Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the efficacy of intrathecal dexmedetomidine combined with bupivacaine versus bupivacaine alone on pain, shivering, nausea, and vomiting following lower limb orthopedic surgery: a randomized double-blind clinical trial in Nasiriyah, Iraq

Protocol summary

Study aim
Comparison of the efficacy of intrathecal dexmedetomidine combined with bupivacaine versus bupivacaine alone on pain, shivering, nausea, and vomiting following lower limb orthopedic surgery

Design
This controlled, parallel-group, double-blinded, randomized phase 3 trial will include 80 patients. Randomization will use computer-generated block sequences with allocation concealment.

Settings and conduct
The study will be conducted at Al-Nasiriyah Teaching Hospital, Nasiriyah, Iraq. Participants will be randomly assigned to receive either intrathecal bupivacaine combined with 5 µg dexmedetomidine or intrathecal bupivacaine with saline. Patients and outcome assessors will be blinded to group allocation. Outcomes will be assessed during the first 24 hours after surgery.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adult patients aged 18-65 years, scheduled for elective lower-limb orthopedic surgery, ASA I–II, and eligible for spinal anesthesia; Exclusion criteria: Known hypersensitivity or contraindication to dexmedetomidine or bupivacaine, contraindications to spinal anesthesia, history of chronic pain syndromes or regular opioid use, significant cardiovascular disease, neurological or psychiatric disorders affecting pain assessment, and pregnancy or lactation.

Intervention groups
All participants will receive standard perioperative care, and spinal anesthesia will be administered according to a standardized protocol. Participants will be randomly assigned to one of two study groups. Group A will receive intrathecal bupivacaine combined with dexmedetomidine, while Group B will receive intrathecal bupivacaine alone.

Main outcome variables
Primary outcome: Postoperative pain intensity.
Secondary outcomes: severity of postoperative shivering, nausea and vomiting, time to first analgesic request, total analgesic consumption, requirement for rescue medications.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130803014251N12**
Registration date: **2026-07-10, 1405/04/19**
Registration timing: **prospective**

Last update: **2026-07-10, 1405/04/19**
Update count: **0**

Registration date
2026-07-10, 1405/04/19

Registrant information

Name
MORTEZA NASIRI

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-07-16, 1405/04/25
Expected recruitment end date
2026-09-16, 1405/06/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy of intrathecal dexmedetomidine combined with bupivacaine versus bupivacaine alone on pain, shivering, nausea, and vomiting following lower limb orthopedic surgery: a randomized double-blind clinical trial in Nasiriyah, Iraq

Public title
Evaluation of the effect of adding dexmedetomidine to spinal anesthesia in lower limb orthopedic surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adult patients aged 18-65 years Scheduled for elective lower-limb orthopedic surgery American Society of Anesthesiologists (ASA) physical status I or II Eligible for spinal anesthesia Ability to understand and provide written informed consent
Exclusion criteria:
Known hypersensitivity or contraindication to dexmedetomidine or bupivacaine Contraindications to spinal anesthesia (e.g., coagulopathy, infection at the injection site, severe hypovolemia) History of chronic pain syndromes or regular opioid use Significant cardiovascular diseases (e.g., severe bradycardia, heart block, uncontrolled hypotension) Neurological or psychiatric disorders affecting pain assessment Pregnancy or lactation
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly allocated in a 1:1 ratio to one of the two study groups using a computer-generated randomization sequence. Block randomization with a block size of four will be used to ensure balanced allocation between the groups. Allocation concealment will be achieved using sequentially numbered, opaque, sealed envelopes (SNOSE), which will be opened only after participants have been confirmed eligible for enrollment.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients, the anesthesiologist performing the spinal anesthesia, surgeons, outcome assessor, and data analyst will all be blinded to group allocation. Study drugs will be prepared by an independent anesthesiologist or nurse who is not involved in patient management, outcome assessment, or data collection. The study solutions will be prepared in identical syringes with equal volumes and labeled with coded identifiers. Outcome assessors will evaluate postoperative pain, shivering, nausea, and vomiting without knowledge of the assigned intervention. The allocation code will remain concealed until completion of data analysis unless unblinding is required for patient safety.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق در پژوهش دانشکده بهداشت و پیراپزشکی دانشگاه علوم پزشکی تهران
Street address
Building of Health School of Tehran University of Medical Sciences, Poursina Alley, Ghods Street, Enghelab Street, Tehran Province, Tehran, Iran
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Province
Tehran
Postal code
1417744361
Approval date
2026-07-02, 1405/04/11
Ethics committee reference number
IR.TUMS.SPH.REC.1405.116

Health conditions studied

1

Description of health condition studied
Postoperative pain following lower limb orthopedic surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Postoperative pain intensity
Timepoint
During the first 24 hours after surgery (at 30 minutes and 1, 2, 4, 6, 12, and 24 hours postoperatively)
Method of measurement
Visual Analog Scale (VAS)

Secondary outcomes

1

Description
Incidence and severity of postoperative shivering
Timepoint
Immediately after spinal anesthesia, on arrival at the post-anesthesia care unit, and at 15, 30, and 60 minutes postoperatively
Method of measurement
Shivering grading scale

2

Description
Incidence of postoperative nausea and vomiting (PONV)
Timepoint
At 2, 6, 12, and 24 hours after surgery
Method of measurement
Direct patient questioning and clinical observation using a 3-point ordinal scale (0 = none, 1 = nausea, 2 = vomiting)

3

Description
Time to first rescue analgesic request
Timepoint
Continuously during the first 24 hours after surgery
Method of measurement
A structured postoperative follow-up form

4

Description
Total analgesic consumption
Timepoint
During the first 24 hours after surgery
Method of measurement
A structured postoperative follow-up form

5

Description
Requirement for rescue medications
Timepoint
During the first 24 hours after surgery
Method of measurement
A structured postoperative follow-up form

Intervention groups

1

Description
Intervention group: Participants in this group will receive spinal anesthesia with 14 mg of intrathecal hyperbaric bupivacaine combined with 5 µg of dexmedetomidine.
Category
Treatment - Drugs

2

Description
Control group: Participants in this group will receive spinal anesthesia with 14 mg of intrathecal hyperbaric bupivacaine combined with 0.5 mL of normal saline.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Nasiriyah Teaching Hospital
Full name of responsible person
Ahmed Jawad Raheem Raheem
Street address
Mortada Street, Nasiriyah, Dhi Qar Governorate, Iraq
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Morteza Nasiri

Position

Assistant Professor

Latest degree

Ph.D.

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

Only a part of patients' demographical data and main outcomes will be shared.

When the data will become available and for how long

After the publishing of the results

To whom data/document is available

Data will be available only for researchers working on academic and university associations.

Under which criteria data/document could be used

Mention of study details and authors name

From where data/document is obtainable

Dr. Morteza Nasiri: Department of Operating Room, School of Allied Medical Sciences, Tehran University of Medical Sciences, Tehran, Iran

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

Information will provide via the following email upon request. Mortezanasiri.or87@yahoo.com

Comments