Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Evaluation of Genicular Nerve Block for Postoperative Pain Management of Anterior Cruciate Ligament Reconstruction Surgery.

Protocol summary

Summary

Objective: Evaluation of Genicular Nerve Block for Postoperative Pain Management of Anterior Cruciate Ligament Reconstruction Surgery. Study design: a single blind randomized clinical trial Inclusion criteria: Patients aged 16-70 years with ASA 3-1 who suffer from anterior cruciate ligament (ACL) injury and who are candidates for rehabilitation and repair of the anterior cruciate ligament and have the ability to collaborate and answer to the study questions. Exclusion criteria : Patients with femoral and sciatica neuropathy; coagulopathy; infection in the blockade side ; Pregnancy; Chronic use of opium over 3 months; contraindication for regional anesthesia; allergy to the used drugs; renal or hepatic failure; uncontrolled epilepsy; contraindication for general anesthesia; severe anxiety and depression. Intervention: 50 patients will be randomly assigned to the one of the two groups of (B) or (S). local block procedure will have performed after induction of anesthesia and before surgery. Three genicular nerves: medial superior genicular nerves , medial inferior genicular nerve, lateral superior genicular nerves are diagnosed by the ultrasound sonography device , by using the Spinal needle gauge 22 patients' knee will be blocked with 5 ml of Marcaine 0.5% added to 25 macro gram -epinephrine in group B while, 5 cc normal saline will be injected in the patients' knee (in the control group = group S). The severity of the pain in the recovery room will be evaluated every 15 minutes by the NRS. The time of the first demand for postoperative analgesics and total morphine consumption will be recorded. In the ward, an PCA pump will used with 0.5 mg / ml of morphine. Patient's pain in the first 24 hours after surgery will be measured at 2, 4, 6, 8, 12, 16, 20, and 24 with the NRS(Numerical Rating Scale). In case of NRS above 4 despite the use of PCA pump, pain will controlled based on the provided protocol in the recovery room . total morphine consumption will be recorded within the first 24 hours after the operation. Morphine-induced complications such as itching, nausea and vomiting, urinary retention, respiratory depression and sleepiness (based on the Wilson criteria) will be recorded at 4, 8, 12, 16, 20 and 24 hours after the operation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081619470N38**
Registration date: **2017-08-23, 1396/06/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-08-23, 1396/06/01

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research,Shiraz University of Medical Sciences

Expected recruitment start date

2016-08-21, 1395/05/31

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Genicular Nerve Block for Postoperative Pain Management of Anterior Cruciate Ligament Reconstruction Surgery.

Public title

Evaluation of Genicular Nerve Block for Postoperative Pain Management of Anterior Cruciate Ligament Reconstruction Surgery.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients aged 16-70 years with ASA 3-1 who suffer from anterior cruciate ligament (ACL) injury and who are candidates for rehabilitation and repair of the anterior cruciate ligament and have the ability to collaborate and answer to the study questions. Exclusion criteria : Patients with femoral and sciatica neuropathy; coagulopathy; infection in the blockade side ; Pregnancy; Chronic use of opium over 3 months; contraindication for regional anesthesia; allergy to the used drugs; renal or hepatic failure; uncontrolled epilepsy; contraindication for general anesthesia; severe anxiety and depression.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Postal code

Approval date

2016-08-19, 1395/05/29

Ethics committee reference number

IR.SUMS.MED.REC.1395.09

Health conditions studied

1

Description of health condition studied

anterior cruciate ligament injury

ICD-10 code

S83.5

ICD-10 code description

Sprain and strain involving (anterior)(posterior) cruciate ligament of knee

Primary outcomes

1

Description

Pain score

Timepoint

24 hours after surgery at 2, 4, 6, 8, 12, 16, 20, and 24

Method of measurement

Numerical rating scale (NRS)

Secondary outcomes

1

Description

Morphine-induced complications

Timepoint

at 4, 8, 12, 16, 20 and 24 hours after the operation

Method of measurement

observasion

Intervention groups

1

Description

Three genicular nerves: medial superior genicular nerves , medial inferior genicular nerve, lateral superior genicular nerves are diagnosed by the ultrasound sonography device , by using the Spinal needle gauge 22 patients’ knee will be blocked with 5 ml of Marcaine 0.5% added to 25 macro gram -epinephrine in group B

Category

Treatment - Drugs

2

Description
5 cc normal saline will be injected in the patients' knee
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Chamran Hospital
Full name of responsible person
Hedye Moghaddasi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Shiraz University of Medical Sciences
Full name of responsible person
Dr Seed Basir Hashemi
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Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty