

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effectiveness of adding Ketamine to Ropivacaine in continues femoral nerve block for postoperative pain control in anterior cruciate ligament reconstruction surgeries

Protocol summary

Summary

Continues femoral nerve block is one of common ways to relieve pain after reconstruction surgery of anterior cruciate ligament of knee. We decided to decrease Ropivacaine concentration and instead adding Ketamine -an NMDA receptor antagonist- to see reasonable analgesia with reduced motor block. Setting: Orthopedic surgery ward of Prophet Muhammad hospital in Tehran University of medical sciences. Study population: patients who are candidate for elective anterior cruciate ligament reconstruction surgery during 2010 and 2011. Sampling: simple sequential sampling. Inclusion Criteria: 1) Age 15 to 60 years; 2) ASA I & II. Exclusion Criteria: 1) A history of drug misuse 2) Allergy to Ketamine and Ropivacaine. Primary objectives: 1) Determination of VAS score by adding Ketamine (1 mg/kg) to Ropivacaine 0.125% in PCRA pump using continuous femoral nerve block; 2) Determination of Quadriceps motor block quality by adding ketamine (1 mg/kg) to ropivacaine 0.125% in PCRA pump using continuous femoral nerve block.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111278221N1**
Registration date: **2013-02-23, 1391/12/05**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-02-23, 1391/12/05

Registrant information

Name

Kayvan Niknam

Name of organization / entity

Tehran University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4481 9954

Email address

kayvanniknam@irimc.org

Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2011-12-21, 1390/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of adding Ketamine to Ropivacaine in continues femoral nerve block for postoperative pain control in anterior cruciate ligament reconstruction surgeries

Public title

Efficacy of adding Ketamine to Ropivacaine in continues femoral nerve block

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1) Age 15 to 60 years; 2) ASA I & II; 3) candidates for elective knee surgery; 4) Written consent.

Exclusion Criteria: 1) A history of drug misuse; 2) Allergy to Ketamine and Ropivacaine; 3) Alcohol and drugs abuse; 4) Pregnancy and breast feeding; 5) Refusing patients studied; 6) Infection in block area; 7) Any neuropathy; 8) Diabetes; 9) Cardiovascular disease; 10) Hypertension; 11) Renal insufficiencies; 12) Liver failure.

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of medical sciences

Street address

Hemat highway

City

Tehran

Postal code

Approval date

2010-06-12, 1389/03/22

Ethics committee reference number

42116

Health conditions studied

1

Description of health condition studied

Ant cruciate ligament strain

ICD-10 code

S83.5

ICD-10 code description

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

Primary outcomes

1

Description

Motor block

Timepoint

48 hours after surgery

Method of measurement

based on Quadriceps muscle weakness

2

Description

Pain

Timepoint

48 hours after surgery

Method of measurement

based on VAS

Secondary outcomes

1

Description

Opioid requirment

Timepoint

48 hours after surgery

Method of measurement

Based on miligram of opioid required

Intervention groups

1

Description

Femoral block with 0.3 cc/kg Ropivacaine %0.2 performed and femoral catheter for continues infusion of medication with pump inserted and 100 cc Ropivacaine %0.2 was placed in infusion pump; infusion rate was 5cc/hour.

Category

Treatment - Drugs

2

Description

Femoral block with 0.3 cc/kg Ropivacaine %0.2 performed and femoral catheter for continues infusion of medication with pump inserted and 100cc Ropivacaine %0.125 with Ketamine 1mg/kg was placed in infusion pump; infusion rate was 5cc/hour. Pumps were refilled if they were finished.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram hospital
Full name of responsible person
Dr. Seyed Hamidreza Faiz
Street address
Rasoul Akram hospital
City
Tehran

City
Tehran
Postal code
Phone
+98 21 64351
Fax
Email
hrfaiz@hotmail.com
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Vice-chancellor of research, Dr. Akbar fotoohi
Street address
Vice-chancellor of research of Tehran University of
medical sciences, Keshavarz Blvd
City
Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Contact

Name of organization / entity
Tehran university ofmedical sciences
Full name of responsible person
Dr. Seyed Hamidreza Faiz
Position
Assistant Professor
Other areas of specialty/work
Street address
Rasoul Akram hospital

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran university of medical sciences
Full name of responsible person
Dr. Seyed Hamidreza Faiz
Position
Assistant Professor
Other areas of specialty/work
Street address
Rasoul Akram hospital
City
Tehran
Postal code
Phone
+98 21 8805 2256
Fax
Email
hrfaiz@hotmail.com
Web page address

Person responsible for updating data

Contact

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