

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6691 0491

###### Email address

a\_tafakhori@sina.tums.ac.ir

##### 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

Ethics committee 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

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733141

**Phone**

+98 21 6119 2424

**Fax**

+98 21 6658 1615

**Email**

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 sahraian

**Street address**

Tehran university of medical since ,qods street, keshavarz blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713137

**Email**

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

**Street address**

imam khomeinin hospital complex , bagherkhan street , tehran

**City**

tehran

**Province**

Tehran

**Postal code**

1419733141

**Phone**

+98 21 6119 2424

**Email**

abbas.tafakhori@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

abbas tafakhori

**Position**

associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurology

**Street address**

imam khomeini hospital complex , bagherkhan street , tehran

**City**

tehran

**Province**

Tehran

**Postal code**

1419733141

**Phone**

+98 21 6119 2424

**Email**

abbas.tafakhori@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

elham mohammad yahya

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurology

**Street address**

imam khomeini hospital complex-bagherkhan street-tehran

**City**

tehran

**Province**

Tehran

**Postal code**

1419733141

**Phone**

+98 61192424

**Email**

elhammohammadyahya@gmoil.com

**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**