

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Isfahan

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

Province

Isfahan

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8174675731

Phone

+98 913 310 1971

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Mehdishafiei82@gmail.com

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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Isfahan

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Isfahan

Postal code

81746-73461

Phone

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Email

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

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mehdi Shafiei

Position

Assistant Professor

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mehdi Shafiei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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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