

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the effect of oral melatonin administration in preventing delirium in patients after neurosurgery

#### Protocol summary

##### Study aim

Evaluation of oral melatonin administration to prevent delirium in patients undergoing neurosurgery.

##### Design

The executive plan is a double-blind study. 38 people participate in this study. This number will be divided into two groups of 19 people. The distribution of these people will be done randomly. 19 of these people will be in the main group and will receive melatonin. The other group will include 19 participants in the project, who will be considered as a control group and will receive a placebo.

##### Settings and conduct

This study will be performed in Imam Khomeini Hospital. Patients will be selected according to the criteria mentioned above. In this study, patients and the medical staff are blind.

##### Participants/Inclusion and exclusion criteria

Study inclusion criteria include: Patients over the age of 65 who are to undergo surgery for degenerative spinal diseases. Exclusion criteria include: Patients with a history of alcoholism Dementia Patients with brain accidents such as stroke, bleeding, infection Taking medications such as: Anticonvulsants / Antidepressants / Antihistamines / Parkinson's / Antipsychotics / Benzodiazepines

##### Intervention groups

The first group receives 5 mg of melatonin the night before surgery and another 5 mg 90 minutes before surgery. The other group receives a placebo in the same way.

##### Main outcome variables

Delirium is very common in different people, especially the elderly who undergo various surgeries and can have significant destructive effects on patients' health and the process of recovery and increase their mortality.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211211053353N1**

Registration date: **2022-01-12, 1400/10/22**

Registration timing: **prospective**

Last update: **2022-01-12, 1400/10/22**

Update count: **0**

##### Registration date

2022-01-12, 1400/10/22

##### Registrant information

##### Name

atefeh karimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5597 5268

##### Email address

ati.karimi97@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-21, 1400/11/01

##### Expected recruitment end date

2022-06-21, 1401/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of oral melatonin administration in preventing delirium in patients after neurosurgery

**Public title**

Evaluation of the effect of melatonin in preventing delirium in patients after neurosurgery

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients undergoing degenerative spine surgery.

**Exclusion criteria:**

Patients with a history of alcoholism  
Dementia  
Patients with brain accidents such as stroke, bleeding, infection  
Taking medications such as: Anticonvulsants / Antidepressants / Antihistamines / Parkinson's / Antipsychotics / Benzodiazepines

**Age**

From 65 years old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: 38

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization by table of random numbers. This will be done by Computerized Random number generator. The information will enter the computer systems and the system will classify the information completely randomly.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants and clinical caregivers are blind in this study, so that none of them knows who is in the main group and the drug and who is in the placebo group.

**Placebo**

Used

**Assignment**

Factorial

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

**Street address**

No.5,Aghamajidi Ali,Avini Ave,Hadisae Square,Rey

**City**

Tehran

**Province**

Tehran

**Postal code**

1843635862

**Approval date**

2022-01-04, 1400/10/14

**Ethics committee reference number**

IR.TUMS.TIPS.REC.1400.209

**Health conditions studied****1****Description of health condition studied**

delirium

**ICD-10 code**

6D70

**ICD-10 code description**

Delirium is characterized by a disturbance of attention, orientation, and awareness that develops within a short period of time, with transient symptoms that may fluctuate depending on the underlying causal condition or etiology. Delirium often includes d

**Primary outcomes****1****Description**

Percentage of people who develop delirium after neurosurgery

**Timepoint**

After surgery and 1,2,3 days after surgery

**Method of measurement**

questionnaire Confusion Assessment Method for the ICU (CAM-ICU)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Melatonin, 5mg, twice: the night before surgery and 90 minutes before surgery, taken orally

**Category**

Treatment - Drugs

**2****Description**

Control group: placebo

**Category**

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Immam khomeini hospital

**Full name of responsible person**

Atefeh Karimi

**Street address**

End of Keshavarz Boulevard, Dr. Gharib Street; Imam Khomeini Hospital Complex

**City**

Tehran

**Province**

Tehran

**Postal code**

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**Phone**

+98 21 6119 0000

**Email**

ati.karimi97@gmail.com

**Web page address**

<https://ikhc.tums.ac.ir/>

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Atefeh Karimi

**Street address**

No.5,Aghamajidi Ali,Avini Ave,Hadisaee Square,Rey

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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**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Atefeh Karimi

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Pharmacy

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## Person responsible for scientific inquiries

### Contact

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Tehran University of Medical Sciences

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Student

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## Person responsible for updating data

### Contact

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student

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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**

Items published in the article are available

**When the data will become available and for how long**

After the publication of the study results

**To whom data/document is available**

Clinical Pharmacists Neurologists

**Under which criteria data/document could be used**

Contact the responsible person

**From where data/document is obtainable**

Contact the responsible person

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

The information is published after the results are completed and analyzed

**Comments**