

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, 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 square

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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

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Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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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

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

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Specialist

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Vesal Aghdasi

Position

medicine student

Latest degree

Medical doctor

Other areas of specialty/work

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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