

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effect of melatonin versus placebo on clinical outcomes in patients with ischemic stroke: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of melatonin versus placebo on clinical outcomes in patients with ischemic stroke

Design

This is a double-blind randomized clinical trial, phase III, in which 66 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with ischemic stroke referring to the Sina Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. 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 between 18 to 85 years old; acute ischemic stroke for the first time; occurrence of stroke within the past 24 hours; focal neurological disorder; NIHSS score of at least 4 and at most 27. Exclusion criteria: pregnancy or breastfeeding; acute or chronic intracranial hemorrhage or aneurism; any type of cognitive or behavioral disorder; concurrent inflammatory disease; taking any antioxidant combination in the last month; sensitivity to melatonin.

Intervention groups

Intervention group: routine treatment plus melatonin tablets (made by Razak Pharmaceutical Co.) 20 mg daily for 5 days. Control group: routine treatment plus placebo tablets (made by School of Pharmacy, Shahid Beheshti University) 20 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: **IRCT20120215009014N378**

Registration date: **2021-01-28, 1399/11/09**

Registration timing: **prospective**

Last update: **2021-01-28, 1399/11/09**

Update count: **0**

Registration date

2021-01-28, 1399/11/09

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2022-02-04, 1400/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of melatonin versus placebo on clinical outcomes in patients with ischemic stroke: a double-blind randomized clinical trial

Public title

Effect of melatonin versus placebo on clinical outcomes in patients with ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age: 18 to 85 years old
Acute ischemic stroke for the first time
Occurrence of stroke within the past 24 hours
Focal neurological disorder
NIHSS score of at least 4 and at most 27

Exclusion criteria:

Pregnancy or breastfeeding
Acute or chronic intracranial hemorrhage or aneurism
Any type of cognitive or behavioral disorder
Concurrent inflammatory disease
Taking any antioxidant combination in the last month
Sensitivity to melatonin

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

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Province

Hamadan

Postal code

6517838695

Approval date

2020-11-08, 1399/08/18

Ethics committee reference number

IR.UMSHA.REC.1399. 679

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 Razak Pharmaceutical Co.) 20 mg daily for 5 days

Category

Treatment - Drugs

2

Description

Control group: routine treatment plus placebo tablets including starch (made by School of Pharmacy, Shahid Beheshti University) 20 mg daily for 5 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital in Hamadan city

Full name of responsible person

Ensieh Rahmani Yeganeh

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Ensieh Rahmani Yeganeh

Position

Student of Pharmacy

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Pharmacologist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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