double blinded, randomized, phase 3

Settings and conduct

In this study, which will be performed as a double-blind clinical trial in Hazrat-e- Rasool hospital. After surgery, patients are randomly divided into two groups: supra and infra inguinal fascia iliaca blocks under ultrasound guide. Pain is the main outcome. Patients and statistical analyzer are binded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients 55-75 years old who are candidates for elective surgery for intra trochanteric femoral fracture, ASA 1 and 2. Exclusion criteria: ASA 3 and 4, Patients candidates for emergency surgery, History of ropivacaine allergy, Liver and kidney problems, Body mass index greater than 40, Coagulation disorders, Receive analgesic in the last 24 hours, Drug addiction

Intervention groups

Intervention group 1: Supra inguinal block of fascia iliaca
Intervention group 2: Infra inguinal block of fascia iliaca

Main outcome variables

Pain, patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120814010599N27**
Registration date: **2021-03-24, 1400/01/04**

Registration timing: **prospective**

Last update: **2021-03-24, 1400/01/04**

Update count: **0**

Registration date

2021-03-24, 1400/01/04

Registrant information

Name

Poupak Rahimzadeh

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 9059

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p-rahimzadeh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-19, 1400/01/30

Expected recruitment end date

2021-05-31, 1400/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between ultrasound guided supra inguinal fascia iliaca block with infra inguinal fascia iliaca block for post operative pain management in intertrochanteric femour fracture

Public title

Effect of supra inguinal fascia iliaca block with infra inguinal fascia iliaca block on pain control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients 55-75 years old who are candidates for elective surgery for intra trochanteric femoral fracture ASA 1 and 2

Exclusion criteria:

ASA 3 and 4 Patients candidates for emergency surgery (non-elective) History of ropivacaine allergy Liver and kidney problems Body mass index greater than 40 Coagulation disorders Receive analgesic in the last 24 hours Drug addiction

Age

From **55 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients, using random allocation software, were randomly divided into supra inguinal fascia iliaca block and infra inguinal fascia iliaca block groups. By selecting the simple randomization method in the randomization box and entering the determined total sample size in this software, numbers were given to the patients and the patients were allocated into two groups according to computer-generated numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the statistical analyzer were unaware that the patient was exposed to the supra inguinal fascia iliaca block and infra inguinal fascia iliaca block methods. Supra Inguinal Fascia iliaca and Infra Inguinal Fascia iliaca block will be performed by an anesthesiologist in the operating room before that the operation was finished under general anesthesia, i.e. the blocks are done when the patients are unconscious. The groups are provided to the statistical analyzer in the form of codes A and B for analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences., Hemmat Highway., Next to Milad Tower., Tehran Town

City

Tehran

Province

Tehran

Postal code

1433933111

Approval date

2021-01-10, 1399/10/21

Ethics committee reference number

IR.IUMS.FMD.REC.1399.571

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

Pain

Timepoint

0-1-4-8-16-24 hours after surgery

Method of measurement

Visual analogue scale

Secondary outcomes

1

Description

Patient satisfaction

Timepoint

0-1-4-8-16-24 hours after surgery

Method of measurement

The tool is based on Likert as follows:poor:0,moderate:1,good:2,very good:3,excellent:4

Intervention groups

1

Description

Intervention group: To perform a supra-inguinal block, the patient is placed in the supine position under the ultrasound guide. The linear prop is placed transversely above the inguinal ligament and parallel to it. 40 cc of ropivacaine 0.2% (made by Cobel company) is injected between the iliac fascia and the iliac muscle. For patients, an intravenous pain control pump containing 2 gr of Apotel (made by Cobel company) and 60 mg of ketorolac (Iranhormone company) with a continuous flow of 6 cc is placed.

Category

Treatment - Drugs

2

Description

Control group: To perform a infra-inguinal block, the patient is placed in the supine position under the ultrasound guide. The linear prop is placed transversely below the inguinal ligament and parallel to it. 40 cc of ropivacaine 0.2% (made by Cobel company) is injected between the iliac fascia and the iliac muscle. For patients, an intravenous pain control pump containing 2 gr of Apotel (made by Cobel company) and 60 mg of ketorolac (Iranhormone company) with a continuous flow of 6 cc is placed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Poupak Rahim Zadeh

Street address

Department of pain, 4th Floor, Hazrat-E-Rasool Hospital, Iran University of Medical Sciences, Niayesh "St.", Sattarkahn "Ave.", Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyyed Abas Motavalian

Street address

Vice chancellor for research, Iran University of Medical Sciences, beside Milad Tower, Hemat "Exp." way

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Poupak Rahimzadeh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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