

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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 admitted 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)

Phone

+98 51 3452 6917

Email address

heydarim10@gmail.com

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**

Addmitted ptients in the intensive care unit

ICD-10 code

G47

ICD-10 code description

Sleep disorders

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

Richards Campbell sleep questionnaire score

Timepoint

before intervention, sixth night after addmitted (fourth night after intervention)

Method of measurement

The person on the line specified in each of the 5 questions (Richards Campbell sleep questionnaire 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 admitted (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

Street address

Bohlool hospital, Sadi Ave., Parastar Blvd.,Gonabad

City

Gonabad

Province

Razavi Khorasan

Postal code

7887906432

Phone

+98 51 5723 6833

Email

info@gmu.ac.ir

Web page address

<http://bohlool.gmu.ac.ir/>

2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Malihe Heydari

Street address

Imam Reza hospital, Imam Reza Square., Ibn-e Sina Ave., Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Fax

+98 51 3859 1057

Email

emamreza@mums.ac.ir

Web page address

<http://emamreza.mums.ac.ir/index.php>

3

Recruitment center

Name of recruitment center

Loghman Hakim hospital

Full name of responsible person

Malihe Heydari

Street address

Loghman Hakim hospital, Valiasr Blvd., Sarakhs

City

Sarakhs

Province

Razavi Khorasan

Postal code

9381737448

Phone

+98 51 3452 2229

Fax

+98 51 3453 8463

Email

heydarim10@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Shahla Khosravan

Street address

Bohloul hospital, Sadi Ave., Parastar Blvd., Gonabad

City

Gonabad

Province

Razavi Khorasan

Postal code

7887906432

Phone

+98 51 5722 3028

Fax

+98 51 5722 0578

Email

khosravan@gmu.ac.ir

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

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 106, keshavarzi Ave, Sarallah Blvd, Sarakhs Town

City

Sarakhs

Province

Razavi Khorasan

Postal code

9381737448

Phone

+98 51 3452 6917

Fax

Email

heydarim10@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Mohsen Saheban Maleki

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Bohloul hospital, Sadi Ave., Parastar Blve., Gonabad

City

Gonabad

Province

Razavi Khorasan

Postal code

7887906432

Phone

+98 51 5723 6833

Email

dr.saheban@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Malihe Heydari

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 106, keshavarzi Ave, Sarallah Blvd, Sarakhs Town

City

Sarakhs

Province

Razavi Khorasan

Postal code

9381737448

Phone

+98 51 3452 6917

Fax

Email

heydarim10@gmail.com

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