Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Evaluation of the Effect of Melatonin on Clinical Outcomes in Patients with Acute Ischemic Stroke: a Randomized Double-Blind Placebo-Controlled Clinical Trial

Protocol summary

Study aim
To assess the effect of Melatonin on clinical outcomes in patients with acute ischemic stroke

Design
This is a double-blind randomized clinical trial, phase III, in which 70 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible patients with acute ischemic stroke referring to the Booali hospital in Tehran city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the Random allocation software. This trial will be double-blinded so that neither patients nor the physician examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age:18 to 85 years old, occurrence of stroke within the past 24 hours, NIHSS score of at least 4 and at most 27, not eligible for thrombolytic therapy and thrombectomy. Exclusion criteria: pregnancy or breastfeeding, acute or chronic intracranial hemorrhage or aneurism, any type of cognitive or behavioral disorder, concurrent inflammatory disease and/or malignancy, patients with transient ischemic attacks, sensitivity to Melatonin.

Intervention groups
Intervention group: routine treatment plus Melatonin tablets (made by Jalinus Pharmaceutical Co.) 10 mg daily for 5 days. Control group: routine treatment plus placebo tablets (made by Jalinus Pharmaceutical Co.) 10 mg daily for 5 days.

Main outcome variables
The severity of neurological function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231220060484N1**
Registration date: **2023-12-27, 1402/10/06**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-27, 1402/10/06**
Update count: **0**

Registration date
2023-12-27, 1402/10/06

Registrant information

Name
Amirhossein Ghanbarzamani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 4406 9924

Email address
amirh.ghzamani@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-19, 1402/09/28

Expected recruitment end date
2024-09-09, 1403/06/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the Effect of Melatonin on Clinical

Outcomes in Patients with Acute Ischemic Stroke: a Randomized Double-Blind Placebo-Controlled Clinical Trial

Public title
Protective effect of Melatonin on clinical outcomes in patients with acute ischemic stroke
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age:18 to 85 years old Occurrence of stroke within the past 24 hours NIHSS score of at least 4 and at most 27 Not eligible for thrombolytic therapy and thrombectomy
Exclusion criteria:
Pregnancy or breastfeeding Acute or chronic intracranial hemorrhage or aneurism Any type of cognitive or behavioral disorder Concurrent inflammatory disease and/or malignancy Patients with transient ischemic attacks Sensitivity to Melatonin
Age
From **18 years** old to **90 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
The blocking process has two stages. In the first stage, the samples with entry criteria are selected by census and in the second stage, the block method will be used for randomization. Blocking process will be done with a random allocation software and the size of the blocks are predicted to be in four. As a result, the number of blocks will be equal to 18. After obtaining informed consent, as predicted by the software the samples are entered in one of A or B groups. Also in order to avoid from identification of A and B groups, instead of A or B labels each participant will be assigned by a random 4-digit code obtained from the computer.
Blinding (investigator's opinion)
Double blinded
Blinding description
The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Department of Pharmaceutical Sciences,Tehran Islamic Azad University of Medical
Street address
Islamic Azad University of Pharmaceutical Sciences Branch, Yakhchal Ave., Gholhak, Dr Shariati Ave.
City
Tehran
Province
Tehran
Postal code
1941933111
Approval date
2023-12-12, 1402/09/21
Ethics committee reference number
IR.IAU.PS.REC.1402.522

Health conditions studied

1

Description of health condition studied
Acute ischemia stroke
ICD-10 code
I67.82
ICD-10 code description
Cerebral ischemia

Primary outcomes

1

Description
The severity of neurological function
Timepoint
Before the intervention and on the fifth day and one and three months after the intervention
Method of measurement
Using the National Institutes of Health Stroke (NIHSS) questionnaire and the modified Rankin Scale (mRS) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: routine treatment plus melatonin tablets (made by Jalinus Pharmaceutical Co.) 10 mg daily

for 5 days

Category

Treatment - Drugs

2

Description

Control group: routine treatment plus placebo tablets including starch (made by Jalinus Pharmaceutical Co.) 10 mg daily for 5 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali hospital

Full name of responsible person

Mahsa rabiee

Street address

Booali Hospital, not reaching Imam Hossein Square, Damavand Street

City

Tehran

Province

Tehran

Postal code

1711734365

Phone

+98 21 3334 8036

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booali.hospital96@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Amirhossein Ghanbarzamani

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No 99, Yakhchal street, Gholhak, Dr Shariati Ave.

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Amirhossein Ghanbarzamani

Position

Clinical pharmacologist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact
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Full name of responsible person
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Pharmacy Student
Latest degree
A Level or less
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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
There is no plan for publishing the protocol of study because it is accessible in IRCT
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All data are shareable after publishing
When the data will become available and for how long
Start the access period 6 months after publishing the result
To whom data/document is available
All researchers
Under which criteria data/document could be used
For used in clinical practice and also future meta-analysis
From where data/document is obtainable
amirh.ghzamani@gmail.com
What processes are involved for a request to access data/document
Sending email to Dr Amirhossein Ghanbarzamani
Comments