

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of the analgesic effects of intra-articular injection of Ropivacaine 7.5% with dexmedetomidine and Ropivacaine 7.5% with magnesium and Ropivacaine 7.5% with ketamine after ACL surgery

Protocol summary

Study aim

Comparison of the analgesic effects of intra-articular injection of ropivacaine 7.5% with dexmedetomidine, ropivacaine 7.5% with magnesium and ropivacaine 7.5% with ketamine after ACL surgery.

Design

Clinical trial without control group, with parallel groups, double-blind, randomized, phase 2 on 60 patients. A table of random numbers will be used for randomization. 60 patients in three groups of 20 are subjected to three types of intervention.

Settings and conduct

This study prospectively compares the analgesic effects of intra-articular injection of ropivacaine 7.5% with dexmedetomidine, ropivacaine 7.5% with magnesium and ropivacaine 7.5% with ketamine after ACL surgery. At the end of the surgery, drugs are injected intra-articularly and the pain level of the patients will be evaluated at 1, 2, 6, 12 and 24 hours after the operation and will be compared between the three groups. This study is double-blind and patients and evaluators will be unaware of the type of treatment. Also, the data analyst will only have the code of the intervention groups and will not be able to distinguish the treatment groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 60 years, Elective ACL surgery candidate, ASA I and II physical condition
Exclusion criteria: Sensitivity to the drugs used in the study, Pregnancy and breastfeeding, Having diabetes, alcohol consumption, Severe liver and kidney failure

Intervention groups

1. Ropivacaine 7.5% with dexmedetomidine (100 µg in 10 ml of normal saline) 2. Ropivacaine 7.5% with magnesium (500 mg of 5% magnesium sulfate solution) 3. Ropivacaine 7.5 % together with ketamine (0.5 mg/kg)

Main outcome variables

The pain level of the patients at 1, 2, 6, 12 and 24 hours

after the operation will be evaluated using the Visual Analogue Scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230626058586N2**

Registration date: **2024-01-03, 1402/10/13**

Registration timing: **prospective**

Last update: **2024-01-03, 1402/10/13**

Update count: **0**

Registration date

2024-01-03, 1402/10/13

Registrant information

Name

Nasim Sohrabifar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 938 229 6766

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nasimsohrabifar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the analgesic effects of intra-articular injection of Ropivacaine 7.5% with dexmedetomidine and Ropivacaine 7.5% with magnesium and Ropivacaine 7.5% with ketamine after ACL surgery

Public title
Investigating the analgesic effects of ropivacaine compounds in ACL surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
age between 18-60 A candidate for elective ACL surgery
Physical status ASA I and II
Exclusion criteria:
Allergy to the drugs used in the study Pregnancy and breastfeeding Having diabetes alcohol consumption
Severe liver and kidney failure

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The website www.Randomization.com was used for randomization (online randomization). For this purpose, a simple randomization model was used. The randomization unit was individual and on this website, after specifying the number of intervention groups, which were three groups, and the required number in each of these groups, the website provided us with a random table of repetitions that represented the patient number. To hide the random allocation, central randomization was used. In this method, a random sequence is placed in the possession of an individual or a specific center, and sampling is done in one or more centers at the same time. Based on the order in which the participants entered the study, the researcher contacted the relevant center and asked about the random assignment of the participants to a special group.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study was double-blind and the patients and evaluators were unaware of the type of treatment. Also, the study data analyst only had the codes of the treatment groups (1, 2, and 3) and they were not able to

distinguish the treatment groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid beheshti University of Medical Sciences

Street address
Shahid Beheshti University of Medical Sciences, Arabi St., Student Blvd., Valenjak, Tehran

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2023-12-26, 1402/10/05

Ethics committee reference number
IR.SBMU.MSP.REC.1402.491

Health conditions studied

1

Description of health condition studied
Pain after ACL surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain level of patients after ACL surgery

Timepoint
1, 2, 6, 12 and 24 hours after the operation

Method of measurement
Using the Visual Analogue Scale.

Secondary outcomes
empty

Intervention groups

1

Description

Intervention group: Intervention group: intra-articular injection of ropivacaine 7.5% with dexmedetomidine (100 micrograms in 10 ml of normal saline).
Manufacturer of Rupivacaine: Sina Pishgam Darou nowin.
Manufacturer of dexmedetomidine: Exir.

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group: intervention group: intra-articular injection of ropivacaine 7.5% with magnesium (500 mg of 5% magnesium sulfate solution). Manufacturer of Rupivacaine: Sina Pishgam Darou nowin. Magnesium manufacturing company: Nasr.

Category

Treatment - Drugs

3

Description

Intervention group: Intervention group: Intervention group: intra-articular injection of 7.5% ropivacaine with ketamine (0.5 mg/kg). Manufacturer of Rupivacaine: Sina Pishgam Darou nowin. Ketamine manufacturing company: Exir

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Mohammad reza Moshari

Street address

Tehran - Shahid Chamran Highway, Yemen St. - Shahid Arabi St., next to Shahid Beheshti University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad reza Moshari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data can be shared after de-identification of
individuals and coding of patients, including outcome
demographics.

When the data will become available and for how long

The access period will start after the results are printed.

To whom data/document is available

The data will be available only to researchers working in
academic and scientific institutions.

Under which criteria data/document could be used

Email and request from the person in charge of the
study.

From where data/document is obtainable

Send a message to the email below.
rmoshari@yahoo.com

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

After the request by email, the person in charge of the
study will send the data to the individual.

Comments