Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Evaluation of the effect of melatonin on biomarkers of mitochondrial damage in patients with brain injury hospitalized in Alzahra hospital, Isfahan: A randomized placebo-controlled clinical trial

Protocol summary

Study aim

Comparison the effect of Melatonin with the placebo on biomarkers of mitochondrial injury in patients with brain injury

Design

Randomized placebo-controlled, parallel group, double-blinded clinical trial

Settings and conduct

Setting: Intensive care units and neurology wards of Alzahra hospital affiliated to Isfahan University of Medical Sciences. Intervention: Patients with traumatic or non-traumatic brain injury will be randomized to the intervention group (will be received melatonin 20 mg per day for 5 days) or palcebo and biomarkers of mitochondrial injury will be measured before and after intervention. Patient and the researcher who measured the study outcomes will be blinded until the completion of the study and the detection of its codes.

Participants/Inclusion and exclusion criteria

Adult patients with traumatic or non-traumatic brain injury will included in the study. Patients with length of hospitalization less than 5 days and hepatic, renal or heart failure will not be included in the study.

Intervention groups

Patients in the intervention group will receive Melatonin 20 mg (four 5 mg tablets) (Razak Co., Iran) for 5 days. Patients in the control group will receive placebo (which will produce by pharmacy faculty) with the same dose for 5 days.

Main outcome variables

The variables including S100β and MDA and CRP will be measured and compared as the main outcomes in both groups of patients at day 1 and 5 of the study. To assess neurological status of the patients, the GCS will be examined daily until the fifth day. Cognitive-Functional status using (FIM+FAM) Functional Assessment Measure will be evaluated on the first day before the intervention and three months after the intervention.The patient's mortality rate (28 days), the length of hospitalization and the number of days without ventilator (28 days) will also be assessed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081208001497N8**
Registration date: **2019-05-07, 1398/02/17**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-07, 1398/02/17**
Update count: **0**

Registration date

2019-05-07, 1398/02/17

Registrant information

Name

Sarah Mousavi

Name of organization / entity

Clinical Pharmacy Department, Pharmacy Faculty, Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of melatonin on biomarkers of mitochondrial damage in patients with brain injury hospitalized in Alzahra hospital, Isfahan: A randomized placebo-controlled clinical trial

Public title

Effect of Melatonin in brain injury

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patients (age more than 18) who had traumatic brain injury included skull fracture, subdural hemorrhage, subarachnoid hemorrhage, brain contusion and laceration, intracerebral hemorrhage, intraventricular hemorrhage and traumatic axonal injury Non-traumatic brain injury included strokes, infections, hypoxia and brain tumors Admission within 72 hours after brain injury in intensive care unit or other wards such as neurology or neurosurgery Healthy gastrointestinal tract (capable of oral ingestion or gavage of drug)

Exclusion criteria:

Length of hospitalization less than 5 days in intensive care units or other wards Hypersensitivity to melatonin Hepatic failure (class C according to Child-pugh) Renal failure (need dialysis) Severe heart failure (Class 3 and 4 according to Newyork heart association) Sepsis within first 5 days of admission

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After the preparation of Melatonin and its placebo, each packet is assigned a code using the random number table, and the two codes are allocated to the drug and the placebo. Block randomization will performed in random blocks of four. At the end of the study, the code of each patient is decoded and the type of drug is determined.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient and the researcher who measuring the study outcomes are blind to the distribution of patients in the melatonin and placebo groups until the completion of the study and the detection of its codes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, P.O. Box 319, Hezar-Jerib Ave.

City

Isfahan

Province

Isfehan

Postal code

81746 73461

Approval date

2019-05-04, 1398/02/14

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.032

Health conditions studied

1

Description of health condition studied

Brain injury

ICD-10 code

S06

ICD-10 code description

Intracranial injury

Primary outcomes

1

Description

Changes in bio markers of mitochondrial injury

Timepoint

Day 1 and 5 of intervention

Method of measurement

Elisa kit

Secondary outcomes

1

Description
Mortality rate of patients
Timepoint
28 days
Method of measurement
Observation

Intervention groups

1

Description
Intervention group: Patients in drug group will be received Melatonin tablet (Razak Pharmaceutical company, Tehran, Iran), 20 mg daily for 5 days.
Category
Prevention

2

Description
Control group: Patients in control group will be received Melatonin tablet (Prepared in pharmacy faculty), 20 mg daily for 5
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Sarah Mousavi
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Hezar Jerib avenue, Isfahan University of Medical Sciences, Alzahra Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Research deputy of Isfahan University of Medical Sciences
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Sarah Mousavi
Position
Assistant professor
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
confidential
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Published article
When the data will become available and for how long
One year
To whom data/document is available
All people
Under which criteria data/document could be used
No condition
From where data/document is obtainable
Scientific responded of the study
What processes are involved for a request to access data/document
Email to corresponding author
Comments