# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Effect of preoperative oral Alprazolam on pain intensity after lumbar disc surgery

### Protocol summary

**Study aim**
The effect of preoperative oral alprazolam on postoperative pain intensity following lumbar disc surgery.

**Design**
This is a phase 3, randomized, double-blind, parallel-group, controlled clinical trial conducted on 42 patients. For randomization, the RAND function in Microsoft Excel software was utilized.

**Settings and conduct**
This randomized, double-blind, placebo-controlled trial at Imam Khomeini Hospital, Sari, evaluates preoperative oral alprazolam's effect on postoperative pain in elective discectomy patients. Via block randomization, Group A receives 0.5mg alprazolam and Group B receives a placebo one hour pre-surgery. Patients and outcome assessors are blinded. Following standardized general anesthesia, patients' pain, nausea, vomiting, and itching are evaluated before recovery discharge, and at four and 24 hours post-surgery.

**Participants/Inclusion and exclusion criteria**
IInclusion Criteria: Confirmed lumbar disc disease, informed consent, elective surgery, age 35–70, and no benzodiazepine hypersensitivity. Exclusion Criteria: Consent withdrawal, emergency surgery, more than two disc involvement, opioid use within 12 hours prior, intraoperative complications, benzodiazepine allergy, or alprazolam contraindications..

**Intervention groups**
Group A receives one tablet of alprazolam 0.5 mg, and Group B receives a placebo, one hour prior to surgery

**Main outcome variables**
Postoperative pain intensity, The amount of postoperative opioid consumption.

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20250630066304N5**
Registration date: **2026-06-16, 1405/03/26**
Registration timing: **prospective**

Last update: **2026-06-16, 1405/03/26**
Update count: **0**

**Registration date**
2026-06-16, 1405/03/26

**Registrant information**

**Name**
Samira Sobhani

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**recruiting**

**Funding source**

**Expected recruitment start date**
2026-06-22, 1405/04/01

**Expected recruitment end date**
2027-01-21, 1405/11/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Effect of preoperative oral Alprazolam on pain intensity after lumbar disc surgery

**Public title**

Effect of preoperative oral Alprazolam on pain intensity after lumbar disc surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Confirmation of diagnosis through physical examination, CT scan, and MRI Patient’s willingness to participate in the study and provision of informed consent. Candidate for non-emergency discectomy surgery. Age between 35 and 70 years. No history of hypersensitivity to benzodiazepines.

**Exclusion criteria:**

Patient’s withdrawal of consent to continue participation at any time. Emergency discectomy surgery. Presence of more than two lumbar disc involvements. Use of opioid analgesics within 12 hours prior to the intervention. History of alcohol or substance abuse. Occurrence of any unusual intraoperative complications. Known hypersensitivity to benzodiazepines. 8. Patients with contraindications to alprazolam, including severe respiratory failure, pregnancy and lactation, or history of addiction and substance abuse.

**Age**

From **35 years** old to **70 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **42**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization with a block size of 4 was used. The random allocation sequence was generated by an independent person using Random Allocation software. Allocation concealment was ensured through the use of sequentially numbered, sealed, opaque envelopes. The drug codes remained concealed until the end of statistical analysis. equally into two groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

To reduce bias, this study is designed as a double-blind study, meaning that: 1. Patients will not be aware of their treatment group. 2. Doctors and medical staff responsible for assessing pain severity and recording side effects will also be unaware of the assigned group. 3. The medications will be provided and numbered in identical, unmarked packages of the same color and size by someone outside the research team.

**Placebo**

Used

**Assignment**

Factorial

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Imam Khomeini Educational and Therapeutic Hospital, Sari – Mazandaran University of Medical Sciences

**Street address**

Central Headquarters of Mazandaran University of Medical Sciences and Health Services, Beginning of Valiasr Highway, Juybar Junction, Sari, Mazandaran, Iran

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815733971

**Approval date**

2024-11-11, 1403/08/21

**Ethics committee reference number**

IR.MAZUMS.IMAMHOSPITAL.REC.1403.069

## Health conditions studied

### 1

**Description of health condition studied**

En Postoperative pain

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Intensity of postoperative pain after lumbar disc surgery

**Timepoint**

Immediately upon arrival in recovery (time zero) and then 4 hours and 24 hours after surgery

**Method of measurement**

Visual Analogue Scale from zero to one hundred millimeters where zero means no pain and one hundred means the worst imaginable pain

## Secondary outcomes

### 1

**Description**

total amount of opioid analgesic (fentanyl) consumed during the first twenty four hours after surgery

**Timepoint**

Twenty four hours after surgery (cumulative consumption is measured)

**Method of measurement**

Recording the total dose of fentanyl consumed (in milligrams) from the patient's medical record

**2**

**Description**

(Postoperative Nausea and Vomiting) Occurrence of nausea or vomiting after surgery (Postoperative Nausea and Vomiting)

**Timepoint**

First twenty four hours after surgery

**Method of measurement**

Recording any episode of nausea or vomiting lasting more than five minutes using an adverse event checklist

**3**

**Description**

Time interval between the end of surgery and the patient's first request for analgesic medication

**Timepoint**

At the time of occurrence (continuous measurement during the first twenty four hours after surgery)

**Method of measurement**

Recording the exact time (in minutes) of the patient's first request for analgesic medication after surgery

## Intervention groups

**1**

**Description**

Intervention group: Intervention group: Oral alprazolam0.5mg (manufactured by Actoverco Company). Patients received a single 0.5mg 1hours before surgery

**Category**

Prevention

**2**

**Description**

Control group: Control group: Placebo tablet (produced by Sari School of Pharmacy, composed of starch, identical in size, shape, and color to alprazolam). Patients received one tablet 1 hours before 1hours before surgery, identical to the intervention group schedule.

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Imam Khomeini Educational and Therapeutic Hospital

**Full name of responsible person**

Dr. Samira Sobhani

**Street address**

Imam Khomeini Educational and Therapeutic Center, Razi Street

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## Sponsors / Funding sources

**1**

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Mazandaran 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**

Mazandaran 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**
Mazandaran University of Medical Sciences
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Dr.Samira Sobhani
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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**
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**
Not applicable
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
Shared documents and data: Individual Participant Data (IPD): De-identified data of 75 patients in three groups (placebo,alprazolam 0.5mg, ) including age, weight, fasting blood glucose, surgery duration, pain intensity by VAS at 8 time points (0,30min,4,24h), fentanyl consumption within 24h, PONV incidence, time to first analgesic. Study Protocol: Full protocol in Persian and English (introduction, objectives, methodology, criteria, randomization, blinding, intervention, outcomes, sample size, statistical analysis). Statistical Analysis Plan (SAP): Complete analysis plan with SPSS 24, tests (Shapiro-Wilk, chi-square, ANOVA, repeated measures ANOVA, GEE), significance level 0.05. Informed Consent Form: Patient-signed form without personal identifiers. Clinical Study Report (CSR): Final report including full results, tables, figures, subgroup analyses. Data Dictionary: Definition of all variables, types, ranges, coding, and units.
**When the data will become available and for how**

**long**

Six months after final publication of study results in a peer-reviewed journal (access start date: six months after article acceptance). Access will remain available for five years from that date.

**To whom data/document is available**

Researchers affiliated with reputable academic or research institutions (domestic or international) who have ethics committee approval for a research proposal related to postoperative pain management or meta-analysis. Industry-affiliated individuals may be allowed only with explicit permission from the principal investigator and a commitment to non-commercial use.

**Under which criteria data/document could be used**

Data and documents may be used solely for academic research purposes (including meta-analysis, re-analysis, secondary studies related to postoperative pain or its complications). Commercial or for-profit use is strictly prohibited. Any publication derived from these data must cite the original clinical trial as the source. Requests must include a one-to-three-page research proposal specifying objectives, analysis methods, and expected outputs, along with ethics committee approval from the applicant's institution. The applicant must sign a confidentiality and non-commercial use agreement.

**From where data/document is obtainable**

Requests should first be sent to the Principal Investigator (corresponding author) via email: (Aliehzamani@gmail.com). If no response within four weeks, requests may be directed to the Vice-Chancellor for Research and Technology, Mazandaran University of Medical Sciences at: Moallem Square, Building No. 2, Third Floor, Sari, Iran, Postal code 33971-48157, Tel +98 33044001, Email pajhoheshi@mazums.ac.ir. Mailing address: pajhoheshi@mazums.ac.ir.

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

Applicant submits written request including research proposal and ethics approval to PI's email. Request reviewed by PI and a selected research team member within two weeks (scientific and ethical evaluation). If approved, applicant signs confidentiality and non-commercial use agreement. Data (encrypted SPSS or Excel file) and requested documents sent via secure cloud link or encrypted email. Entire process from request receipt to data delivery takes a maximum of four weeks. If denied, written explanation is provided.

**Comments**

All shared data will be devoid of patient identifiers (name, surname, medical record number, national ID, phone number). Access to raw data is subject to compliance with data protection and confidentiality laws of the Islamic Republic of Iran and international standards (e.g., GDPR for international collaborators). Researchers from outside Iran must also sign a data protection compliance agreement. No custom analysis scripts/codes exist because all analyses were performed using SPSS software with graphical user interface.