

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

A clinical trial to compare the effectiveness of bupivacaine along with dexmedetomidine with bupivacaine on adductor canal block after unilateral total knee arthroplasty

Protocol summary

Study aim

To compare the effectiveness of bupivacaine along with dexmedetomidine with bupivacaine on adductor canal block after unilateral total knee arthroplasty

Design

A randomized and double-blind clinical trial with parallel and control groups will be conducted on 48 patients using random number tables.

Settings and conduct

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

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients candidate for unilateral total knee arthroplasty; age over 18 years. Exclusion criteria: Having a contraindication for adductor canal block; having diabetes mellitus; having local anesthetics allergies; bradycardia; long-term use of analgesics; having liver failure; having renal failure.

Intervention groups

The intervention group will receive 15 mg bupivacaine 0.5% along with 1 mg/kg dexmedetomidine to adductor canal block after unilateral total knee arthroplasty. The control group will receive 15 mg bupivacaine 0.5% and 1 mg/kg fentanyl to adductor canal block after unilateral total knee arthroplasty.

Main outcome variables

Evaluation the rate of pain, prescribing the first pain reliever after surgery, the rate of pain reliever consumption and 100-step walking test time.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230215057432N1**

Registration date: **2023-02-21, 1401/12/02**

Registration timing: **prospective**

Last update: **2023-02-21, 1401/12/02**

Update count: **0**

Registration date

2023-02-21, 1401/12/02

Registrant information

Name

Hossein Khademi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3854 3031

Email address

khademihs1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of bupivacaine along with dexmedetomidine with bupivacaine on adductor canal block after unilateral total knee arthroplasty

Public title

The effectiveness of dexmedetomidine on pain relief after unilateral total knee arthroplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients candidate for unilateral total knee arthroplasty
Age over 18 years

Exclusion criteria:

Having a contraindication for adductor canal block
Having diabetes mellitus
Having local anesthetics allergies
Bradycardia
Long-term use of analgesics
Having liver failure
Having renal failure

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be simple randomly assigned to intervention groups using a random table type and opaque envelopes will be used for concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants and responsible for data collection are 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

2022-10-11, 1401/07/19

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.618

Health conditions studied

1

Description of health condition studied

Unilateral total knee arthroplasty

ICD-10 code

Z96.6

ICD-10 code description

Presence of orthopaedic joint implants

Primary outcomes

1

Description

The rate of pain

Timepoint

1, 3, 6, 12, 18 and 24 hours after intervention

Method of measurement

Visual analogue scale (VAS)

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

2

Description

Prescribing the first pain reliever after surgery

Timepoint

After intervention

Method of measurement

Based on minutes after surgery

3

Description

100-step walking test time

Timepoint

Before, one and two days after intervention

Method of measurement

Based on minutes

Intervention groups

1

Description

Intervention group: The intervention group will receive 15 mg bupivacaine 0.5% (Darou Darman Pars, Iran) along with 1 mg/kg dexmedetomidine (Darou Darman Arang, Iran) to adductor canal block after unilateral total knee arthroplasty.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive 15 mg bupivacaine 0.5% (Darou Darman Pars, Iran) and 1 mg/kg fentanyl (Caspian Tamin, Iran) to adductor canal block after unilateral total knee arthroplasty.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Maryam Sharafi

Street address

Imam Reza Hospital, Imam Reza Square

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Sharafim991@mums.ac.ir

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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vcresearch@mums.ac.ir

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

Maryam Sharafi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

Maryam Sharafi provides the data analysis to the applicants via email: Sharafim991@mums.ac.ir.

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