# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Comparison of Zolpidem and melatonin in postoperative pain control in intervertebral disc herniation surgery under general anesthesia

## Protocol summary

**Study aim**
Comparison of Zolpidem and melatonin in postoperative pain control in intervertebral disc herniation surgery under general anesthesia

**Design**
The study will be double blind and clinical trial.60 patients will be randomly divide into 2 groups. The groups are parallel. The trial phase is 3.

**Settings and conduct**
Patients with herniated lumbar intervertebral disc surgery in Valiasr hospital in Arak are divided into 3 groups by simple randomization with envelopes. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Candidate for intervertebral disc herniation surgery, 17 to 65 years, absence of coagulation disorders, no history of drug use in the last 48 hours, psychedelics and alcohol, lack of platelet count less than 150 thousand, no family history of thromboembolism, L2 - L5 surgery and laminectomy
Exclusion criteria: Reluctance to participate in the study

**Intervention groups**
Intervention group 1: We will receive 6 milligram of sublingual melatonin (Webber Natural Co) dissolved in water (final volume 5 ml) 90 minutes before surgery.
Intervention group 2:We will receive 10 milligram of zolpidem in the form of tablets dissolved in water (manufactured by Hakim Pharmaceutical Company - Iran) 90 minutes before surgery.

**Main outcome variables**
Pain ,mean of narcotics consumption in 24 hours after surgery

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20141209020258N161**
Registration date: **2021-06-22, 1400/04/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-22, 1400/04/01**
Update count: **0**

**Registration date**
2021-06-22, 1400/04/01

**Registrant information**

**Name**
Fariba Farokhi

**Name of organization / entity**
Arak University of Medical Sciences

**Country**
Iran (Islamic Republic of)

**Phone**
+98 86 3222 2003

**Email address**
f.farokhi@arakmu.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-06-15, 1400/03/25

**Expected recruitment end date**
2022-06-15, 1401/03/25

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparison of Zolpidem and melatonin in postoperative pain control in intervertebral disc herniation surgery under general anesthesia

**Public title**
Comparison of Zolpidem and melatonin in postoperative pain control in intervertebral disc herniation surgery under general anesthesia
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Candidate for intervertebral disc herniation surgery 17 to 65 years Both gender Absence of coagulation disorders Absence of liver disease and renal disease and heart disease No history of drug use in the last 48 hours No addiction to drugs, psychedelics and alcohol Lack of sensitivity to the studied drugs Lack of platelet count less than 150 thousand No family history of thromboembolism Absence of severe hemodynamic instability L2 - L5 surgery and laminectomy
**Exclusion criteria:**
Reluctance to participate in the study
**Age**
From **17 years** old to **65 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Simple individual randomization with random allocation with envelopes in 2 groups A and B . In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Outcome assessor and data analyzer and participant are blind (double blind). Outcome assessor and data analyzer and participant don't aware from grouping. The intern is unaware of the drugs prescribed in each group and the anesthesiologist prepares the drugs and provides them to the intern. Also, the patients do not know about their group.The syringes are covered with foil.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics comittee of Arak University of Medical Sciences
**Street address**
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,Sardasht,Arak
**City**
Arak
**Province**
Markazi
**Postal code**
3848176941
**Approval date**
2021-04-21, 1400/02/01
**Ethics committee reference number**
IR.ARAKMU.REC.1400.006

## Health conditions studied

### 1

**Description of health condition studied**
Herniated lumbar intervertebral disc
**ICD-10 code**
M51.26
**ICD-10 code description**
Other intervertebral disc displacement, lumbar region

## Primary outcomes

### 1

**Description**
Pain
**Timepoint**
During recovery and at 2, 4, 6, 12 and 24 hours after surgery
**Method of measurement**
Visual analog scale of pain

### 2

**Description**
Mean of narcotics consumption
**Timepoint**
24 hours after surgery
**Method of measurement**
Patient file

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group 1: We will prescribe 6 milligram of sublingual melatonin (Webber Natural Co) dissolved in water (final volume 5 ml) 90 minutes before surgery.
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group 2:We will prescribe 10 milligram of zolpidem in the form of tablets dissolved in water (manufactured by Hakim Pharmaceutical Company - Iran) 90 minutes before surgery.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Valiasr hospital
**Full name of responsible person**
Dr Hesamodin Modir
**Street address**
Valiasr hospital, Valiasr squre
**City**
Arak
**Province**
Markazi
**Postal code**
3848176941
**Phone**
+98 86 3222 2003
**Email**
modir.he@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Arak University of Medical Sciences
**Full name of responsible person**
Dr Alireza Kamali
**Street address**
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
**City**
Arak
**Province**
Markazi
**Postal code**
3848176941
**Phone**
+98 86 3222 2003
**Fax**
+98 86 3222 2003
**Email**
alikamaliir@yahoo.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Arak 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**
Arak University of Medical Sciences
**Full name of responsible person**
Dr Esmaeel Moshiri
**Position**
Associate professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Anesthesiology
**Street address**
Shahid Shirodi street, Valiasr square, Valiasr hospital
**City**
Arak
**Province**
Markazi
**Postal code**
3814957558
**Phone**
+98 86 3222 2003
**Fax**
+98 86 3222 2003
**Email**
modir.he@gmail.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Arak University of Medical Sciences
**Full name of responsible person**
Dr Hesamedin Modir
**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Valiasr Hospital, Valiasr squre, Shahid Shirodi street

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Email**

modir.he@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Vesal Aghdasi

**Position**

medicine student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Fax**

+98 86 3222 2003

**Email**

vesal.sghdasi@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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