Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 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

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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≤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)
Age
From **18 years** old to **60 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target 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
Kerman
Province
Kerman
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-1β
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
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Full name of responsible person
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Person responsible for updating data

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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