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 (HIS) 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)

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+98 31 1792 2110

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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
Isfehan

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
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8174673461
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2

Recruitment center
Name of recruitment center
Imam Musa Sadr Clinic
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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