

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison between ultrasound guided periarterial femor block and femoral nerve block on intraoperative hypertension during tourniquet closure in anterior cruciate ligament surgery under general anesthesia: a double-blind randomized clinical trial

Protocol summary

Study aim

Comparison between ultrasound guided periarterial femor block and femoral nerve block on intraoperative hypertension during tourniquet closure in ACL surgery under general anesthesia

Design

The study has two intervention groups, which are divided into two groups of 25 based on the sample size formula and previous studies. Patients are randomly assigned to two groups on the sealed envelope website, and the study is conducted in a double-blind manner.

Settings and conduct

Study location: Study is performed in general operation room of Rasool hospital Tehran-Iran; Study population: Patients between 18-75 years old who have ACL knee surgery; Type of study: The study is double blinded , patient and observer don't aware of type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: oral and written consent; being at the age of 18-75 years old; ACL surgery; Weight more than 50 kg. exclusion criteria: Patient diagnosed with chronic pain; Opium addiction; pregnancy; local infection.

Intervention groups

In our study we have two intervention groups .All patients are having ACL surgery under general anesthesia. First intervention group will have periarterial femoral block under ultrasound guidance with ropivacaine . Second intervention group will have classic femoral nerve block under ultrasound guidance with ropivacaine.

Main outcome variables

Pain during surgery , Post operation pain, Anesthesia depth, arterial blood pressure before inflating tourniquet and after deflating tourniquet, arterial blood pressure during tourniquet inflation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220904055873N1**

Registration date: **2022-10-10, 1401/07/18**

Registration timing: **prospective**

Last update: **2022-10-10, 1401/07/18**

Update count: **0**

Registration date

2022-10-10, 1401/07/18

Registrant information

Name

Arezo Hosseinkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2273 6391

Email address

parham_c11@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-06, 1401/08/15

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Not used
Scientific title	Assignment
Comparison between ultrasound guided periarterial femor block and femoral nerve block on intraoperative hypertension during tourniquet closure in anterior cruciate ligament surgery under general anesthesia: a double-blind randomized clinical trial	Parallel
	Other design features
	Secondary Ids
	empty
Public title	Ethics committees
Comparison between ultrasound guided periarterial femor block and femoral nerve block effects in anterior cruciate ligament surgery under general anesthesia	1
Purpose	Ethics committee
Treatment	Name of ethics committee
Inclusion/Exclusion criteria	Ethics committee of Iran University of Medical Sciences
Inclusion criteria:	Street address
oral and written consent Being at the age of 18-75 years old ACL surgery Weight more than 50kg	ran University of Medical Sciences; Hemmat highway
Exclusion criteria:	City
Patient diagnosed with chronic pain Opium addiction or other drugs pregnancy local infection Allergy to local anesthetic weight less than 50 or BMI more than 30 Coagulopathy Patient unable to evaluate pain score Chronic uncontrolled disease Blood loss more than 500 cc during surgery Surgery duration longer than 3 hours	Tehran
Age	Province
From 18 years old to 75 years old	Tehran
Gender	Postal code
Both	149614535
Phase	Approval date
N/A	2022-04-23, 1401/02/03
Groups that have been masked	Ethics committee reference number
- Participant - Care provider - Outcome assessor - Data analyser	IR.IUMS.FMD.REC.1401.078
Sample size	Health conditions studied
Target sample size: 50	1
Randomization (investigator's opinion)	Description of health condition studied
Randomized	Knee surgery
Randomization description	ICD-10 code
For randomization we use block randomization method. we put patients in two groups and use www.sealedenvelope.com website for making sequence. In each block we have 5 cases. We use A for group who are having periarterial femoral block and use B for the second group (classic femoral block). Then we have A and B sequences in 10 blocks for 50 cases which will be divided into two groups containing 25 cases. At last we put cards with the blocks written on them in envelopes. by this method allocation concealment is done.	ICD-10 code description
Blinding (investigator's opinion)	2
Double blinded	Description of health condition studied
Blinding description	ACL surgery
The observer and patient doesn't know type of the block. The procedure is done when the patient put under general anesthesia. The patient and the person who observe the patient are unaware of block type.	ICD-10 code
Placebo	ICD-10 code description
	3
	Description of health condition studied
	Femoral block
	ICD-10 code
	ICD-10 code description
	Primary outcomes
	1
	Description
	Pain during surgery
	Timepoint
	During surgery
	Method of measurement

ANI (analgesia nociception index)

2

Description

post operation pain

Timepoint

after surgery

Method of measurement

Visual Analogue Scale (VAS)

3

Description

Mean arterial blood pressure before inflating tourniquet and after deflating

Timepoint

10 minutes interval 3 times

Method of measurement

arterial line

4

Description

Mean arterial blood pressure after inflating of tourniquet

Timepoint

Every 15 minutes till the end of surgery

Method of measurement

Arterial line

5

Description

Anesthesia depth

Timepoint

Every 30 minutes till the end of general surgery

Method of measurement

Bispectral index(BIS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Periarterial femoral block for patients between 18 to 75 years who are having ACL surgery under general anesthesia. Patients in each group are routinely anesthetized(with Propofol,Fentanyl , Midazoalm and Cisatracrium according to patient weight) . First group are having Periarterial femoral block under ultrasound guidance with 15cc rupivacaine 0.5% then needed data is observed during and after general anesthesia.

Category

Treatment - Drugs

2

Description

Intervention group: femoral block for patients between 18 to 75 years who are having ACL surgery under general anesthesia. Patients in each group are routinely anesthetized(with Propofol,Fentanyl , Midazoalm and Cisatracrium according to patient weight) . First group are having calssic femoral nerve block under ultrasound guidance with 15cc rupivacaine 0.5% then needed data is observed during and after general anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram hospital

Full name of responsible person

Arezo Hosseinkhani

Street address

Rasool Akram hospital, Mansoori st., Niyayesh st., Sattarkhan st.

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 1000

Email

rasoolhospital@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hossein Keyvani

Street address

Iran University of Medical Sciences, Near Milad tower, Hemmat highway, Tehran, Iran

City

Tehran

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Postal code

1449614535

Phone

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admins@iums.ac.ir

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
Arezoo Hossienkhani
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
No.12, Minoo street, Sadeghie Gomi street, Nivaran street.
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available