Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Evaluation of the effect of adding dexmedetomidine to 0.5% hyperbaric bupivacaine on the quality of spinal anesthesia in lower limb surgeries

Protocol summary

Study aim
Research on the effect of dexmedetomidine on improving the quality of spinal anesthesia with bupivacaine in lower limb surgeries
Design
A phase 2, double-blind, randomized, parallel-group, controlled clinical trial was used on 60 patients for simple randomization.
Settings and conduct
The location of the study is Besat Hospital in Hamadan. The study type is a double-blind randomized clinical trial.The research population is patients referred to Besat Hospital in Hamadan who are candidates for lower limb surgery, and the research sample is any patient eligible for lower limb surgery with spinal anesthesia who refers to Besat Hospital and meets the study inclusion criteria.
Participants/Inclusion and exclusion criteria
Inclusion criteria: No history of hypertension - No allergy to the study drugs Inclusion criteria: Infection at the injection site - Coagulation problem
Intervention groups
Intervention group: 1.5 cc of 0.5% hyperbaric bupivacaine plus 5 micrograms of sufentanil along with 5 micrograms of dexmedetomidine (0.5 ml, reconstituted with dexmedetomidine) Control group: Normal saline (0.5 ml, reconstituted with normal saline) along with 1.5 cc of 0.5% hyperbaric bupivacaine plus 5 micrograms of sufentanil
Main outcome variables
Assessment of pain in the postoperative period, cumulative use of rescue analgesics

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20241211064021N14**
Registration date: **2026-01-04, 1404/10/14**
Registration timing: **prospective**

Last update: **2026-01-04, 1404/10/14**
Update count: **0**
Registration date
2026-01-04, 1404/10/14

Registrant information
Name
Faeze Noori
Name of organization / entity
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-01-05, 1404/10/15
Expected recruitment end date
2026-12-20, 1405/09/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of adding dexmedetomidine to 0.5% hyperbaric bupivacaine on the quality of spinal anesthesia in lower limb surgeries

Public title
Evaluation of the effect of adding dexmedetomidine to 0.5% hyperbaric bupivacaine on the quality of spinal

anesthesia in lower limb surgeries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 65 years No use of drugs affecting the central nervous system and anesthesia within the past 24 hours. Informed consent to participate in the study

Exclusion criteria:

history of hypertension allergies to the drugs being studied

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method will be used to implement random assignment. In this way, 60 consecutive numbers (from 1 to 60) will be written separately on paper and placed in a container.Each participant in the experiment is then asked to randomly select one of these 30 numbers from a container of numbers. Those who selected numbers 1 to 30 will be assigned to Group A ("Intervention Group 1"), and those who selected numbers 31 to 60 will be assigned to Group B ("Intervention Group 2").

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, blinding is performed in a double-blind manner, so that neither the patient nor the anesthesiologist responsible for the injection is aware of the group assignment. Drug solutions are prepared by someone other than the researchers and are identical in volume, color, and appearance. Group coding remains hidden until the end of statistical analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Hamadan University of Medical Sciences

Street address

Shahid Fahmideh St

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2025-11-15, 1404/08/24

Ethics committee reference number

IR.UMSHA.REC.1404.688

Health conditions studied

1

Description of health condition studied

Studying the effect of dexmedetomidine on improving the quality of spinal anesthesia with bupivacaine in lower limb surgeries

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Severity of pain after surgery in the early hours

Timepoint

At intervals of 6, 12 and 24 hours after the completion of surgery

Method of measurement

Visual Pain Scale and Numerical Pain Scale

Secondary outcomes

1

Description

Duration of need for oral painkillers

Timepoint

Until discharge.

Method of measurement

Record the number of days the patient required oral painkillers (other than usual home remedies) to control pain.

Intervention groups

1

Description
In the intervention group, patients will receive dexmedetomidine. The drug is administered at a dose of 0.5 micrograms per kilogram of body weight as a slow intravenous infusion over 10 minutes before induction of general anesthesia. The purpose of administering this drug is to investigate its effects on reducing stress, the need for anesthetic drugs, and hemodynamic stabilization during surgery. During and after surgery, the patients' state of consciousness and vital signs will be recorded and monitored. No other sedative or anesthetic drugs will be changed at this stage, and all patients will be under the supervision of an anesthesiologist

Category
Treatment - Drugs

2

Description
In the control group, instead of dexmedetomidine, patients receive an equal volume of normal saline (0.9%) as a slow intravenous infusion over the same period of time (10 minutes before induction of anesthesia). Patients in this group will also be placed under the same general anesthesia conditions and other anesthetics will be administered as in the intervention group. During and after the procedure, vital signs, level of consciousness, and need for anesthetics will be monitored and recorded to allow for a precise comparison between the two groups.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat Hospital, Hamadan City

Full name of responsible person
Puran Hajian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

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
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Ebadollah Fadaei Athar

Position
assistant

Latest degree
Medical doctor

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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All potential data can be shared after de-identifying individuals

When the data will become available and for how long
After printing the article

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
There is no prohibition to access the data

From where data/document is obtainable
Ebadollah fadaei athar

What processes are involved for a request to access data/document
First, send an email to fadaeiebad@gmail.com and introduce yourself.

Comments