

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the efficacy of propranolol alone and propranolol plus melatonin on the severity, duration, and number of migraine attacks in patients with migraine headaches

#### Protocol summary

##### Study aim

To compare the efficacy of propranolol alone and propranolol plus melatonin on the severity, duration, and number of migraine attacks in patients with migraine headaches

##### Design

Two-arm, parallel-group, randomized, and non-blinded, phase 3 clinical trial with 40 patients. Twenty cards with letter A and 20 cards with letter B were placed in a box, and each patient was asked to draw out one card randomly.

##### Settings and conduct

One group was treated with 20 mg propranolol tablets, and the second group was treated with 20 mg of propranolol plus 3 mg oral melatonin tablets. The study was performed without blinding.

##### Participants/Inclusion and exclusion criteria

Major inclusion criteria: an average of two migraine attacks per month; a minimum of one-year history of migraine; and age between 18 and 65 years. Major exclusion criteria: a history of headaches lasting longer than 15 days a month; a history of any neurological disorder other than migraine; and allergy to the study medications.

##### Intervention groups

Intervention group 1 (propranolol): propranolol, 20 mg oral tablets, once daily for three months. Intervention group 2 (propranolol plus melatonin): 20 mg propranolol tablets plus 3 mg melatonin capsules, each once daily for three months

##### Main outcome variables

Pain severity; pain duration; number of migraine attacks.

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20170316033099N12**

Registration date: **2021-01-02, 1399/10/13**

Registration timing: **retrospective**

Last update: **2021-01-02, 1399/10/13**

Update count: **0**

#### Registration date

2021-01-02, 1399/10/13

#### Registrant information

##### Name

Mohammad Bagher Roozgar

##### Name of organization / entity

Birjand University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3239 5680

##### Email address

roozgar@bums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2020-03-03, 1398/12/13

#### Expected recruitment end date

2020-11-20, 1399/08/30

#### Actual recruitment start date

2020-03-03, 1398/12/13

#### Actual recruitment end date

2020-11-20, 1399/08/30

#### Trial completion date

2020-11-20, 1399/08/30

#### Scientific title

Comparison of the efficacy of propranolol alone and

propranolol plus melatonin on the severity, duration, and number of migraine attacks in patients with migraine headaches

**Public title**

The effectiveness of melatonin on migraine headaches

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Confirmed migraine as per the indices of the International Headache Society Age between 18 and 65 years Residence in South Khorasan Province An average of two migraine attacks per month A minimum of one-year history of migraine The first migraine attack occurring before age 50 Informed consent for participation

**Exclusion criteria:**

History of headaches lasting longer than 15 days a month History of any neurological disorder other than migraine Allergy to the study medications Presence of debilitating diseases such as cancer and autoimmune diseases, advanced diabetes, etc. Pregnancy and lactation Persistent headache History of seizures and epilepsy History of neurological and mental illnesses

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

Actual sample size reached: **37**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Each patient was assigned to either the intervention group (A) or group (B) by removing one card from a box containing 20 A and 20 B cards.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Birjand University of Medical

Sciences

**Street address**

Ghaffari Ave.

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Approval date**

2020-03-02, 1398/12/12

**Ethics committee reference number**

lr.bums.REC.1398.389

**Health conditions studied****1****Description of health condition studied**

migraine

**ICD-10 code**

G43

**ICD-10 code description**

Migraine

**Primary outcomes****1****Description**

pain severity

**Timepoint**

study onset, fourth week, eighth week, and twelfth week

**Method of measurement**

visual analog scale

**2****Description**

pain duration

**Timepoint**

fourth week, eighth week, and twelfth week

**Method of measurement**

patient's report

**3****Description**

Number of migraine attacks

**Timepoint**

fourth week, eighth week, and twelfth week

**Method of measurement**

patient's report

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group 1 (propranolol): propranolol, 20 mg oral tablets, once daily for three months

### Category

Treatment - Drugs

## 2

### Description

Intervention group 2 (propranolol plus melatonin): 20 mg propranolol tablets plus 3 mg melatonin capsules, each once daily for three months

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Razi Hospital

#### Full name of responsible person

Sajjad Rafiei

#### Street address

Ghaffari Ave.

#### City

Birjand

#### Province

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#### Postal code

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#### Phone

+98 56 3162 6000

#### Email

q.armageddon@gmail.com

## 2

### Recruitment center

#### Name of recruitment center

Imam Reza Hospital

#### Full name of responsible person

Sajjad Rafiei

#### Street address

Taleghani St.

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## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Birjand University of Medical Sciences

#### Full name of responsible person

Dr. Tooba Kazemi

#### Street address

Ghaffari Ave.

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#### Phone

+98 56 3239 5641

#### Email

Dr.toobakazemi@gmail.com

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Birjand 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

Birjand University of Medical Sciences

#### Full name of responsible person

Sajjad Rafiei

#### Position

Medical student

#### Latest degree

Medical doctor

#### Other areas of specialty/work

General Practitioner

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Dr. Zahra Ahmadi

**Position**

Neurologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Mohammad Bagher Roozgar

**Position**

Translator

**Latest degree**

Master

**Other areas of specialty/work**

Others

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**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**

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

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

IPD

**When the data will become available and for how long**

Up to six months from the publication of the article extracted from the study project

**To whom data/document is available**

researchers

**Under which criteria data/document could be used**

for research purposes

**From where data/document is obtainable**

personal correspondence with the corresponding author via email

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

email to the corresponding author

**Comments**