

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

A clinical trial to compare the effectiveness of 0.5% bupivacaine with 0.25% bupivacaine on adductor canal block after unilateral knee arthroplasty

Protocol summary

Study aim

To compare the effectiveness of 0.5% bupivacaine with 0.25% bupivacaine on adductor canal block after unilateral knee arthroplasty

Design

This randomized and single-blind clinical trial with parallel and control groups will be conducted on 48 patients who will be randomly selected using the blocks.

Settings and conduct

Patients candidate for unilateral knee arthroplasty referring to Imam Reza Hospital, Mashhad, Iran are chosen as the participants of the study. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. Intervention group will receive the 0.5% bupivacaine and control will receive 0.25% bupivacaine after surgery. The responsible for data collection is blind to group allocation and the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with ASA I or II, who are candidate for unilateral knee arthroplasty; age over 18 years; BMI less than 35. Exclusion criteria: history of neuropathy; having coagulation disorder; drug abuse; having local anesthetics allergies.

Intervention groups

The intervention group will receive 0.25% bupivacaine to adductor canal block after unilateral knee arthroplasty. The control group will receive 0.5% bupivacaine to adductor canal block after unilateral knee arthroplasty.

Main outcome variables

Evaluation the rate of pain, muscle strength and the rate of pain reliever consumption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220731055587N1**

Registration date: **2022-07-31, 1401/05/09**

Registration timing: **prospective**

Last update: **2022-07-31, 1401/05/09**

Update count: **0**

Registration date

2022-07-31, 1401/05/09

Registrant information

Name

Hosneh Esmalili Namghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3854 3031

Email address

esmailinamghih@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of 0.5% bupivacaine with 0.25% bupivacaine on adductor canal

block after unilateral knee arthroplasty

Public title

The effectiveness of bupivacaine on pain relief after unilateral knee arthroplasty

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with ASA I or II, who are candidate for unilateral knee arthroplasty Age over 18 years BMI less than 35

Exclusion criteria:

History of neuropathy Having coagulation disorder Drug abuse Having local anesthetics allergies

Age

From **18 months** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the restricted randomization method of block randomization. All blocks are the same size, and in this two-group experiment we will have 6 blocks (including 3 participants in the intervention group and 3 participants in the control group). Random allocation software software is also used to randomize random sequence production software (Random allocation software). To conceal, we use Allocation concealment, which refers to the method used to perform a random sequence on study participants, so that the assigned group is not identified before the individual is assigned. Using non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes of the letter will be opened in order and the assigned group of the participant will be revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients candidate for unilateral knee arthroplasty referring to Imam Reza Hospital, Mashhad, Iran are chosen as the participants of the study. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. Intervention group will receive the 0.5% bupivacaine and control will receive 0.25% bupivacaine after surgery. The responsible for data collection is blind to group allocation and the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Approval date

2021-11-06, 1400/08/15

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.802

Health conditions studied**1****Description of health condition studied**

Unilateral knee arthroplasty

ICD-10 code

T84.9XXA

ICD-10 code description

Unspecified complication of internal orthopedic prosthetic device, implant and graft, initial encounter

Primary outcomes**1****Description**

The rate of pain

Timepoint

3, 6, 12 and 24 hours after intervention

Method of measurement

Visual analogue scale (VAS)

2**Description**

Muscle strength

Timepoint

12 and 24 hours after intervention

Method of measurement

Maximum voluntary isometric contraction (MVIC)

Secondary outcomes

1

Description

The rate of pain reliever consumption

Timepoint

24 hours after intervention

Method of measurement

Type and amount of pain reliever consumed by the patient

Intervention groups

1

Description

Intervention group: The intervention group will receive 0.25% bupivacaine to adductor canal block after unilateral knee arthroplasty.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive 0.5% bupivacaine to adductor canal block after unilateral knee arthroplasty.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Hosnieh Esmaeili Namghi

Street address

Imam Reza Hospital, Imam Reza Square

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9137913316

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hosnie.esmaili@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Hosnieh Esmaeili Namghi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The research data obtained from the main outcomes of the study can be shared freely as 'open data'.

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

The research data is exclusively accessible to the researchers working at universities and centers for scientific research.

Under which criteria data/document could be used

The research data is exclusively accessible to the researchers working at universities and centers for scientific research.

From where data/document is obtainable

Hosnieh Esmaeili Namghi provides the data analysis to the applicants via email: hosnie.esmaili@gmail.com.

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

Applicants can send emails to him and receive a response within a week.

Comments