Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

evaluation of melatonin efficacy on frequency and intensity of catamenial migraine headache comparing to naproxen

Protocol summary

Study aim
Evaluation of the effect of administration of melatonin on the frequency and severity of headache in menstrual migraine patients compared with administration of non-steroidal anti-inflammatory drugs

Design
A double-blind, randomized, controlled trial

Settings and conduct
The study was conducted at Imam Khomeini Hospital's neurology clinic on patients with menstrual migraine. The patients were divided into two groups and assigned to one group of naproxen and the other group received melatonin and at the beginning and one month later and three months after the severity And frequency headache were studied. The patients and the person who completed the questionnaire and analyzed the blind.

Participants/Inclusion and exclusion criteria
Women with menstrual migraine who are not pregnant and who are not suffering from other primary headaches and chronic headaches

Intervention groups
Administration of melatonin and its efficacy compared with administration of naproxen and evaluation of the effects of administration of melatonin

Main outcome variables
Effect of Melatonin as Prophylaxis and Study of Complications of Melatonin Administration and Effectiveness in Sleep Disorders in Patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20121110011424N4**
Registration date: **2019-05-08, 1398/02/18**
Registration timing: **registered_while_recruiting**
Last update: **2019-05-08, 1398/02/18**
Update count: **0**

Registration date
2019-05-08, 1398/02/18

Registrant information
Name
Abbas Tafakhori
Name of organization / entity
Iranian Center of Neurological Research
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-28, 1397/06/06

Expected recruitment end date
2019-08-28, 1398/06/06

Actual recruitment start date
2018-08-28, 1397/06/06

Actual recruitment end date
2019-08-28, 1398/06/06

Trial completion date
2019-10-23, 1398/08/01

Scientific title
evaluation of melatonin efficacy on frequency and intensity of catamenial migraine headache comparing to naproxen

Public title
Melatonin in catamenial migraine headache compare with naproxen

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

women in fertility age with pure catamenial migraine
women in fertility age with migraine headache associated with catamenial headache

Exclusion criteria:

patient with other primary headache patient with chronic migraine patient with DM- HTN- peptic ulcer

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **30**
Patients with catamenial migraine referred to Neurology Clinic of Imam Khomeini Hospital in 2017
Actual sample size reached: **60**
More than 1 sample in each individual
Actual sample size in each individual: **30**
Patients with catamenial migraine referred to Neurology Clinic of Imam Khomeini Hospital in 2017

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who had entry criteria were then randomly assigned to two groups by randomly assigned random access to the study type and the consent form for a group of melatonin and for the other naproxen. Patients and prescribing physicians They were unaware and the instructions for how to take the medication were also given to the patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

The person filling the questionnaire and analyzing the information and patients were unaware of the form of drug packaging and drug form, but the method of using the drug and other information needed by the person who delivered the drug to patients was explained to them.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ehics committeemee of Tehran University of Medical Science

Street address

Imam khomeini Hospital complex , Bagher khan street

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2018-02-20, 1396/12/01

Ethics committee reference number

IR.TUMS.IKHC.REC.1396.4567

Health conditions studied

1

Description of health condition studied

Women with Catamenial migraine headache

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Change in frequency and severity of headache

Timepoint

baseline,1 month after intervention,3 months after intervention

Method of measurement

migraine diary questionnaire

2

Description

sleep change

Timepoint

baseline,1 month after intervention,3 months after intervention

Method of measurement

Berlin sleep questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: women with catamenial migraine treated with Naproxen

Category
Treatment - Drugs

2

Description
Intervention group: women with catamenial migraine treated with Melatonin

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam khomeini hospital complex

Full name of responsible person
Abbas tafakhori

Street address
Imam khomeini hospital complex-Bagherkhan street

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Imamhospital@tums.ac.ir

Web page address
http://ikhc2.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ali sahraiyan

Street address
Tehran university of medical since ,qods street, keshavarz blvd

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1411713137

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info@tums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
abbas tafakhori

Position
Associated professor

Latest degree
Specialist

Other areas of specialty/work
Neurology

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Person responsible for scientific inquiries

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Position
associate professor

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Person responsible for updating data

Contact
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The results of the analysis of the information contained in the questionnaires and the related graphs resulted from the spss program
When the data will become available and for how long
Start the access period 9 months after the results are published
To whom data/document is available
Researchers working in academia and academia
Under which criteria data/document could be used
There is no specific restriction
From where data/document is obtainable
Email elhammohammadyahya@gmail.com
What processes are involved for a request to access data/document
After receiving the email within a month, information will be sent to them
Comments