Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of agomelatine on the severity and numbers of migraine attacks in patients with migraine

Protocol summary

Study aim
To determine the effectiveness of agomelatine on the severity, number of attacks, and days of migraine headaches

Design
Parallel randomized controlled trial design Patients referred for migraine treatment, if they consent to enter the study, will be randomly assigned to one of the intervention or control groups. The groups are treated by agomelatine or placebo. The sample size in this study will be 50 people for each group. The prescribing physician and the data collector will not be aware of the allocation method, and only the principal investigator will label the drug and placebo as A and B. The addition of this study is 3

Settings and conduct
Ziyaian and Imam Hospital Neurology Clinic patients were sampled consecutively over several months Sampling among the eligible patients if they were satisfied

Participants/Inclusion and exclusion criteria
Patients with migraine headache between 18 and 60 years who referr to a hospital for treatment of migraine . Patients with migraine who have other chronic diseases such as cardiovascular or brain diseases are not included in the study

Intervention groups
Receiving agomelatine 25 mg daily by the intervention group Receiving placebo vitamin B1 with the same shape and design as the medicine of the intervention group in the amount of 25 mg

Main outcome variables
Severity of headache; Number of headache attacks; Midas; Number of days with headache

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230303057599N1**
Registration date: **2023-05-24, 1402/03/03**
Registration timing: **retrospective**

Last update: **2023-05-24, 1402/03/03**
Update count: **0**

Registration date
2023-05-24, 1402/03/03

Registrant information

Name
Mahdi Shafiee Sabet

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 7707 8738

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-06, 1400/06/15

Expected recruitment end date
2022-02-09, 1400/11/20

Actual recruitment start date
2021-09-23, 1400/07/01

Actual recruitment end date
2022-03-16, 1400/12/25

Trial completion date
empty

Scientific title
The effectiveness of agomelatine on the severity and numbers of migraine attacks in patients with migraine

Public title

effect of Agomelatin on the migraine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Migraine without aura without the use of preventive medicine

Exclusion criteria:

Pregnant woman those taking certain medications

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Actual sample size reached: **49**

Randomization (investigator's opinion)

Randomized

Randomization description

based on random table For this random assignment method in order to create groups with the same number Half of the total number of people who are going to enter will be randomly selected from the table of random numbers. The random number between 0 and 4 get the word AB, and if it was between 5 and 9, BA is assigned to it, then according to the entry, people will be in one of the two groups - intervention or control. For example, for a sample size of 60 people, if 30 random numbers are as follows: 396147224160811382693361771706 According to the above contract: From left to right, equal to the number: 3, AB Equivalent to 9, BA Equivalent to 6, BA Equation 1: AB Equation 4: AB

Blinding (investigator's opinion)

Triple blinded

Blinding description

The Medications were made by the relevant company in the same shape and design and in the same size, and only the main researcher was aware of the type of Tablets. The neurologist who prescribed, as well as the data collector and the data analyst, were unaware of which intervention the patient had undergone.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Imam Khomeini Hospital; Tehran University of Medical Sciences

Street address

Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Approval date

2021-09-01, 1400/06/10

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.219

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura [common migraine]

Primary outcomes

1

Description

Severity and number of headache attacks

Timepoint

Three months after the intervention

Method of measurement

Checklist and interview

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group receives agomelatine 25 mg daily in tablet form for three months

Category

Treatment - Drugs

2

Description

Control group: This group receives vitamin B1 tablets with the same shape and design and weight of 25 mg equivalent to agomelatine for three months

Category

Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology Clinic of Imam Khomeini Hospital
Full name of responsible person
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2

Recruitment center
Name of recruitment center
Ziaian Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shafiee Sabet Mahdi
Position
Faculty Member
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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