Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 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
Mehdi Harorani
Name of organization / entity
Arak University of Medical Sciences
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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
Street address
Vice Chancellery For Research And Education, Pardis Site Of University Of Medical Sciences, Basij Sq, Arak
City
Arak
Province
Markazi
Postal code
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
Befor 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

Street address

Amiralmomenin hospital, Sardasht, Arak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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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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