Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of melatonin versus placebo on infarct size in patients with ischemic stroke

Protocol summary

Study aim
Studying the effect of melatonin on infarct size in patients with ischemic stroke hospitalized in the neurology department of Imam Khomeini Hospital, Urmia.

Design
A single-blind, parallel-group, controlled clinical trial with 40 patients. Patients will be assigned to the intervention and control groups using random numbers generated in Random allocation software.

Settings and conduct
Patients with acute ischemic stroke admitted to Imam Khomeini Hospital in Urmia are randomly assigned to intervention and control groups. The study is single-blinded, so that the form of the drugs and placebo are completely identical and the patient will not know the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 80 years; Ability and willingness to participate in the study (obtaining informed consent); Acute stroke that occurred within 7 days prior to admission to the ward; Diagnosis of acute ischemic stroke confirmed by computed tomography (CT) or magnetic resonance imaging (MRI) at the time of admission. Exclusion criteria: History of myocardial infarction; prior primary hemorrhagic stroke; significant cognitive impairment or dementia before the stroke; other neurological diseases (e.g., Parkinson’s disease); severe liver disease; severe kidney disease; severe thyroid disease; severe cardiac, respiratory, or organ failure

Intervention groups
Intervention group: Routine treatment including antiplatelet and atorvastatin plus melatonin tablets 20 mg daily for 5 days. Control group: Routine treatment plus placebo tablets containing starch (made by the Faculty of Pharmacy) 20 mg daily for 5 days

Main outcome variables
Size of cerebral infarction (volume of ischemic area)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20241229064208N2**
Registration date: **2025-10-14, 1404/07/22**
Registration timing: **prospective**

Last update: **2025-10-14, 1404/07/22**
Update count: **0**

Registration date
2025-10-14, 1404/07/22

Registrant information
Name
Rezvan norouzzadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-12-22, 1404/10/01
Expected recruitment end date
2026-06-21, 1405/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparison of the effect of melatonin versus placebo on infarct size in patients with ischemic stroke

Public title
Effect of melatonin in patients with ischemic stroke
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 80 years Ability and willingness to participate in the study (obtaining informed consent) Acute stroke that occurred within 7 days prior to admission to the ward Diagnosis of acute ischemic stroke confirmed by computed tomography (CT) or magnetic resonance imaging (MRI) at the time of admission
Exclusion criteria:
Patient with a history of heart attack Primary hemorrhagic stroke Pre-stroke diagnosis indicating significant decline in mental function or impairment A valid neurological disease in addition to stroke, such as Parkinson's disease Severe liver, kidney, or thyroid disease, or heart failure, respiratory failure, or other organ failure Chronic inflammatory diseases, immune or hematological disorders History of depression (clinical diagnosis or previous treatment) or other mental disorders Patients who are not accessible
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Forty patients will be randomly assigned to two groups: intervention and control. Randomization will be performed using block randomization. First, blocks of size 5 with the sequence (ABABA) will be listed, and each block will be assigned a code. Based on the total sample size of 40, 8 blocks will be selected, and patients will be assigned to the intervention and control groups according to these codes.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study will be conducted in a single-blinded manner, so that the form of the drugs and placebo will be completely identical and the patient will not know the type of intervention.and control groups
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Imam Khomeini Educational and Medical Center, Urmia University of Medic
Street address
Imam Khomeini University Hospital, Ershad Ave, Modarres Blvd, Urmia, Iran
City
Urmia
Province
West Azarbaijan
Postal code
5715781351
Approval date
2025-07-30, 1404/05/08
Ethics committee reference number
IR.UMSU.HIMAM.REC.1404.039

Health conditions studied

1

Description of health condition studied
Acute Ischemic Stroke
ICD-10 code
I63.9
ICD-10 code description
Cerebral infarction, unspecified

Primary outcomes

1

Description
• Size of cerebral infarction (volume of ischemic area)
Timepoint
1. Baseline (before intervention) – in the first 7 days after stroke and before treatment begins, 2. Follow-up (follow-up) – three months after intervention
Method of measurement
Brain CT scan

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine treatment includes antiplatelet and atorvastatin plus melatonin tablets 20

mg daily for 5 days.

Category

Treatment - Drugs

2

Description

Control group: Routine treatment with placebo tablets containing starch (made by the Faculty of Pharmacy) 20 mg daily for 5 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Imam Khomeini Hospital

Full name of responsible person

Dr. Rizvan Norouzzadeh

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Imam Khomeini University Hospital., Ershad Ave., Modarres Blvd., Urmia.,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saber Gholizadeh

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Rizvan Norouzzadeh

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

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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
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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available