Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigation of Melatonin Therapeutic Effect in Patients with Moderate Brain Trauma

Protocol summary

Study aim
Improve the state of Glasgow Coma Scale (GCS)

Design
In the random block method, people are divided into two groups, and then medication is administered by the clinical caregiver with a specific code for them, and it is provided to the researcher (student). The researcher evaluates the patients using a questionnaire and records the results based on the patient code. Patients are also not aware of the type of surgery. Also, the analyzer is not aware of the group in which the patient is placed.

Settings and conduct
In the random block method, people are divided into two groups, and then medication is administered by the clinical caregiver with a specific code for them, and it is provided to the researcher (student). The researcher evaluates the patients using a questionnaire and records the results based on the patient code. Patients are also not aware of the type of surgery. Also, the analyzer is not aware of the group in which the patient is placed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with a consciousness coefficient between 9 and 13 Conscious consent of first - degree companions to enter the study Exclusion criteria: A history of any brain disorders Liver Function Test normal Previous use of melatonin.

Intervention groups
For the case group, the treatment of Melatonin begins 48 hours to the first 72 hours immediately after the patient's gaze begins. Three mg daily (once a day) is prescribed before bedtime. The witness group will also receive the placebo (an ineffective material made at the School of Pharmaceuticals similar to Melatonin for 6 months for 6 months).

Main outcome variables
Glasgow Outcome Score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221108056446N5**
Registration date: **2023-11-27, 1402/09/06**
Registration timing: **prospective**

Last update: **2023-11-27, 1402/09/06**
Update count: **0**

Registration date
2023-11-27, 1402/09/06

Registrant information

Name
Mehdi Mahmoodkhani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 913 686 3733

Email address
mahmoodkhani@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01

Expected recruitment end date
2024-05-21, 1403/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigation of Melatonin Therapeutic Effect in Patients with Moderate Brain Trauma

Public title
Melatonin in medium brain trauma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with a consciousness coefficient between 9 and 13 Conscious consent of first -degree companions to enter the study
Exclusion criteria:
A history of any brain disorders Liver function tests normal Previous use of melatonin.
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Easy sampling methods from those who are eligible to enter the study are randomly divided into two groups of cases and control. In this study, the segmentation of individuals is performed as a quadruple block. In this method A reflects the person who receives the intervention and B represents the person in the control group. Considering the four -block block, we give the AABB Code 0, to the ABAB Code 1, to ABBA Code 2, to BAAB Code 3, to BBAA Code 4 and BABA Code 5 to 9. Then, using the random numbers table, select the starting point randomly and then consider the numbers in a row or column. Considering the order of the table numbers, we replace each number we have hit. Finally, 3 people will be divided into two groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In the random block method, people are divided into two groups, and then medication is administered by the clinical caregiver with a specific code for them, and it is provided to the researcher (student). The researcher evaluates the patients using a questionnaire and records the results based on the patient code. Patients are also not aware of the type of surgery. Also, the analyzer is not aware of the group in which the patient is placed.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Esfahan University of Medical Sciences
Street address
Hazar Jarib Street, Azadi Square
City
Esfahan
Province
Isfehan
Postal code
8174673461
Approval date
2023-05-30, 1402/03/09
Ethics committee reference number
IR.MUI.MED.REC.1402.099

Health conditions studied

1

Description of health condition studied
Moderate brain trauma
ICD-10 code
S06.2
ICD-10 code description
Diffuse traumatic brain injury

Primary outcomes

1

Description
Improve the state of Glasgow Coma Scale (GCS)
Timepoint
One, three and 6 months after the injury
Method of measurement
Glasgow coma scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Melatonin treatment is started for the first 48 hours to 72 hours immediately after the patient's gavage. Three milligrams daily (once a day) is prescribed for the patient before going to bed.
Category
Treatment - Drugs

2

Description
Control group: They will receive a placebo (an ineffective substance made in the Faculty of Pharmacy similar to Melatonin daily for 5 months) in the same way as the case group.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-zahra Hospital

Full name of responsible person
Mehdi Shafiei

Street address
Al-Zahra Hospital, Safa Street

City
Isfahan

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8174675731

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Gholamreza Asgari

Street address
Hazar Jarib Street, Azadi Square

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81746-73461

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mui@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Esfahan University of Medical Sciences

Proportion provided by this source
1

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
Esfahan University of Medical Sciences

Full name of responsible person
Mehdi Shafiei

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

Contact

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Position
Associate professor

Latest degree
Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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