Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Ir.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
South Khorasan
Postal code
9717853577
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.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3162 6000
Email
q.armageddon@gmail.com

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.
City
Birjand
Province
South Khorasan
Postal code
9717853577
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
Street address
Ghaffari Ave.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3239 5641
Email
q.armageddon@gmail.com

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

Street address
Ghaffari Ave.

City
Birjand

Province
South Khorasan

Postal code
9717853577

Phone
+98 56 3162 6000

Email
zahra.ahmadi83@yahoo.com

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

Street address
Ghaffari Ave.

City
Birjand

Province
South Khorasan

Postal code
9717853577

Phone
+98 56 3239 5632

Email
roozgar@BUMS.ac.ir

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