Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

The effects of melatonin on oxidative pathways in patients with acute ischemic stroke: A randomized double-blind clinical trial

Protocol summary

Study aim
The effects of melatonin on oxidative pathways in patients with acute ischemic stroke

Design
Based on the randomization table (permuted block method in blocks of 4), patients are candidates to receive melatonin or placebo for 5 days. All patients included in the study, who are 60 and placed in parallel groups, will receive a standard treatment regimen.

Settings and conduct
Patients with MS referred to Bo Ali Sina Educational Center who meet the inclusion criteria and do not have the exclusion criteria are included in the study and are divided into two groups according to the randomization table and are evaluated for 12 weeks. The treating doctor, the patient and the evaluator are unaware of the type of therapeutic intervention.

Participants/Inclusion and exclusion criteria
Adults over 18 years of age with diagnosis of acute ischemic stroke according to brain CT scan findings will be included. Pregnant and lactating women, people with severe psychiatric disorders, severe hepatic insufficiency, NIHSS more than 25, and lacunar infarct will be excluded from the study.

Intervention groups
Intervention: Melatonin 30 mg daily for 5 days Control: Placebo (same shape and color) daily for 5 days

Main outcome variables
The effectiveness of melatonin on inflammatory biomarkers serum levels reduction, Oxidative stress biomarker serum levels reduction, stroke induced disability improvement according to mRS, Melatonin tolerability

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190804044429N10**
Registration date: **2023-01-22, 1401/11/02**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-22, 1401/11/02**
Update count: **0**

Registration date
2023-01-22, 1401/11/02

Registrant information

Name
Monireh Ghazaeian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8863 6864

Email address
ghazaeianm@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-21, 1401/11/01

Expected recruitment end date
2023-09-22, 1402/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of melatonin on oxidative pathways in patients with acute ischemic stroke: A randomized double-blind clinical trial

Public title

Melatonin ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults over the age of 18 and diagnose with acute ischemic stroke according to brain CT scan findings NIHSS more than 4

Exclusion criteria:

Hemorrhagic stroke Lacunar infarct TIA NIHSS more than 25 Pregnancy Lactation Severe hepatic insufficiency History of apnea

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization using the block method by a person who is not related to the study. Packages containing the drug and placebo are completely similar in shape and color. Randomization of serial numbers of drug packages and placebo by a person who is not involved in the project according to randomized table. The number of the bottle corresponded with the number of the patient. Random block method will be used to allocate the samples to two groups. Blocks will be considered as 4 blocks and in each block of 4 people, two people in the intervention group and two people in the control group will be selected. The selection of the order type in each group for each person will be done through second version of random allocation software.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double_ blind. Outcome elevator and participant are blinded (double blind) and aware from grouping (intervention or placebo)

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran university of medical Sciences

Street address

Ibn Sina hospital, Pasdaran Blvd

City

Sari

Province

Mazandaran

Postal code

4816864193

Approval date

2022-08-10, 1401/05/19

Ethics committee reference number

IR.MAZUMS.REC.1401.258

Health conditions studied

1

Description of health condition studied

Cerebellar stroke syndrome

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes

1

Description

Glutathione serum level

Timepoint

days 0 and 5th of the study

Method of measurement

Spectroscopy

2

Description

Antioxidant serum levels

Timepoint

at days 0 and 5th of the study

Method of measurement

Spectroscopy

Secondary outcomes

1

Description

Disability following stroke

Timepoint

At days 0, discharge and month three of the study

Method of measurement

According to mRS

2

Description
Tolerability of melatonin
Timepoint
During the study period
Method of measurement
History taking

Intervention groups

1

Description
Intervention group: patients in the intervention group will receive 30 mg melatonin following acute ischemic stroke for 5 days
Category
Treatment - Drugs

2

Description
Control group: patients in the control group will receive a placebo in the form of tablets with the same color, size and packaging as the intervention group and without the active pharmaceutical ingredient for five days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ibn Sina hospital
Full name of responsible person
Monireh Ghazaeian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Pedram Ebrahimnejad
Street address
Vice chancellor for Research, Mazandaran University of medical Sciences, Joybar 3way, Sari,Iran
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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
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Mazandaran University of Medical Sciences
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Clinical pharmacy
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
Data related to the initial outcoms of the study will be shared

When the data will become available and for how long
The data will be available one year after publication

To whom data/document is available
Academic reseachers, medical team and scientific institutes

Under which criteria data/document could be used
Requests for sharing data should be sent to the person responsible for general inquiries

From where data/document is obtainable
Requests for sharing data should be sent to the person responsible for general inquiries. Ghazaeianm@gmail.com

What processes are involved for a request to access data/document
Person in charge of scientific study will reply to the request within 10 days

Comments