Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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,Hadisaee 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
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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

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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 updating data

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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