

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Investigation of melatonin effect on the outcome of moderate and severe diffuse axonal injury(DAI) in men admitted in Kerman Educational And Traputical Center Of Shahid Bahonar: changes in inflammatory, oxidant activity and injury factors

Protocol summary

Study aim

Determination of melatonin effect on the outcome of moderate and severe diffuse axonal injury(DAI) in men admitted to Kerman Educational And Traputical Center Of Shahid Bahonar: changes in inflammatory, oxidant activity, and injury factors

Design

The research has two parallel groups with a control group and is double-blind, randomized on 70 patients, randomization will do with random allocation software.

Settings and conduct

This study is a double-blind randomized controlled clinical trial (Bahonar Hospital, Kerman). 70 participants are randomly assigned to two groups receiving melatonin and receiving a placebo orally. In the intervention group, 3 mg of melatonin was administered upon admission and from the day after the injury, once a day two hours before bedtime for 4 weeks. The control group takes a placebo. In blinding the patient, the nurse and the researcher are unaware of the nature of the medicine.

Participants/Inclusion and exclusion criteria

Inclusion: Male, Age between 18 and 60 years old, Moderate and severe diffuse axonal damage, Less than 4 hours of admission time Exclusion criteria: brain death, sepsis, electrolyte disorders, use of steroids, hypertension, diabetes, metabolic acidosis, liver trauma, cancer, depression, cardiovascular risk factors, autoimmune diseases, respiratory failure, fractures, severe hypothermia

Intervention groups

In the intervention group, 3 mg of melatonin (Razek company) was prescribed at the entrance to the emergency room and from the day after the injury, once a day two hours before going to bed at 22:00 for 4 weeks.

Main outcome variables

Primary outcomes: GOS and FIM score at 6 months post-injury and mortality Secondary outcomes: change in daily GCS score until discharge, hospitalization duration, mortality rate, GCS during discharge, GOS and FIM score in the first and third months after trauma, and chemical factors in 24 hours and 1 month.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190717044248N6**

Registration date: **2023-03-19, 1401/12/28**

Registration timing: **retrospective**

Last update: **2023-03-19, 1401/12/28**

Update count: **0**

Registration date

2023-03-19, 1401/12/28

Registrant information

Name

Zahra Saghafi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-22, 1401/07/30

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of melatonin effect on the outcome of moderate and severe diffuse axonal injury(DAI) in men admitted in Kerman Educational And Traputical Center Of Shahid Bahonar: changes in inflammatory, oxidant activity and injury factors

Public title

Investigation of melatonin effect on outcome of moderate and severe diffuse axonal injury(DAI) in men admitted in Kerman Educational And Traputical Center Of Shahid Bahonar: changes in inflammatory, oxidant activity and injury factors

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Man Gender Age between 18 to 60 Moderate (GCS:9-12) and Sever (GCS \leq 9) diffuse axonal injury less than 4 hours from accident

Exclusion criteria:

Brain death sepsis electrolyte disorders use of steroids need for surgery except neurosurgery personal dissatisfaction high blood pressure diabetes metabolic acidosis (bicarbonate below 12) liver trauma cancer depression cardiovascular risk factors Autoimmune diseases respiratory failure fractures severe hypothermia (temperature less than 35 degrees Celsius)

AgeFrom **18 years** old to **60 years** old**Gender**

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **70****Randomization (investigator's opinion)**

Randomized

Randomization description

70 eligible people are randomly assigned using random allocation software with a ratio of 1 to 1 in two groups receiving melatonin and receiving placebo orally.

Blinding (investigator's opinion)

Double blinded

Blinding description

The method of blinding: The patient, the nurse who delivers the medicine, and the physician or researcher who is responsible for evaluating GCS and other outcomes are unaware of the original nature or placebo of the medicine.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway

City

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Province

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Postal code

7616913555

Approval date

2021-07-12, 1400/04/21

Ethics committee reference number

IR.KMU.REC.1400.228

Health conditions studied**1****Description of health condition studied**

diffuse axonal injury

ICD-10 code

S06.30

ICD-10 code description

Unspecified focal traumatic brain injury

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

GOSE:Standard leveling is obtained based on death, vegetative state, severe disability, low level, high level, and moderate level.

Timepoint

Admit time, first month, third month and sixth month

Method of measurement

Extended- Glasgow Coma Scale

2

Description

Measurement of dependence in motor and cognitive domains where a higher score is a sign of higher recovery or less damage.

Timepoint

Admit time, first month, third month and sixth month

Method of measurement

The Functional Independence Measure Scale

3

Description

Glasgow criteria is obtained based on language, verbal and motor responses.

Timepoint

Admission and discharge time

Method of measurement

physical examination

Secondary outcomes

1

Description

IL-1 β

Timepoint

24 hours and one month after admission

Method of measurement

Using the relevant kit

2

Description

Serum melatonin level

Timepoint

Twice a day in the first 24 hours after the injury, once every 12 hours, and twice on the fifteenth day after the injury, once every 12 hours, and twice on the last day of use, once every 12 hours (6 times in total)

Method of measurement

Using the relevant kit

3

Description

IL-10

Timepoint

24 hours and one month after admission

Method of measurement

Using the relevant kit

4

Description

IL6MDA

Timepoint

24 hours and one month after admission

Method of measurement

Using the relevant kit

5

Description

pyridyl triazine

Timepoint

24 hours and one month after admission

Method of measurement

Using the relevant kit

6

Description

Nerve growth factor

Timepoint

24 hours and one month after admission

Method of measurement

Using the relevant kit

7

Description

Thiobarbituric acid

Timepoint

24 hours and one month after admission

Method of measurement

Using the relevant kit

8

Description

S100B-Protean

Timepoint

24 hours and one month after admission

Method of measurement

Using the relevant kit

Intervention groups

1

Description

Intervention group: including 35 participants with diffuse axonal injury, each patient received 3 mg of melatonin (Razak Company) manufactured in Iran upon admission time and from the day after the injury: once a day, two hours before Sleep at 10 pm (because after the trauma, the melatonin secretion cycle is disturbed and its secretion may be more during the day than night) and they receive it for 4 weeks.

Category

Treatment - Drugs

2

Description

Control group: Including 35 participants who consume a placebo in the same form and during the same period of time as the intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahinar Hospital

Full name of responsible person

Alireza Ghaedamini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Alireza Ghaedamini

Position

Clinical Assistant of Neurosurgery

Latest degree

Medical doctor

Other areas of specialty/work

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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

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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