

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Feb 2026

### The effect of Melatonin on the incidence of Delirium in hospitalized patients in the Intensive Care Unit

#### Protocol summary

##### Study aim

The effect of Melatonin on the incidence of Delirium in patients hospitalized in the Intensive Care Unit

##### Design

Randomized clinical trial with control group, parallel groups, double-blind

##### Settings and conduct

In this study, 140 patients admitted to the intensive care unit at Shahid Sadoughi Hospital in Yazd and Shahid Beheshti Hospital of Taft from 1/13/2015 to 1/15/2016 were entered into the study on the basis of inclusion and exclusion criteria. Then by random numbers and without the knowledge of the type of intervention divided in 2 groups. In the first group (intervention) 3 mg melatonin and in second group (control) placebo administration will be performed at 9 p.m. for a week or until discharge from ICU. The assessment of delirium will be done on a daily basis by a single educated nurse using Confusion Assessment Method for the ICU (CAM-ICU).

##### Participants/Inclusion and exclusion criteria

Patients age 30 and over with less than 24 hours duration from ICU admission, with Glasgow coma scale (GCS) > 8 Patients, without mechanical ventilation with informed consent entered the study and Patients with history of Delirium or mood disorder before ICU admission, Trauma and intracranial hemorrhage, receive medications such as Benzodiazepines, History of epilepsy and seizure attack were excluded.

##### Intervention groups

Intervention: Melatonin (Nature Made), tablet 3 mg, once daily (21:00 AM), orally for 7 consecutive days Control group: Placebo (consists of tricalcium phosphate, magnesium stearate and starch glue which is made in pharmacy faculty of Yazd Shahid Sadoughi University of Medical Sciences), once daily (at 21:00 AM), orally, for 7 consecutive days.

##### Main outcome variables

Delirium

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150928024236N5**

Registration date: **2018-10-07, 1397/07/15**

Registration timing: **retrospective**

Last update: **2018-10-07, 1397/07/15**

Update count: **0**

##### Registration date

2018-10-07, 1397/07/15

##### Registrant information

##### Name

Fatemeh Hosseini

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3263 2005

##### Email address

hosseini.k.f@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-07-22, 1395/05/01

##### Expected recruitment end date

2017-07-23, 1396/05/01

##### Actual recruitment start date

2016-07-22, 1395/05/01

##### Actual recruitment end date

2017-07-23, 1396/05/01

##### Trial completion date

2017-08-01, 1396/05/10

## Scientific title

The effect of Melatonin on the incidence of Delirium in hospitalized patients in the Intensive Care Unit

## Public title

Effects of Melatonin on the incidence of Delirium

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients age 30 and over with less than 24 hours duration from ICU admission Patients with Glasgow coma scale (GCS) > 8 Patients without mechanical ventilation Patients with informed consent

### Exclusion criteria:

History of delirium or mood disorder before ICU admission Trauma and intracranial hemorrhage Receive medications such as Benzodiazepines History of epilepsy, seizure attack

## Age

From **30 years** old to **60 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **140**

Actual sample size reached: **140**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The random number generator was used in our study to assign each patient randomly in intervention or control group.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The random number generator was used in our study to assign each patient randomly in intervention or control group (Randomized clinical trial). The random numbers were given by a study coordinator, who also encodes the drugs with matching random numbers. In addition, we formulated placebo with the same appearance to Melatonin tablet. Therefore, neither the patients nor the researchers evaluating the study outcome knew which patient is receiving Melatonin or placebo, until the study is over and the random code was revealed.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Sadoghi university of Medical Sciences

##### Street address

Shahid Sadoughi University of Medical Sciences, Bahonar Sq, Yazd.

##### City

Yazd

##### Province

Yazd

##### Postal code

8916978477

##### Approval date

2015-05-31, 1394/03/10

##### Ethics committee reference number

IR.SSU.MEDICINE.REC.1394.368

## 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

Daily (from initial of study for 7 days)

#### Method of measurement

Questionnaire of CAM-ICU

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention : Melatonin (Nature Made), tablet 3 mg, once daily (21:00 AM), orally for 7 consecutive days

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Placebo (consists of tricalcium phosphate,

magnesium stearate and starch glue which is made in pharmacy faculty of Shahid Sadoughi University of Medical Sciences), once daily (at 21:00 AM), orally, for 7 consecutive days.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Mohammad Sadegh Afshar hospital

**Full name of responsible person**

Fateme Hosseini

**Street address**

Mohammad Sadegh Afshar hospital, Yazd Shahid Sadoughi university of medical sciences

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**Postal code**

8913817391

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**Email**

hosseini.k.f@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Amir Houshang Mehrparvar

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Yazd Shahid Sadoughi university of medical sciences, Bahonar Sq, Yazd

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ahmehrparvar@ssu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Fateme Hosseini

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Mental Hospital, Taft, Yazd

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yazd University of Medical Sciences

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**Position**

Assistant Professor

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Assistant Professor

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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