Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of melatonin as a potential drug for the improvement of clinical outcome, reduction of infarct size, sleep parameters and cognitive functions in post-stroke patients: A randomized, double blind, placebo-controlled study

Protocol summary

Summary

The aim of this study is to evaluate the effects of melatonin on clinical outcome (functional and neuro-cognitive) and sleep parameters in post-stroke patients. A randomized, double-blind, placebo-controlled study will be conducted including 60 cases of ischemic-stroke. Subjects will be enrolled in the study if they meet the inclusion criteria including: Clinical diagnosis of acute stroke in middle cerebral artery (MCA) territory (left or right MCA), established by MRI imaging; Males and females between18 to 70 years old; NIHSS score of 5-20 with a motor deficit of 2 or more (for either one arm or leg); Signed informed consent and Level of consciousness less than 2 in NIHSS scale. Patients will be excluded from the study if they have: Clinically relevant preexisting neurological deficit or previous CVA; Primary intracerebral hemorrhage; Coma (level of consciousness more than 2 in NIHSS scale); or Negative swallow test. Patients eligible to participate in the study,will randomly be divided into two groups (N=30/group) and will receive either melatonin (6mg/day at bed time) (treatment group) or cellulose (6mg/day at bed time) (placebo group) for 90 days. Before and 90 days after treatment, patients will be assessed for: 1) clinical functional outcome using modified NIHSS and MRS score; 2) infarct size using voxel-based volumetry; 3) sleep parameters subjectively using PSQI and PIRS questionnaires and objectively using full-setup overnight polysomnography (the polysomnography will be applied on patients who have poor sleep according to PSQI and PIRS questionnaires); and 4) cognitive functions using the Addenbrook's Cognitive Examination.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201609059566N2**
Registration date: **2016-12-17, 1395/09/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-12-17, 1395/09/27

Registrant information

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Masoumeh Emamghoreishi
Name of organization / entity
Shiraz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Shiraz University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of melatonin as a potential drug for the improvement of clinical outcome, reduction of infarct size, sleep parameters and cognitive functions in post-stroke patients: A randomized, double blind, placebo-controlled study

Public title
A clinical trial of comparing the effect of melatonin and placebo on improving the neurological complications, infarct size and sleep and cognitive impairments in patients with ischemic stroke.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria : Clinical diagnosis of acute stroke in middle cerebral artery (MCA) territory established by MRI imaging; Males and females between18 to 70 years old; NIHSS score of 5-20 with a motor deficit of 2 or more; Level of consciousness less than 2 in NIHSS scale; Signed informed consent; More than 12 years education
Exclusion criteria : Clinically relevant preexisting neurological deficit or previous CVA; Primary intracerebral hemorrhage; Coma; Negative swallow test; History of epilepsy or seizure at onset of stroke; Systolic BP is >220 mmHg, diastolic BP>120 ; Atrial fibrillation or other arrhythmias ; Ejection Fraction less than 30%; Aphasia; Malignancy or premalignant state within 5 years; Significant liver disease (Bilirubin > 20 mmoll/L); Respiratory failure (FEV1 < 1.5 L, pO2 < 70 in room air, pCO2 > 45); Psychiatric illness requiring hospital admission; Chronic kidney disease ; NIHSS> 20 ; Pregnancy or breast feeding; Inability to follow up the instructions of the study; Autoimmune disease; Steroid consumption

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
permuted block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Science

Street address
Shiraz-Zand street-opposite of Felestin street-

City
Shiraz

Postal code
14336 - 71348

Approval date
2016-08-21, 1395/05/31

Ethics committee reference number
ir.sums.rec.1395.104

Health conditions studied

1

Description of health condition studied
stroke

ICD-10 code
163

ICD-10 code description
Cerebral infarction

Primary outcomes

1

Description
Clinical outcome

Timepoint
90 days

Method of measurement
NIHSS and MRS questionnairies

2

Description
Cognitive function

Timepoint
90 days

Method of measurement
Addenbrook questionnaire

3

Description
Infarct size

Timepoint
90 days

Method of measurement
Voxel-based volumetry

4

Description

Subjective sleep assessment

Timepoint

90 days

Method of measurement

self-rated 19-item PSQI questionnaire and PIRS questionnaire

5

Description

Objective sleep assessment

Timepoint

90 days

Method of measurement

polysomnography

Secondary outcomes

empty

Intervention groups

1

Description

placebo (microcrystalline cellulose powder [Avicel], 6mg/day at bed time) for 90 days

Category

Placebo

2

Description

melatonin (6 mg/day at bed time) for 90 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital (a tertiary medical center affiliated with Shiraz University of Medical Sciences, Sh

Full name of responsible person

Dr. Afshin Borhan Haghighi

Street address

Namazi Square- Namazi Hospital- Department of Neurology

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Science

Full name of responsible person

Dr. Postfrosh

Street address

Shiraz-Zand street-opposite of Felestin street-

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shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Science

Full name of responsible person

Dr.Masoumeh Emamghoreishi

Position

Full Professor/Ph.D

Other areas of specialty/work

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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty