

# 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

mofidian-s@mail.kaums.ac.ir

##### 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, femure 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

###### Street address

Ghotbe Ravandi Blvd.

###### City

Kashan  
**Province**  
Isfahan  
**Postal code**  
8715981151  
**Phone**  
+98 31 5554 0026  
**Email**  
mofidian-s@mail.kaums.ac.ir  
**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Hamid Reza Banafshe  
**Street address**  
Kashan University of Medical Sciences, Ghotberavandi Blvd.  
**City**  
Kashan  
**Province**  
Isfahan  
**Postal code**  
8715981151  
**Phone**  
+98 31 5554 0021  
**Email**  
mofidian-s@mail.kaums.ac.ir  
**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  
**Street address**  
Kashan University of Medical Science, Ghotberavandi Blv  
**City**  
Kashan  
**Province**  
Isfahan  
**Postal code**  
8715973474  
**Phone**  
+98 31 5554 0021  
**Email**  
banafshe\_h@kaums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Saba Mofidian  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Diba 5th, Sanat Blv  
**City**  
Kashan  
**Province**  
Isfahan  
**Postal code**  
8714881998  
**Phone**  
+98 31 5542 1451  
**Email**  
mofidian-s@mail.kaums.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Saba Mofidian  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Diba 5th, Sanat Blv  
**City**  
Kashan  
**Province**

Isfahan

**Postal code**

8714881998

**Phone**

+98 31 5542 1451

**Email**

mofidian-s@mail.kaums.ac.ir

## 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