Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effects of Melatonin, Gabapentin and Dextromethorphan on post operative pain control in patients undergoing hip fracture surgery with general anesthesia

Protocol summary

Study aim

The effects of Melatonin, Gabapentin and Dextromethorphan on post operative pain control in patients undergoing hip fracture surgery with general anesthesia

Design

This double-blind and clinical trial .120 patients who are candidate for hip bone surgery at Valiasr Hospital in Arak. We will divide patients in 4 groups by simple randomization. Groups are parallel.

Settings and conduct

This double-blind and clinical trial .120 patients who are candidate for hip bone surgery at Valiasr Hospital in Arak.The patients are divided into 4 groups by simple randomization with envelopes.The study is double-blind.Outcome elevator and analyzer and participant are blind (double blind).

Participants/Inclusion and exclusion criteria

Inclusion criteria:Candidate for hip fracture surgery, 17 to 65 years old, both sexes ,absence of fractures in other organs ,absence of coagulation disorders, lack of renal and hepatic and cardiovascular disease, no history of drug use in the past 48 hours, no drug and psychotropic addiction and alcohol Exclusion criteria:Unwillingness to participate in the study, severe hemodynamic instability

Intervention groups

Intervention group 1: We treat patients with 6 milligram Melatonin sublingual (Webber Natural.Canadian Co.) dissolved in water (final volume is 5 millimeter) 90 minute before surgery. Intervention group 2: We treat patients with 1 milligram in kilogram oral Dextromethorphan (Porcina Pharmaceutical Co. Iran)dissolved in water (final volume is 5 millimeter) 90 minutes before surgery. Intervention group 3: We treat patients with 600 milligram tablet of Gabapantin (Tehran shimi Co. Iran)dissolved in water (final volume is 5 millimeter) 90 minutes before surgery. Control group:We treat patients with 5 millimeter distilled water orally 90 minutes before surgery.

Main outcome variables

Pain, sedation, mean opiate drug use

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N136**
Registration date: **2020-03-13, 1398/12/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-13, 1398/12/23**
Update count: **0**

Registration date

2020-03-13, 1398/12/23

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of Melatonin, Gabapentin and Dextromethorphan on post operative pain control in patients undergoing hip fracture surgery with general anesthesia

Public title
The effects of Melatonin, Gabapentin and Dextromethorphan on post operative pain control in patients undergoing hip fracture surgery with general anesthesia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for hip fracture surgery 17 to 65 years old Both sexes Absence of fractures in other organs Absence of coagulation disorders Lack of renal and hepatic and cardiovascular disease No history of drug use in the past 48 hours No drug and psychotropic addiction and alcohol
Exclusion criteria:
Unwillingness to participate in the study Severe hemodynamic instability
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: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple individual randomization with randomization with envelopes in 4 groups A and B and C and D . 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
This study is clinical trial.Outcome elevator and analyzer and participant are blind (double blind).Outcome elevator and analyzer and participant don't aware from grouping.
Placebo
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 Center, Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Approval date
2020-01-12, 1398/10/22
Ethics committee reference number
IR.ARAKMU.REC.1398.286

Health conditions studied

1

Description of health condition studied
Hip fracture surgery
ICD-10 code
S32.4
ICD-10 code description
Fracture of acetabulum

Primary outcomes

1

Description
Pain
Timepoint
At recovery time, 2, 4, 6, 12 and 24 hours after surgery
Method of measurement
Visual analog scale

2

Description
Sedation
Timepoint
24 hours after surgery
Method of measurement

Ramsy score

3

Description
Mean of opiate drug
Timepoint
24 hours after surgery
Method of measurement
Milligram

4

Description
Mean blood pressure
Timepoint
Every 15 minutes during surgery and recovery time
Method of measurement
Barometer

5

Description
Mean heart rate
Timepoint
Every 15 minutes during surgery and recovery time
Method of measurement
Count

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: We treat patients with 6 milligram Melatonin sublingual (Webber Natural.Canadian Co.) dissolved in water (final volume is 5 millimeter) 90 minute before surgery.
Category
Treatment - Drugs

2

Description
Intervention group 2: We treat patients with 1 milligram in kilogram oral Dextromethorphan (Porcina Pharmaceutical Co. Iran)dissolved in water (final volume is 5 millimeter) 90 minutes before surgery.
Category
Treatment - Drugs

3

Description
Intervention group 3: We treat patients with 600 milligram tablet of Gabapantin (Tehran shimi Co. Iran)dissolved in water (final volume is 5 millimeter) 90 minutes before surgery.
Category
Treatment - Drugs

4

Description
Control group:We treat patients with 5 millimeter distilled water orally 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
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Arak
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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
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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 Behnam Mahmodie

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Valiasr Hospital, Valiasr squre, Shahid Shirodi street

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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

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Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Armita Behnami moghadam

Position
Medicine student

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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armita.behnami1995@gmail.com

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
When we publish article in journal

When the data will become available and for how long
After the article is published

To whom data/document is available
Researcher in university

Under which criteria data/document could be used
If there are additional questions

From where data/document is obtainable
Dr Hesamodin Modir

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

They have to write letters to the professors and the university.

Comments