

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of melatonin on sleep quality in patients with mild traumatic brain injury

Protocol summary

Study aim

Determining the effect of melatonin on sleep quality in patients with mild traumatic brain injury

Design

two arm parallel group double blinded randomised trial

Settings and conduct

Patients who are diagnosed with mTBI after hospitalization will be placed in one of three groups of 20 people A, B and C based on random blocks if they have sleep disorders and inclusion criteria. For blinding, drugs (melatonin, clonazepam, and placebo) are packaged in separate but similar packages and labeled A, B, and C. Medications will be received and labeled by a third party. As a result, the prescriber (researcher) and the patient will be unaware of the type of drug in each package and will not know what drugs are in the three packages. the way of prscription the drug for the melatonin group 3 mg melatonin tablets, for the clonazepam group, 1 mg clonazepam tablets and for the placebo group, one placebo is prescribed overnight. The duration of treatment for different groups will be 4 weeks. The instruments used to assess patients will be a researcher-made demographic questionnaire and the Iranian questionnaire of Petersburg quality of sleep and App Worth questionnaire, which will be done at the beginning of the study, after the end of treatment, one month and three months after treatment (4 times).

Participants/Inclusion and exclusion criteria

mTBI patients in kashan referred to Shahid Beheshti Hospital in Kashan.

Intervention groups

For melatonin group, 3 mg melatonin tablets, for clonazepam group, 1 mg clonazepam tablets and for placebo group, one placebo is prescribed overnight.

Main outcome variables

sleep quality/ habitual sleep efficiency/ sleep latency/ sleep duration/ sleep disturbance/ use of sleeping medications/ daytime dysfunction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220504054738N1**

Registration date: **2023-03-08, 1401/12/17**

Registration timing: **prospective**

Last update: **2023-03-08, 1401/12/17**

Update count: **0**

Registration date

2023-03-08, 1401/12/17

Registrant information

Name

seyede mahshad moosavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3464 5043

Email address

mahshad.m125@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2023-08-22, 1402/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of melatonin on sleep quality in patients with mild traumatic brain injury	
Public title	The effect of melatonin on sleep quality in patients with mild traumatic brain injury
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Not having a proved sleep disorder History of mTBI during one past month Not having allergy to both if the drugs Not having hepatic failure Not having respiratory problems or apnea and not consuming opiates Not having cognitive disorders or dementia Age between 18 to 60 Exclusion criteria: Cessation of therapy Consuming other hypnotic drugs otherwise the ones ordered in this study Manifestation of adverse drug reaction during the study
Age	From 18 years old to 60 years old
Gender	Both
Phase	3
Groups that have been masked	• Participant • Care provider
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	In this study, block randomization method with blocks of equal and constant size (there will be 6 blocks, in each block two people from the intervention group, two people from the control group, two people from the routine treatment group) In order to create balance and comply with the condition of randomization in sampling and allocating the sample to each of the studied groups, it will be used. It is worth mentioning that the sample will be entered in each of the pre-designed blocks according to the time of entering the study.
Blinding (investigator's opinion)	Double blinded
Blinding description	For blinding, drugs (melatonin, clonazepam, and placebo) will be packaged in separate but similar packages and labeled A, B, and C. Medications will be received and labeled by a third party. As a result, the prescriber (researcher) and the patient will be unaware of the type of drug in each package and will not know what drugs are in the three packages
Placebo	Used
Assignment	Parallel
Other design features	

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee in medical and dental school researches

Street address

Kashan.Qutb Ravandi Blvd.hekmat56.

City

کاشان

Province

Isfahan

Postal code

8715973474

Approval date

2023-01-08, 1401/10/18

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1401.198

Health conditions studied

1

Description of health condition studied

mild traumatic brain injury

ICD-10 code

S06.0X

ICD-10 code description

Concussion

Primary outcomes

1

Description

sleep quality

Timepoint

Measurements will be taken at the beginning of the study, after the end of treatment, one month and three months after treatment (4 times).

Method of measurement

The instruments used to examine patients will be a researcher-made demographic questionnaire and the Petersburg Sleep Quality index Questionnaire and Epworth Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 3 mg melatonin tablet from Razek

Pharmaceutical Company is prescribed at night (one hour before bedtime). If there is no proper response in the melatonin group, the amount of drug will increase to 6 mg, provided there are no side effects. The duration of treatment for the intervention group will be 4 weeks.

Category

Treatment - Drugs

2

Description

Intervention group: 1 mg clonazepam tablet from Sobhan Daru Pharmaceutical Company is prescribed overnight (one hour before bedtime). If there is no proper response in the clonazepam group, it will be increased to 2 mg provided there are no side effects. The duration of treatment for this group will be 4 weeks.

Category

Treatment - Drugs

3

Description

Control group: For the placebo group, one placebo is prescribed overnight (one hour before bedtime)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid beheshti hospital

Full name of responsible person

Aidin Omidvar

Street address

Qutb-e-Ravandi Boulevard

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kashan

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Isfahan

Postal code

8715973474

Email

mahshad.m125@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholam Ali Hamidi

Street address

Qutb-e-Ravandi Boulevard

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kashan

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Phone

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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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Aidin Omidvar

Position

professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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

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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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The effect of melatonin on sleep quality in patients with mild traumatic brain injury

When the data will become available and for how long

till ten year after gathering of datum

To whom data/document is available

people who are introduced by research institutes, universities and prestigious scientific centers or from ethics committees.

Under which criteria data/document could be used

To conduct meta-analysis studies in the field of study

From where data/document is obtainable

Vice President of Technology and Research of Kashan School of Medical Sciences

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

Sending a letter to the Deputy of Technology and Research of Kashan University of Medical Sciences. Examination of the letter in the research and ethics committee of this vice president, approval of the request by this committee. Send the data file to the requesting person.

Comments