

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

The effect of melatonin supplementation on symptoms of headache and CGRP in women with migraine

Protocol summary

Study aim

The effect of melatonin supplementation on calcitonin gene-related peptide (CGRP) and headache symptoms in women with migraine

Design

A randomized controlled clinical trial with parallel groups, double-blind, randomized

Settings and conduct

The present study is a double-blind, randomized, parallel clinical trial. The target population includes those with migraines referred to the Khorshid Clinic and Imam Musa Sadr Clinic who are diagnosed according to the criteria of the International Headache Society (IHS) by a neurologist. Split and study for 8 weeks. Before and after the intervention, severity of headache, frequency of headache and duration of headache, serum CGRP level, depression, stress, anxiety and quality of life of migraine patients will be measured. To double-blind this study, all capsules were coded as A and B prior to study initiation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women from the age of 18 to before menopause; diagnosis of migraine by a neurologist; willingness to cooperate with the plan. Exclusion criteria: people with a history of overdose of analgesics according to IHS criteria for antidepressant abuse; pregnancy or breast-feeding; history of significant complications or recent use of melatonin supplements; severe depression in the past year.

Intervention groups

Control group (n=44): one placebo (50 mg starch) half an hour before bedtime, 8 weeks. Intervention group (n=44): Melatonin 3 mg half an hour before bedtime, 8 weeks.

Main outcome variables

Migraine severity score; migraine frequency; duration of migraine; CGRP inflammatory factor, depression, stress, anxiety, quality of life, weight, body mass index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121216011763N40**

Registration date: **2019-12-15, 1398/09/24**

Registration timing: **prospective**

Last update: **2019-12-15, 1398/09/24**

Update count: **0**

Registration date

2019-12-15, 1398/09/24

Registrant information

Name

Gholamreza Askari

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2110

Email address

askari@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of melatonin supplementation on symptoms of headache and CGRP in women with migraine

Public title

The effect of melatonin supplementation on migraine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women from the age of 18 to menopause
Diagnosis of migraine by a neurologist
Willing to work with the project

Exclusion criteria:

People with a history of overdose of analgesics according to IHS criteria for antidepressant abuse
Pregnancy or breast-feeding
History of significant complications or recent use of melatonin supplements
Severe depression in the past year

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

The total number of specimens randomly assigned by the process will be divided into two groups by random blocks and each group will consist of 44 persons. The blocking method will be used for randomization. To do this, a random allocation sequence will be created through the reputable website <https://www.sealedenvelope.com/simple-randomiser/v1/lists>.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double blind clinical trial (participant, researcher). Melatonin supplement and placebo will be packaged in similar boxes and the researcher and patients will not be informed of the contents of the packs until 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 Isfahan University of Medical Sciences

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

8135798111

Approval date

2019-11-05, 1398/08/14

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.499

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43.0

ICD-10 code description

Migraine

2

Description of health condition studied

Migraine

ICD-10 code

G43.1

ICD-10 code description

Migraine

Primary outcomes

1

Description

Migraine symptoms (severity, frequency, duration of migraine)

Timepoint

Week 0 and Week 8

Method of measurement

Questionnaire

2

Description

Serum levels of calcitonin-associated peptide (CGRP)

Timepoint

Week 0 and Week 8

Method of measurement

Laboratory analysis (blood test)

Secondary outcomes

1

Description

Depression, stress, anxiety

Timepoint

week 0 and week 8

Method of measurement

DASS-21questionnaire

2

Description

Quality of Life in Migraine Patients

Timepoint

week 0 and week 8

Method of measurement

Migraine -Specific Quality of Life(MSQ)questionnaire

Intervention groups

1

Description

Intervention group: Daily melatonin 3 mg half an hour before bedtime for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: One placebo daily (50 mg starch) half an hour before bedtime for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorshid clinic

Full name of responsible person

Gholamreza Askari

Street address

Ostandari St.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 1792 2110

Email

askari@mui.ac.ir

2

Recruitment center

Name of recruitment center

Imam Musa Sadr Clinic

Full name of responsible person

Gholamreza Askari

Street address

Foroughi St.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 1792 2110

Email

askari@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Hezar Jarib

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 8138

Email

sh_haghjoo@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Fatemeh Moradi
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Hezar Jarib
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 1792 2110
Email
f.moradi224@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Hezar Jajrib
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 1792 2110
Email
askari@mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Fatemeh Moradi
Position
masters student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Hezar Jarib
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 1792 2110
Email
f.moradi224@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

An identifiable data file related to the main outcome will be shared.

When the data will become available and for how long

12 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

To do similar designs

From where data/document is obtainable

Dr. Gholamreza Askari askari@mui.ac.ir

What processes are involved for a request to access data/document

Information will be sent after receiving the request

Comments