

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Feb 2026

Comparing melatonin and placebo in prevention of postoperative delirium after orthopedic surgery under spinal anesthesia in the elderly.

Protocol summary

Study aim

Prevention of delirium

Design

Double-blind randomized clinical trial with control group and parallel group design, randomization with random block method, With a sample size of 72.

Settings and conduct

In this prospective, double-blind, randomized study, 72 patients over 60 years of age undergoing femoral bone fractures or knee arthroplasty or hip joint surgery with a spinal anesthesia hospitalized in Shahid Beheshti Hospital of Kashan were included. Patients were randomly divided into two groups: the patients in the melatonin group received oral 5 mg melatonin a night before the operation and the control group received placebo. The Abbreviated Mental Test (AMT) was used to detect delirium. The delirium test was performed by the checklist three days after the operation and the patient's AMT score was recorded. If the score was below 8, the delirium was considered to be positive. The obtained data included the demographic characteristics of the patients, the type of operation, and the results of the AMT test in the questionnaire. The data were entered into the SPSS software and finally analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 60 years; Under orthopedic surgery; Under spinal anesthesia. Non-inclusion criteria: History of drug abuse; Sensory loss including deafness and blindness; Dementia; History of seizures.

Intervention groups

In the intervention group, the night before surgery and until three nights later operation, every night the melatonin capsule will be given; and for placebo group, the night before surgery and until three nights after operation, the placebo capsule will be given every night.

Main outcome variables

Delirium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190419043320N1**

Registration date: **2019-05-20, 1398/02/30**

Registration timing: **prospective**

Last update: **2019-05-20, 1398/02/30**

Update count: **0**

Registration date

2019-05-20, 1398/02/30

Registrant information

Name

Saba Mofidian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5542 1451

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-28, 1398/03/07

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing melatonin and placebo in prevention of postoperative delirium after orthopedic surgery under spinal anesthesia in the elderly.

Public title

The effect of Melatonin on Delirium Prevention

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All patients over the age of 60 under hip, femur or knee surgery Surgery under spinal anesthesia

Exclusion criteria:

Drug abuse Dementia Sensory loss including blindness and deafness Epilepsy

Age

From **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Random block method was used. First we designed blocks of size 4 of A&B in which one of them indicated drug & one of them indicated placebo. Then based on random numbers we wrote a sequence of A&B. Patients were allocated to the groups based on the sequence

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient, person who give the drug to patient ,nurses and the person who evaluates delirium do not know which group the patient is in.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

Ghotberavandi Blv, Kashan University of Medical Sciences

City

Kashan

Province

Isfahan

Postal code

8715973474

Approval date

2019-03-06, 1397/12/15

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1398.007

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05.8

ICD-10 code description

Other delirium

Primary outcomes

1

Description

Delirium

Timepoint

At the beginning of the study and T the first, second and third days after the intervention

Method of measurement

MMT Test Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One melatonin 5-milligram capsule; night before surgery and the night of surgery and two nights later (one capsule every night)

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Beheshti Hospital

Full name of responsible person

Dr Saba Mofidian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Hamid Reza Banafshe
Position
Vice Chancellor of Research & Technology
Latest degree

Ph.D.

Other areas of specialty/work

Pharmacology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available