

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

A study of the effect of melatonin on prevention of delirium in Intensive Care Unit (ICU) inpatients

Protocol summary

Summary

This randomized double blind placebo controlled clinical trial which will be conducted on 92 alert and non-delirious inpatients in the ICU ward Imam Reza Hospital, in Kermanshah, to prevent delirium incidence. After inclusion and exclusion criteria implementation, patients will be selected, patients will be divided in 2 groups randomly. In the first group (case) 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. Patients will be matched for underlying disease. 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). All data will be recorded and then analyzed. After final analysis, the results will be announced.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061234482N1**

Registration date: **2017-09-01, 1396/06/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-01, 1396/06/10

Registrant information

Name

Maryam Shirzadi

Name of organization / entity

Kermanshah University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 83 3826 5255

Email address

m_shirzadi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study of the effect of melatonin on prevention of delirium in Intensive Care Unit (ICU) inpatients

Public title

effect of melatonin on prevention of delirium in admitted patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age 18 or above; admitted in ICU; Consciousness Exclusion criteria: Dementia; Critically ill patients; having contraindication of melatonin use; being a current user of melatonin

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 92

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomly by tossing coin

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Number 2 Building, Shahid Beheshti Boulevard

City

Kermanshah

Postal code

4733315444

Approval date

2017-02-05, 1395/11/17

Ethics committee reference number

KUMS.REC.1395.761

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05

ICD-10 code description

Delirium, not induced by alcohol and other psychoactive substances

Primary outcomes

1

Description

Delirium incidence

Timepoint

Daily

Method of measurement

CAM-ICU

Secondary outcomes

1

Description

number of admission days

Timepoint

after discharge from hospital

Method of measurement

patient records

Intervention groups

1

Description

Intervention group: 3 mg melatonin at 9 p.m for a week or till discharge from ICU

Category

Prevention

2

Description

control group: Placebo tab at 9 p.m for a week or till discharge from ICU

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah Imam Reza Hospital

Full name of responsible person

Dr Maryam Shirzadi

Street address

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Dr Behrouz Hamzeh

Street address

Number 2 Building, Shahid Beheshti Boulevard

City

Kermanshah

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, Kermanshah 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**

Kermanshah University Of Medical Science

Full name of responsible person

Dr Maryam Shirzadi

Position

Assistant Professor Of Psychiatry

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Web page address**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