Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of melatonin, gabapentin and dranabinol in pain control of patients after hip fracture repair surgery.

Protocol summary

Study aim
Comparison of melatonin, gabapentin and dranabinol in pain control of patients after hip fracture repair surgery.

Design
The present study is a double-blind, parallel-group, randomized clinical trial (using block randomization) conducted on 120 patients.

Settings and conduct
In this randomized, double-blind clinical trial, patients scheduled for femoral fracture repair surgery at Valiasr Hospital in Arak will be randomly allocated, using block randomization, into three groups (A, B, and C). Blinding will be achieved through labeling of the drug containers and coding of the patients, and the study outcomes will ultimately be compared between the groups.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients undergoing surgical repair of femoral fracture؛ Having informed consent to participate in the study؛ Performing surgery on one side؛ Exclusion Criteria: Having systemic diseases including kidney, liver, cardiovascular, high blood pressure, diabetes, or malignancy؛ Having a history of drug or chronic pain medication use؛ Known hypersensitivity to the studied drugs and presence of seasonal allergy.

Intervention groups
Melatonin group: Patients in this group will receive two 3-mg melatonin tablets (Razak Pharmaceutical Company), totaling 6 mg, one hour before surgery. Gabapentin group: Patients in the gabapentin group will receive two 300-mg gabapentin capsules (Actoverco Pharmaceutical Company) one hour before surgery. Dronabinol group: Patients in the dronabinol group will receive two 2.5-mg dronabinol capsules (Roxane, Columbus, Ohio) one hour before surgery.

Main outcome variables
Pain score, adverse effects, mean arterial pressure, heart rate, SaO_2, Ramsay score

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191104045328N44**
Registration date: **2025-10-08, 1404/07/16**
Registration timing: **prospective**

Last update: **2025-10-08, 1404/07/16**
Update count: **0**

Registration date
2025-10-08, 1404/07/16

Registrant information
Name
Amin Haji seyyed hoseini
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 86 3366 7583
Email address
amin.medstu@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-10-17, 1404/07/25
Expected recruitment end date
2026-01-15, 1404/10/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparison of melatonin, gabapentin and dranabinol in pain control of patients after hip fracture repair surgery.

Public title
Pain control after femoral fracture surgery with melatonin, gabapentin, and dronabinol.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing surgical repair of femoral fracture. Having informed consent to participate in the study. Performing surgery on one side
Exclusion criteria:
Having systemic diseases including kidney, liver, cardiovascular, high blood pressure, diabetes, or malignancy. Having a history of drug or chronic pain medication use. Known hypersensitivity to the studied drugs and presence of seasonal allergy.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be assigned to three intervention groups in order of arrival and based on a randomization sequence that will be generated in advance. This sequence is unpredictable and its arrangement is completely random. A block randomization method with blocks of 9 will be used to allocate the samples. Thus, using the block random number generation software, a randomization sequence proportional to the required sample size will be generated for the three groups. Initially, all the cases in which the 3 letters A, B, and C can be arranged together in a block of 9 are performed. Then, a block is randomly selected from the blocks by placement, and the arrangement pattern in that block will be used to allocate the participants. Then this block is placed in the main container and another block will be selected again. All these steps will be performed with a software called Sealed Envelope. Concealment will also be observed using this method. The concept of concealment is to make the assignment of individuals to groups unpredictable. In fact, the researcher will not be able to predict which group the next person will be placed in.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be conducted in a double-blind design. None of the patients will be aware of the type of medication they receive. The drugs will be administered by the anesthesiologist. Each patient's medication will be placed in a container and handed to them, without the patient knowing its contents. The assigned intern responsible for outcome recording will also be unaware of the group allocation; patients will be evaluated based on their medical record number, and the collected data will be delivered to the supervising attending physician.
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
Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran
City
Arak
Province
Markazi
Postal code
3848176941
Approval date
2026-02-24, 1404/12/05
Ethics committee reference number
IR.ARAKMU.REC.1403.355

Health conditions studied

1

Description of health condition studied
Femur fracture repair surgery
ICD-10 code
S72.3
ICD-10 code description
Fracture of shaft of femur

Primary outcomes

1

Description
Pain score
Timepoint
Upon arrival to the operating room, and at 2, 4, 6, 12, and 24 hours post-operatively.
Method of measurement
Visual Analog Scale

2

Description
Ramsey Score
Timepoint
Upon arrival to the operating room, and at 2, 4, 6, 12, and 24 hours post-operatively.
Method of measurement
By registering the Ramsey Score

3

Description
Side effects
Timepoint
After the intervention.
Method of measurement
History and examination

4

Description
Opioid dosage
Timepoint
24 hours after surgery.
Method of measurement
Patient file

Secondary outcomes

1

Description
Mean arterial pressure
Timepoint
At the beginning of surgery, every 15 minutes intra-operatively until the end of surgery, in the recovery room, and at 2 and 4 hours post-operatively.
Method of measurement
NIBP monitoring device

2

Description
Heart rate
Timepoint
At the beginning of surgery, every 15 minutes intra-operatively until the end of surgery, in the recovery room, and at 2 and 4 hours post-operatively.
Method of measurement
Cardiac monitoring device

3

Description
Arterial blood oxygen saturation
Timepoint
At the beginning of surgery, every 15 minutes intra-operatively until the end of surgery, in the recovery room, and at 2 and 4 hours post-operatively.
Method of measurement
Pulse oximetry

Intervention groups

1

Description
Intervention group: Patients in this group will receive two 3-mg melatonin tablets (Razak Pharmaceutical Co.), totaling 6 mg, one hour prior to surgery.
Category
Treatment - Drugs

2

Description
Intervention group: Patients in the gabapentin group will receive two 300-mg gabapentin capsules (Actoverco Pharmaceutical Co.) one hour prior to surgery.
Category
Treatment - Drugs

3

Description
Intervention group: Patients in the dronabinol group will receive two 2.5-mg dronabinol capsules (Roxane, Columbus, OH) one hour prior to surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak Valiasr Hospital
Full name of responsible person
Dr. Hesamuddin Modir
Street address
Vali Asr hospital, Shahid Shiroudi Street, Arak, Iran
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3814957558
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Behzad Khansari Nejad
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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. Esmaeil Moshiri

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Dr. Hesamuddin Modir

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Niloufar Minaei Aghdohloo

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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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
No - There is not 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

After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

When the data will become available and for how long

Access will be from 2026/2/21 to 2029/2/21 for 3 years.

To whom data/document is available

University researchers

Under which criteria data/document could be used

Academic researchers or university professors or students who intend to use the data of this study, after obtaining permission from the relevant people mentioned, can use the information of this study in the field of metallurgical studies or other relevant review studies. In addition, if requested, they can use the information of this study for the prerequisites of their future studies and the existence of questions and ambiguities. Using the information of this study is subject to mentioning the names and logos of the responsible persons in this study.

From where data/document is obtainable

University researchers and university professors can request Dr. Ahmadreza Behrouzi to use the data after contacting the relevant professor via message or email. Dr. Hesamuddin Modiri: Phone: 09183615107 Email: he_modir@arakmu.ac.ir, Address: Valiasr Hospital, Arak, Vice-Chancellor of Hospital Education

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

Letter writing should be done with professors and universities.

Comments