Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Aug 2026

Comparison of the effects of melatonin and clonidine in the prevention of postoperative delirium in patients undergoing major orthopedic surgeries

Protocol summary

Study aim
To determine the effect of clonidine and melatonin on delirium prevention in patients undergoing major orthopedic surgeries

Design
A total of 150 patients with elective orthopedic surgery, who have been admitted to Imam Reza Hospital in Birjand, will be selected. Participants will be randomly allocated to two intervention groups and one control group, and each participant will be assigned a code (n=50 per group).

Settings and conduct
The study will be conducted in Imam Reza Hospital in Birjand during 2019 and 2020. Participants will be randomly allocated into three groups of 50. One group will receive 100 micrograms clonidine the night before surgery at bedtime and 100 micrograms 90 minutes before surgery. In the second intervention group, melatonin will be given at a dose of 5 milligrams the night before surgery at bedtime and 5 mg 90 minutes before surgery. The control group does not receive any intervention. The level of delirium in patients will be assessed on days 1, 2, and 3 after surgery using abbreviated mental test and cognitive status examination.

Participants/Inclusion and exclusion criteria
Major inclusion criteria: Patients undergoing major elective orthopedic surgery and age above 65 years. Major exclusion criteria: abbreviated mental test score below 8; blood pressure lower than 100 millimeters of mercury; and history of depression that has resulted in hospitalization or use of psychiatric drugs.

Intervention groups
There are two intervention groups and one control group. The first intervention group will receive 100 micrograms clonidine the night before surgery at bedtime and 100 micrograms 90 minutes before surgery. In the second intervention group, melatonin will be given at a dose of 5 milligrams the night before surgery at bedtime and 5 mg 90 minutes before surgery. The control group does not receive any intervention.

Main outcome variables
Delirium

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170316033099N7**
Registration date: **2019-03-25, 1398/01/05**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-25, 1398/01/05**
Update count: **0**

Registration date
2019-03-25, 1398/01/05

Registrant information

Name
Mohammad Bagher Roozgar
Name of organization / entity
Birjand University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-26, 1397/12/07

Expected recruitment end date
2020-02-25, 1398/12/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of melatonin and clonidine in the prevention of postoperative delirium in patients undergoing major orthopedic surgeries

Public title

Effect of melatonin and clonidine on postoperative delirium

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing major elective orthopedic surgery Age above 65 years Informed consent for participation

Exclusion criteria:

Abbreviated mental test score below 8 Blood pressure lower than 100 millimeters of mercury History of depression that has resulted in hospitalization or use of psychiatric drugs Dementia History of head trauma causing hematoma or dementia History of tumor and cerebral infarction History of common disorders of the glands such as hyperthyroidism and hypothyroidism Chronic metabolic disorders History of head and neck radiotherapy History of poisoning with heavy metals and carbon monoxide Alcohol consumption for more than a year Chronic liver and kidney disease Presence of chronic infectious diseases Consumption of psychiatric and hypnotic drugs on a regular basis

Age

From **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Each patient is assigned a code, and they will be allocated into intervention or control groups using the table of random numbers.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Ghaffari Ave.

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2019-02-25, 1397/12/06

Ethics committee reference number

Ir.bums.rec.1397.355

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05.9

ICD-10 code description

Delirium, unspecified

Primary outcomes

1

Description

Delirium

Timepoint

24, 48, and 72 hours after syrgery

Method of measurement

abbreviated mental test and mini-mental state examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 (clonidine): They will receive 100 micrograms clonidine the night before surgery at bedtime and 100 micrograms 90 minutes before surgery.

Category

Prevention

2

Description

Intervention group 2 (melatonin): In this group, melatonin will be given at a dose of 5 milligrams the night before surgery at bedtime and 5 milligrams 90 minutes before surgery.

Category
Prevention

3

Description
Control group: They will receive the routine treatment of the center.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Dr Amirhosain Ebrahimi

Street address
Taleghani St.

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9717853577

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Birjand 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
Birjand 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
Birjand University of Medical Sciences

Full name of responsible person
Dr Amirhosain Ebrahimi

Position
Medical Student

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Person responsible for scientific inquiries

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Position
Psychiatrist

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Mohammad Bagher Roozgar

Position

Translator

Latest degree

Master

Other areas of specialty/work

Others

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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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Deidentified Individual Participant Data Set

When the data will become available and for how long

When the paper extracted from the project is published and for six months

To whom data/document is available

readers of the paper

Under which criteria data/document could be used

Research purposes upon presentation of proofs

From where data/document is obtainable

personal correspondence with the corresponding author

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

email and an estimated one-week interval for response

Comments