

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 Boali 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)

Phone

+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

Email

booali.hospital96@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Amirhossein Ghanbarzamani

Street address

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

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Province

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1941933111

Phone

+98 21 2264 0599

Email

amirh.ghzamani@gmail.com

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

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

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Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Mahsa Rabiee

Position

Pharmacy Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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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