Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effect of oral melatonin on sleep quality of hospitalized patients in the intensive care unit

Protocol summary

Study aim
study for The effect of oral melatonin on sleep quality of hospitalized patients in the intensive care unit

Design
randomized clinical trial with control and factorial group

Settings and conduct
for the Patients addmited in icu(gonabad, mashhad & sarakhs) complete the demographic information including age, weight, BMI, occupation, education level, Apache 2 form and numerical/face scale of pain.Patients will be divided into control and intervention groups. For the intervention group at the end of the second night of hospitalization, after measuring GCS,RCSQ Questionnaire and numerical/face scale of pain were completed.Then, from the third night of hospitalization for 4 nights at 9 pm, 3 mg of melatonin tablets were given to the patient. the pain score and RCSQ questionnaire were completed at the end of the sixth night for both groups. At the end, patients' sleep quality in both groups was assessed before and after the intervention.

Participants/Inclusion and exclusion criteria
Patients admitted to Gonabad, mashhad and sarakhs Hospitals and they have GCS score ≥10 and stable hemodynamic.they haven't been organ failures such as gastrointestinal and severe heart failure, liver/renal insufficiency, history of convulsions, psychiatric or neurological disease, sleep apnea, deafness, blindness,chronic insomnia, narcolepsy and alcohol/drug use(addiction).patients with out severe pain and narcotic/sedation drug order

Intervention groups
For the patients after measuring GCS,Richard Campbell Sleep Quality Questionnaire and numerical/face scale of pain were completed.Then,from the third night of hospitalization for 4 nights at 9pm, 3 mg of melatonin tablets were given to the intervention group. the pain score and RCSQ questionnaire were completed at the end of the sixth night for both control and intervention groups.

Main outcome variables
pain score, sleep quality, GCS

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191105045342N1**
Registration date: **2020-01-20, 1398/10/30**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-20, 1398/10/30**
Update count: **0**

Registration date
2020-01-20, 1398/10/30

Registrant information

Name
Malihe Heydari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3452 6917

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-16, 1398/09/25

Expected recruitment end date
2020-04-19, 1399/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of oral melatonin on sleep quality of hospitalized patients in the intensive care unit

Public title
The effect of melatonin on sleep quality of patients in the intensive care unit

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Glasgow Coma Scale (GCS) score ≥10 patients with stable hemodynamic patients with out alcohol consumption ≥50 units per week or drug use(addiction) / narcotic or sedation drug order in icu haven't been used of drugs that might alter melatonin secretion and decrease plasma levels of melatonin, such as benzodiazepines, NSAIDs, corticosteroids, beta-blockers, haloperidol and amiodarone / sedation with propofol, morphine, alfentanil and dexmedetomidine has been discontinued for a minimum of 36 hours (48 hours for lorazepam and midazolam) before enter to study Apache II score < 35 and Estimated mortality < 75% patients with out severe pain level (pain score > 7 on the numerical scale of pain) for one hour before the prescribe of melatonin patients with out history of convulsions, psychiatric or neurological disease, deafness or blindness and the lack of any kind of sleep disorder such as sleep apnea, narcolepsy, chronic insomnia, restless legs syndrome (RLS) patients with out liver insufficiency and renal insufficiency (requires dialysis) patients with out severe heart failure (the New York Heart Association classification III/IV) patients with out intestinal obstruction, ileus or other conditions likely to affect the enteral absorption of melatonin Do not be pregnant or breast-feeding women more than 24 hours have passed from general anesthesia or hospitalization age ≥18 years old and ≤ 60 years old

Exclusion criteria:
The incidence of gastrointestinal failure that prevents the absorption of melatonin, including obstruction and ileus
The incidence of renal insufficiency (requires dialysis)
The incidence of any kind of sleep disorder such as sleep apnea, narcolepsy over night sleep Pain scores above 7 on the numerical scale of pain during the intervention
Lack of willingness to cooperate in the study

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Gonabad University of Medical Sciences

Street address
Bohlool hospital, Sadi Ave., Parastar Blvd., Gonabad Town

City
Gonabad

Province
Razavi Khorasan

Postal code
7887906432

Approval date
2019-12-31, 1398/10/10

Ethics committee reference number
IR.GMU.REC.1398.141

Health conditions studied

1

Description of health condition studied
Addmited ptients in the intensive care unit

ICD-10 code
G47

ICD-10 code description
Sleep disorders

Primary outcomes

1

Description
Richards Campbell sleep questionaire score

Timepoint
before intervention, sixth night after addmited (fourth night after intervention)

Method of measurement
The person on the line specified in each of the 5 questions (Richards Campbell sleep questionaire score) gives the best description of his or her sleep last night. The score for each question is between 0 and 100, which in total score is divided by 5 and between 0 and 100 points of sleep quality.

2

Description
Glasgow coma score
Timepoint
before intervention and during the study
Method of measurement
According to the Glasgow coma score table (3-15) . The motor score is 6 points, the verbal score 5 points, and the visual score 4 points.

3

Description
pain scale (numerical/face)
Timepoint
before intervention, during the study and sixth night after addmited (fourth night after intervention)
Method of measurement
The Visual Analogue Scale is a 10 cm vertical linear pain that is numbered from 0 to 10, or points to a symbolic face. Zero means \"completely pain free" and 10 means "maximum pain intensity". On a numerical scale, pain ratings are usually described as 0 -3 as mild pain, 4 to 6 as moderate pain, and 7 to 10 as severe pain.

4

Description
Apache 2 score
Timepoint
The first 24 hours hospitalization
Method of measurement
The Apache 2 scale consists of three components: 1 - Acute physiology score (APS)2 - Age adjustment3 - Chronic health evaluation (CHE). Finally, we summarize the scores obtained from all three components. Patients may receive 0 to 71 points. According to the standard table, if the patient's score is between 0, 15, 16 to 19, 20 to 30 and more than 30 points, the risk of death is 10, 15, 35 and > 75%, respectively.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Tab melatonin, 3 mg, once a day at 9 pm, for 4 night, oral
Category
Treatment - Drugs

2

Description
Control group: with out intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Allameh Bohlool Gonabadi hospital
Full name of responsible person
Malihe Heydari
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3

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Sponsors / Funding sources

1

Sponsor
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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
Gonabad University of Medical Sciences
Proportion provided by this source
70
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
Gonabad University of Medical Sciences
Full name of responsible person
Malihe Heydari
Position
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

All data is shared after unidentifiable people

When the data will become available and for how long

Start accessing 6 months after publishing results

To whom data/document is available

For researchers working only in academic and scientific institutions

Under which criteria data/document could be used

only major consequence

From where data/document is obtainable

Send request to phone number : 0098 51 34526917 and email : heydarim10@gmail.com

What processes are involved for a request to access data/document

Email request in writing

Comments