

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

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+98 35 3263 2005

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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

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

Yazd University of Medical Sciences

Full name of responsible person

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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

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

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Person responsible for updating data

Contact

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Full name of responsible person

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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