

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of femoral nerve block with infrapatellar nerve block under ultrasound guidance in relieving pain; after elective arthroscopic surgery for reconstruction of anterior cruciate ligament

Protocol summary

Study aim

The aim of current study is to compare femoral nerve block with infrapatellar nerve block under ultrasound guidance in relieving pain; after elective arthroscopic surgery for reconstruction of anterior cruciate ligament

Design

Clinical trial study, with two parallel groups, double blinded, randomized

Settings and conduct

Ninety two patients with arthroscopic shoulder surgery were randomly divided into two equal groups and will undergo femoral nerve block or infrapatellar nerve block under ultrasound guidance in relieving pain; after elective arthroscopic surgery for reconstruction of anterior cruciate ligament

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 20-40 years old; ASA I,II. Exclusion criteria: coagulation disorders; injection site infection; neurological disorders and any neuropathy at the surgery site foot; allergy to local anesthesia; drug addiction; BMI>35.

Intervention groups

First group: femoral nerve block. Second group: infrapatellar nerve block

Main outcome variables

Patient's pain will be evaluated 1, 3, 6, 12 and 24 hours after nerve block.

General information

Reason for update

The dates of completion of the patient recruitment were corrected and the correct form of the ethic code was entered. The ethic code is now available in the following URL.
<http://ethics.research.ac.ir/PortalProposalList.php?code=I.R.IUMS.FMD.REC.1398.377&title=&name=&stat=&isAll=>

&GlobalBackPage=http%3A%2F%2Fethics.research.ac.ir%2F

Acronym

IRCT registration information

IRCT registration number: **IRCT20120814010599N22**

Registration date: **2018-10-26, 1397/08/04**

Registration timing: **prospective**

Last update: **2020-02-01, 1398/11/12**

Update count: **2**

Registration date

2018-10-26, 1397/08/04

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

2019-12-08, 1398/09/17

Expected recruitment end date

2020-04-02, 1399/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of femoral nerve block with infrapatellar nerve block under ultrasound guidance in relieving pain; after elective arthroscopic surgery for reconstruction of anterior cruciate ligament

Public title

Femoral nerve block and infrapatellar nerve block under ultrasound guidance in relieving pain; after elective arthroscopic surgery for reconstruction of anterior cruciate ligament

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 20-40 years old Patients with ASA I,II

Exclusion criteria:

Coagulation disorders
Infection
Situational Neurological disorders and any neuropathy at the surgery site
Foot Allergy to local anesthesia
Drug addiction
BMI>35

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are randomly divided by using a computer-generated random number list. The subjects are assigned into different groups by random allocation. Allocation concealment is obtained by maintaining the randomization list by study statistician.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participant and person evaluating the outcome will be blinded to the allocated group.

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., next to Milad Tower., Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-12-01, 1398/09/10

Ethics committee reference number

IR.IUMS.FMD.REC.1398.377

Health conditions studied

1

Description of health condition studied

Pain relieve after elective arthroscopic surgery for reconstruction of anterior cruciate ligament

ICD-10 code

M25.5

ICD-10 code description

Pain in joint

Primary outcomes

1

Description

Pain after elective arthroscopic surgery for reconstruction of anterior cruciate ligament

Timepoint

1, 3, 6,12 and 24 hours after nerve block

Method of measurement

Using Visual Analogue Scale scale

Secondary outcomes

1

Description

Patient's relaxation after nerve block

Timepoint

1, 3, 6, 12 and 24 hours after nerve block

Method of measurement

Using Ramsay scale

2

Description

Total dose of the opioid consumed via the pump

Timepoint

During 24 hours after nerve block

Method of measurement

Using questionnaire information

Intervention groups

1

Description

Intervention group: First group will undergo femoral nerve block under ultrasound guidance after elective arthroscopic surgery for reconstruction of anterior cruciate ligament.

Category

Treatment - Drugs

2

Description

Intervention group: Second group will undergo infrapatellar nerve block under ultrasound guidance after elective arthroscopic surgery for reconstruction of anterior cruciate ligament

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

1445613131

Phone

+98 21 6651 5001

Email

P-Rahimzadeh@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Kazem Malakuti

Street address

Iran University of Medical Sciences., next to Milad Tower., Hemat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8163 3685

Email

PR@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

Poupak Rahimzadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Hazrat Rasul Medical complex, Sattar khan Ave.

City

Tehran

Province

Tehran

Postal code

1916737183

Phone

+98 21 6435 2326

Fax

Email

p-rahimzadeh@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Position

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Other areas of specialty/work

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Fax

+98 21 6650 9059

Email

p-rahimzadeh@tums.ac.ir

Web page address

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

Yes - There is 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

Not applicable

Title and more details about the data/document

We have not yet set a conclusion

When the data will become available and for how long

We have not yet set a conclusion

To whom data/document is available

We have not yet set a conclusion

Under which criteria data/document could be used

We have not yet set a conclusion

From where data/document is obtainable

We have not yet set a conclusion

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

We have not yet set a conclusion

Comments

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Poupak Rahimzadeh

Position

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Latest degree

Subspecialist

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