

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)

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+98 56 3239 5680

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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

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Ghaffari Ave.

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2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Sajjad Rafiei

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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

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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