

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3239 5680

##### Email address

roozgar@bums.ac.ir

##### 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

lr.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 surgery

#### 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.

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3222 2300

**Email**

amirebrahimi100@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Dr Tooba Kazemi

**Street address**

Ghaffari Ave.

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3238 1200

**Email**

drtooba.kazemi@gmail.com

**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

**Street address**

Ghaffari Ave.

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3234 9394

**Email**

amirebrahimi100@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Dr Aliakbar Esmaeili

**Position**

Psychiatrist

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Ghaffari Ave.

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3242 5402

**Email**

esmaeili67@gmail.com

**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

**Street address**

Ghaffari St.,

**City**

Birjand,

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3239 5680

**Fax**

+98 56 3242 0447

**Email**

roozgar@bums.ac.ir

**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**