Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of melatonin on reducing the frequency and intensity of migraine attacks

Protocol summary

Study aim
investigation of the effects of melatonin on reducing the frequency and intensity of migraine attacks

Design
A clinical trial with a control and parallel groups, double-blind, randomized, phase 3 on 60 patients

Settings and conduct
This study is conducted in the neurology clinic of Golestan Ahvaz Medical Education Center as a single center. Patients, doctors, interviewers and data collectors were blinded to the intervention group and the type of treatment received by the patients using the same drug packages, random assignment and coding of the drug packages.

Participants/Inclusion and exclusion criteria
Patients aged 18 or more with a history of migraine for more than a year, without otherwise significant medical conditions possibly affecting drug use or causing headaches.

Intervention groups
In both groups of patients, propranolol 20 mg twice a day is used as a standard anti-migraine treatment. In the intervention group, 3 mg melatonin tablets (Razek Company) and in the control group, placebo tablets similar in terms of shape, color, smell, size and taste are given. The prescription is to take the medicine one hour before going to bed. The intervention will continue for 2 months and the study data will be collected before the intervention, the first month, the second month, the third month and the fourth month after the intervention.

Main outcome variables
The main variables of this study are the intensity and frequency of migraine attacks.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190107042264N5**
Registration date: **2022-11-02, 1401/08/11**
Registration timing: **prospective**

Last update: **2022-11-02, 1401/08/11**
Update count: **0**

Registration date
2022-11-02, 1401/08/11

Registrant information

Name
Ehsan Hedayatinejad

Name of organization / entity

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Iran (Islamic Republic of)

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hedayatee.e@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-06, 1401/08/15

Expected recruitment end date
2023-03-06, 1401/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of melatonin on reducing the frequency and intensity of migraine attacks

Public title
Studying the effect of melatonin on migraine

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of migraine according to the criteria of the International Headache Society Chronic migraine patients who are able to distinguish migraine from non-migraine headaches Patients who do not have primary internal and neurologic complaints, there is no other reason for headache in them Filling the written consent form to participate in the study at least 1 year of migraine history
Exclusion criteria:
Severe and debilitating migraine (to eliminate the therapeutic effects of excessive use of painkillers) Chronic daily headache Taking drugs other than propranolol to prevent attacks or taking sleeping pills Migraine Disability Assessment (MIDAS) Grade 4 Treatment-resistant migraine (history of unsuccessful treatment with two or more migraine drug classes) History of abnormal use of painkillers and Medication Overuse Headache Significant psychological disorders (psychological illnesses leading to chronic drug use for at least six months) Pregnancy and breastfeeding Primary medical conditions and surgeries that require medical interventions (including contraindications to beta-blockers) Presence of multiple chronic headaches other than migraine with or without medical treatment, such as tension headache History of melatonin allergy or adverse events Patient's request to withdraw from the study due to drug side effects or other reasons
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The block randomization method was used in 3 blocks of 20 people, using the free statistical software available on the Randomization.org website without using stratified randomization to create a random sequence. Then, each obtained number was assigned a unique arbitrary code, including capital letters and numbers, using the Random.org website for concealment. The statistician delivers these codes to the pharmacist to prepare medicine packages, and the coding of identical packages is done with them.
Blinding (investigator's opinion)
Double blinded
Blinding description
All participants use the same medicine packages, the contents of which are the same in terms of color, size, smell, and shape. Principal investigators are unaware of the coding performed by the statistician. Doctors, interviewers, and data collection officials are only aware of the code assigned to the patients and do not know to which study group the patient belongs. The study codes will remain with the project statistician until the end of the study. The statistician will decode them during the statistical analysis at the end of the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Faculty of Medicine, Ahvaz Jundishapur University of Medical Sciences, Esfand Street, Golestan, Ahvaz, Iran
City
Ahvaz
Province
Khouzestan
Postal code
1579461357
Approval date
2022-04-19, 1401/01/30
Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1401.022

Health conditions studied

1

Description of health condition studied
Migraine Headaches
ICD-10 code
G43
ICD-10 code description
Migraine

Primary outcomes

1

Description
Severity
Timepoint
1, 2, 3 and 4 months after start of treatment
Method of measurement

Visual Analog Scale

2

Description
Frequency
Timepoint
1, 2, 3 and 4 months after start of treatment
Method of measurement
Headache Diary

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In both groups of patients, propranolol 20 mg twice a day is used as a standard anti-migraine treatment. In the Intervention group, 3 mg melatonin tablets (Razak company) are given. The prescription is to take medicine one hour before going to bed. The intervention will continue for two months, and the study data will be collected before the intervention, in the first month, the second month, the third month, and the fourth month after the intervention.
Category
Treatment - Drugs

2

Description
Control group: In both groups of patients, propranolol 20 mg twice a day is used as a standard anti-migraine treatment. In the control group, the same placebo in terms of shape, color, smell, size and taste prepared at the Faculty of Pharmacy of Jundishapur University of Ahvaz is given. The prescription is to take the medicine one hour before going to bed. The intervention will continue for 2 months and the study data will be collected before the intervention, the first month, the second month, the third month and the fourth month after the intervention.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Teaching Hospital
Full name of responsible person
Asieh Mehramiri
Street address
Golestan Teaching Hospital - Farvardin St - Golestan
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Email
mehramiri.ac@gmail.com
Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehrnoosh Zakerkish
Street address
Central library, Ahvaz Jundishapur University of Medical Sciences, Esfand St, Golestan
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Postal code
6135715794
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+98 61 3373 8383
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Zakerkish-m@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Asieh Mehramiri
Position
Assistant Professor
Latest degree

Subspecialist
Other areas of specialty/work
Neurology
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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