

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of melatonin in clinical improvement of patients with ischemic stroke

Protocol summary

Summary

The aim of the present study is to determine the effect of Melatonin on stroke severity as it is one of the most important determinants of prognosis of the outcome. In a triple-blind, placebo-controlled clinical trials, 58 patients with ischemic stroke will be randomized to oral Melatonin 3 mg or placebo daily for 2 months. Severity of stroke will be studied by assessing CNSS (Canadian Neurological Scale of Stroke) on baseline and after 2 months of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012917811N6**

Registration date: **2015-02-11, 1393/11/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-11, 1393/11/22

Registrant information

Name

Shayan Amjadi

Name of organization / entity

Students Research Committee, Arak University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3502

Email address

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Recruitment status

Recruitment complete

Funding source

grant from Office of Vice Chancellor for Research of Arak university of Medical Sciences (GRANT #397)

Expected recruitment start date

2013-06-01, 1392/03/11

Expected recruitment end date

2014-03-31, 1393/01/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of melatonin in clinical improvement of patients with ischemic stroke

Public title

Melatonin and Stroke

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria : Patients admitted in Valiasr Hospital of Arak city with acute ischemic stroke approved by a neurologist and imaging that caused hemiparesis or hemiplegia ; Those who aged between 18 years and 85 years exclusion criteria : severe post-stroke disability (National Institutes of Health stroke scale [NIHSS] score >20) ; substantial pre-morbid disability ; or a pre-existing deficit that could interfere with assessments— ie residual motor deficit from a previous stroke ; pregnancy and other major diseases that would prevent follow-up

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences , Sardasht , Arak , Iran

City

Arak

Postal code**Approval date**

2013-03-14, 1391/12/24

Ethics committee reference number

92-156-3

Health conditions studied**1****Description of health condition studied**

ischemic brain stroke

ICD-10 code

I63

ICD-10 code description

Cerebral infarction

Primary outcomes**1****Description**

Severity of stroke

Timepoint

baseline and after 2 months

Method of measurement

Canadian Neurological Scale of Stroke (CNSS)

Secondary outcomes

empty

Intervention groups**1****Description**

intervention group : 1 melatonin tablet (3mg) every night for 2 months. all patients will receive standard treatment of stroke(Plavix tablet 75mg /daily)

Category

Treatment - Drugs

2**Description**

patients whom randomized to placebo group will received placebo tablets during 8 weeks of clinical trial course

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

valiasr hospital

Full name of responsible person

dr. fardin Faraji

Street address

Valiasr hospital, Valiasr sq. , Arak , Iran

City

Arak

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences , Office of Vice Chancellor for Research

Full name of responsible person

Dr.Mohammad Rafii

Street address

Arak University of Medical Sciences , Sardasht , Arak , Iran

City

Arak

Grant name**Grant code / Reference number**

397

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

Yes

Title of funding source

Arak University of Medical Sciences , Office of Vice Chancellor for Research

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

Arak University Of Medical Sciences , Arak , Iran

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Web page address**Person responsible for updating data****Person responsible for general inquiries****Contact****Name of organization / entity**

Students Research Committee , Medicine faculty , Arak
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Full name of responsible person

Shayan Amjadi

Position

M.D

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Neurology Department , Medicine faculty, Arak
University of Medical Sciences

Full name of responsible person

Fardin Faraji

Position

Neurology specialist, Associate Professor

Other areas of specialty/work**Street address****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