# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Nov 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**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 61 3334 3368

**Email address**
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
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
6135733118
**Phone**
+98 61 3374 3001
**Email**
mehramiri.ac@gmail.com
**Web page address**
http://hgolestan.ajums.ac.ir

## 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
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
6135715794
**Phone**
+98 61 3373 8383
**Email**
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
**Street address**
Golestan Teaching Hospital - Farvardin St - Golestan
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
6135733118
**Phone**
+98 61 3374 3001
**Email**
mehramiri.ac@gmail.com

## Person responsible for scientific 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
**Street address**
Golestan Teaching Hospital - Farvardin St - Golestan
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
6135733118
**Phone**
+98 61 3374 3001
**Email**
mehramiri.ac@gmail.com

## Person responsible for updating data

**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
**Street address**
Golestan Teaching Hospital - Farvardin St - Golestan
**City**
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**Province**
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**Postal code**
6135733118
**Phone**
+98 61 3374 3001
**Email**
mehramiri.ac@gmail.com

## 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