Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Email address
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

City
Tehran

Province
Tehran

Postal code
1433933111

Phone
+98 21 6650 9059

Email
poupak_rah@hotmail.com

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

City
Tehran

Province
Tehran

Postal code
1433933111

Phone
+98 21 6650 9059

Email
poupak_rah@hotmail.com

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

Street address
Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1433933111

Phone
+98 21 6650 9059

Fax
+98 21 6650 9059

Email
p-rahimzadeh@tums.ac.ir

Person responsible for scientific 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
Street address
Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1433933111
Phone
+98 21 6650 9059
Fax
+98 21 6650 9059
Email
p-rahimzadeh@tums.ac.ir

Person responsible for updating data

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
Street address
Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1433933111
Phone
+98 21 6650 9059
Fax
+98 21 6650 9059
Email
p-rahimzadeh@tums.ac.ir

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