

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of oral melatonin on the clinical feature in patients with ischemic stroke: a randomized clinical trial

Protocol summary

Study aim

The aim of the present study is to determine the effect of oral melatonin on the clinical feature in patients with ischemic stroke .

Design

A randomized, double-blind, clinical trial study, single center, controlled placebo, 60 Samples selected via patients with ischemic stroke referred to the emergency of Amiralmomenin Hospitals of Arak in 8 months and block randomized into two groups.

Settings and conduct

60 patients referring to Amiralmomenin hospital diagnosed as ischemic stroke will be randomly allocated to receive either melatonin or placebo. Patients in the intervention group will receive 1 melatonin tablet (3 mg) every night from the beginning of the study to the time of discharge and patients whom randomized to placebo group will received placebo tablets every night from the beginning of the study to the time of discharge. melatonin and placebo will be encapsulated and for this reason patients and assessing physicians do not have any knowledge about the type of treatment.

Participants/Inclusion and exclusion criteria

inclusion criteria: Patients admitted in Amiralmomenin Hospital of Arak city with acute ischemic stroke approved by a neurologist and imaging; Those who aged between 18 years and 80 years exclusion criteria: Unwillingness to cooperate; pregnancy and other major diseases that would prevent follow-up.

Intervention groups

Patients in the intervention group will receive 1 melatonin tablet (3 mg) every night from the beginning of the study to the time of discharge. patients whom randomized to placebo group will received placebo tablets every night from the beginning of the study to the time of discharge.

Main outcome variables

Main outcome measures: Sleep quality measured at before and one month after intervention; Vital signs

measured at before intervention, then every 6 hours;
Volume of red blood cells measured at before intervention, then every 48 hours.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130424013110N7**

Registration date: **2019-08-24, 1398/06/02**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-24, 1398/06/02**

Update count: **0**

Registration date

2019-08-24, 1398/06/02

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral melatonin on the clinical feature in patients with ischemic stroke: a randomized clinical trial

Public title

The effect of oral melatonin on the clinical feature in patients with ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 to 80 years old Patients satisfaction GCS 14-15 receiving narcotics and sedatives at least six hours previously Ischemic stroke

Exclusion criteria:

Recent use of CNS depressant drugs Impending death Unwillingness to cooperate

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study the randomization will be done using blocking method.

Blinding (investigator's opinion)

Double blinded

Blinding description

melatonin and placebo will be encapsulated and for this reason patients and assessing physicians do not have any knowledge about the type of treatment.

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

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Vice Chancellery For Research And Education, Pardis Site Of University Of Medical Sciences, Basij Sq, Arak

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38149 - 5 - 7558

Approval date

2019-07-07, 1398/04/16

Ethics committee reference number

IR.ARAKMU.REC.1398.98

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

Ischemic stroke

ICD-10 code

I63

ICD-10 code description

Cerebral infarction

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

Sleep quality

Timepoint

Before intervention and 1 month after start of intervention

Method of measurement

The Pittsburgh Sleep Quality Index

2**Description**

Vital signs

Timepoint

Before intervention, then every 6 hours

Method of measurement

Blood pressure will measured by Sphygmomanometer, pulse and breathing by counting in a minute by a hand watch.

3**Description**

Volume of red blood cells

Timepoint

Before intervention, then every 48 hours

Method of measurement

in mili liter

4**Description**

Score of NIHSS scale

Timepoint

Before intervention, time of discharge and one month after intervention
Method of measurement
NIHSS questionnaire (0-42) score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group will receive 1 melatonin tablet (3 mg) every night from the beginning of the study to the time of discharge.

Category

Treatment - Drugs

2

Description

Control group: patients whom randomized to placebo group will received placebo tablets every night from the beginning of the study to the time of discharge.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin hospital

Full name of responsible person

Dr Abolfazl Jokar

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Amiralmomenin hospital, Sardasht, Arak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr mehran fazel

Position

Resident of emergency medicine

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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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

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

Arak University of Medical Sciences

Full name of responsible person

Dr mehran fazel

Position

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