

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Aug 2026

The effects of melatonin versus placebo on delirium prophylaxis in patients hospitalized in intensive care unit of Alzahra hospital, Isfahan, 2014-2015

Protocol summary

Summary

This randomized, double-blind, controlled clinical trial is designed to examine the role of melatonin in prophylaxis of delirium in patients admitted to ICU of Alzahra hospital during 2015-2016. After informed consent, adult patients with less than 24 hours ICU stay, tolerance of tablet dosage form and Glasgow coma scale (GCS) > 8 were included in the study and those with less than 5 days ICU stay duration, hypersensitivity to melatonin or any ingredient of melatonin tablet or placebo, past medical history of epilepsy, seizure attack or history of delirium or mood disorder before ICU admission, severe heart failure, head trauma and those with the Richmond Agitation-Sedation Scale (RASS) -4 or -5 were excluded from the study until sample size of 140 patients. Thereafter, eligible patients will be randomly allocated in intervention or control group. Patients received 3 mg orally melatonin or placebo at 21:00 AM for 5 consecutive days and then they will be followed for more 3 days to evaluate delirium within eight days after start of the study medication. However, if delirium is detected, daily assessment will be continued until presence of delirium or until ICU discharge of patient. Occurrence of delirium will be evaluated daily as primary outcome according to the Confusion Assessment Method-ICU (CAM-ICU). In addition, other related demographic and clinical parameters will be collected.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015022421159N1**
Registration date: **2015-06-13, 1394/03/23**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-13, 1394/03/23

Registrant information

Name

Shadi Farsaei

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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farsaei@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of melatonin versus placebo on delirium prophylaxis in patients hospitalized in intensive care unit of Alzahra hospital, Isfahan, 2014-2015

Public title

The effect of melatonin on delirium prophylaxis

Purpose

Prevention

Inclusion/Exclusion criteria
 Inclusion Criteria: 1. Adult patients (> 18 years old) with less than 24 hours duration from ICU admission 2. Normal gastrointestinal function (can tolerate tablet dosage form) Exclusion Criteria: 1. GCS $\leq$ 8 2. Duration of ICU stay less than 5 days 3. Hypersensitivity to melatonin or any ingredient of melatonin tablet or placebo 4. Past medical history of epilepsy or any seizure attack. 5. Severe heart failure (New York Heart Association classification III/IV) 6. Head trauma 7. RASS (The Richmond Agitation-Sedation Scale) = -4 or -5 8. Past medical history of delirium or mood disorder before ICU admission

Age
 From **18 years** old to **100 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **140**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features
 The random number generator is 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 formulate placebo with the same appearance to melatonin tablet. Therefore, neither the patients nor the researchers evaluating the study outcome know which patient is receiving melatonin or placebo, until the study is over and the random code is revealed.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib Ave, Isfahan University of Medical Sciences.

City

Isfahan

Postal code

Approval date

2014-10-02, 1393/07/10

Ethics committee reference number

393811

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05.9

ICD-10 code description

Delirium, unspecified

Primary outcomes

1

Description

Occurrence of delirium

Timepoint

Daily (from initial of study for 8 days)

Method of measurement

CAM-ICU

Secondary outcomes

1

Description

Duration of delirium

Timepoint

Daily (from initial of study for 8 days)

Method of measurement

Daily evaluation of delirium by CAM-ICU

Intervention groups

1

Description

Intervention: Melatonin (Nature Made), tablet 3 mg, once daily (21:00 AM), orally for 5 consecutive days

Category

Prevention

2

Description

Control group: Placebo (consists of tricalcium phosphate, magnesium stearate and starch glue which is made in pharmacy faculty of Isfahan University of Medical Sciences), once daily (at 21:00 AM), orally, for 5 consecutive days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Intensive care unit of Alzahra hospital, Isfahan

Full name of responsible person

Saeed Abbasi

Street address

Isfahan University of Medical Sciences

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Mehdi Nematbakhsh

Street address

Hezar Jarib Ave, Isfahan University of Medical Sciences

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Isfahan

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

Yes

Title of funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Shadi Farsaei

Position

Academic member/Pharm. D., BCPS

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty