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)
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+98 51 3854 3031
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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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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 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
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