

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 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

Registration timing: **prospective**

Study aim

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

Last update: **2026-01-04, 1404/10/14**

Update count: **0**

Registration date

2026-01-04, 1404/10/14

Design

A phase 2, double-blind, randomized, parallel-group, controlled clinical trial was used on 60 patients for simple randomization.

Registrant information

Name

Faeze Noori

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 81 3131 4033

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ethics@umsha.ac.ir

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.

Recruitment status

recruiting

Funding source

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

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

Main outcome variables

Assessment of pain in the postoperative period, cumulative use of rescue analgesics

Scientific title

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241211064021N14**

Registration date: **2026-01-04, 1404/10/14**

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

Street address

Shahid Fahmideh St

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6517838678

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+98 81 3131 0000

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fadaeiebad@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Alireza Soltanian

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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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Person responsible for scientific inquiries

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Latest degree

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Person responsible for updating data

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Position

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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