

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Effect of Melatonin on the incidence of delirium in patients admitted to the intensive care unit: A randomized controlled clinical trial

Protocol summary

Study aim

To determine the effectiveness of Melatonin on prevention of delirium in patients admitted to intensive care units.

Design

Clinical trials with control group, with parallel groups, triple blinded, randomized on 70 patients in each group

Settings and conduct

The study is carried out at the of Besat Hospital in Hamedan. To ensure blinding, the allocation sequence will be created by a different investigator than the one enrolling participants. A third investigator will be responsible for patient follow-up and assessments. Patients will not know what group they are in. Patients, researchers, and data collectors will not be aware of patient grouping. The two intervention and control groups will not be specified for the statistician. The medication regimen of the intervention and control group patients has different pills, the intervention group patients will not know which pill is melatonin.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages 17 to 70 years old; Having the power of communication; Hospitalized for at least seven days in ICU ward; RASS score equal to or greater than -3 ; Non-inclusion criteria: history of psychiatric disorders such as psychosis and mental retardation

Intervention groups

Intervention group: receiving 7 days of 3 mg sublingual melatonin tablets at 9 pm + receiving standard treatment in the intensive care unit Control group: receiving standard treatment in the intensive care unit

Main outcome variables

Delirium incidence; number of admission days

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100816004578N8**

Registration date: **2020-05-12, 1399/02/23**

Registration timing: **retrospective**

Last update: **2020-05-12, 1399/02/23**

Update count: **0**

Registration date

2020-05-12, 1399/02/23

Registrant information

Name

Farshid Rahimibashar

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 811264002151

Email address

f.rahimi@umsh.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-03-15, 1398/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Melatonin on the incidence of delirium in patients admitted to the intensive care unit: A randomized controlled clinical trial

Public title

Effect of Melatonin on prevention of delirium

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Ages 17 to 70 years Having the power of communication
RASS score equal to or greater than -3 Hospitalized for at least seven days in ICU ward

Exclusion criteria:

Vision and hearing problems History of mental disorders such as psychosis and mental retardation History of antipsychotic medication use

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization (groups of 2) will be performed using random numbers list generated by Random Allocation Software © (RAS; Informer Technologies, Inc., Madrid, Spain). The numbers will be placed into sequential containers that will be kept in a secure location until allocation consignment. Enrollment and randomization will be occurred in the emergency department from available admitted ICU patients on a convenience basis. Only patients will be admitted to the ICU through the emergency department will be eligible for inclusion. The consignment will be implemented though: A person who divides patients into control and intervention groups will not be aware of the grouping of individuals.

Blinding (investigator's opinion)

Triple blinded

Blinding description

To ensure blinding, the allocation sequence will be created by a different investigator than the one enrolling participants. A third investigator will be responsible for patient follow-up and assessments. Patients will not know what group they are in. Patients, researchers, and data collectors will not be aware of patient grouping. The two intervention and control groups will not be specified for the statistician. The medication regimen of the intervention and control groups has different pills, the intervention group patients will not know which pill is Melatonin.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamedan University of Medical Sciences

Street address

Hamadan University of Medical Science, Shahid Fahmide boulevard, Hamadan

City

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Province

Hamadan

Postal code

6514845411

Approval date

2019-12-07, 1398/09/16

Ethics committee reference number

IR.UMSHA.REC.1398.723

Health conditions studied**1****Description of health condition studied**

Delirium

ICD-10 code

F05

ICD-10 code description

Delirium due to known physiological condition

Primary outcomes**1****Description**

Delirium incidence

Timepoint

Daily

Method of measurement

Confusion Assessment Method for the ICU (CAM-ICU);
Intensive Care Delirium Screening Checklist (ICDSC)

Secondary outcomes**1****Description**

Number of admission days

Timepoint

after discharge from hospital

Method of measurement

patient's records

Intervention groups

1

Description

Intervention group: Melatonin 3 mg tablet, orally at 9 p.m, every night for one week or till discharge from ICU
+ Receiving standard treatment of the intensive care unit

Category

Prevention

2

Description

Control group: Receiving standard treatment of the intensive care unit

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Farshid Rahimi-Bashar

Street address

General ICU, Besat Hospital, Shahid Motahhari boulevard, Resalat square, Hamadan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeid Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Farshid Rahimi-Bashar

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available