Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Comparison effect of migroherb herbal drug(Tanacetum parthenium, Matricaria chamomilla and magnesium) and Venlafaxine on the severity and frequency of headache and the quality of life of migraine sufferers

Protocol summary

Study aim

General goal:compare the effect of migroherb with venlafaxine in migraine exclusive Determining the demographic and clinical status of migraine patients in the two groups of venlafaxine and migroherb Determining and comparing the severity, duration, frequency of disease attacks and quality of life of migraine patients before and after treatment in two groups

Design

Clinical trial with two parallel groups, three blinded, randomized, phase 3 on 70 patients. Randomization by Permuted block method

Settings and conduct

The research carried out in 2023-2024 in the Beheshti clinic in Kashan.70 patients with episodic migraine with written consent, and they were randomly assigned to one of the two groups of migroherb or venlafaxine. All receive standard treatment with sodium valproate. The duration of the study is 12 weeks. The monthly HIT6 test, the beginning and the end of the study, MIDAS test are performed. At the end, the changes of the subjects will be checked and compared with the beginning of the study in each group and between the two groups. Blinding: the drugs are prepared in the same packaging and appearance and size, and then they are coded based on the codes that have been previously prepared using a table of random numbers.The doctor, the patient, and the data collector act based on the code during the research

Participants/Inclusion and exclusion criteria

Entry requirements: Age 18-65 years and confirmation of episodic migraine by a neurologist Exit conditions:Taking corticosteroids, OCP, other anti-migraine drugs (except sodium valproate 200 daily);Tension headache or chronic migraine;History of liver, kidney, diseases;pregnancy and lactation;Migraine onset after age 50; psychosis, major depression, bipolar

Intervention groups

group one :venlafaxine and sodiumvalproate Group two :migroherb and sodiumvalproate

Main outcome variables

Frequency, intensity, duration of attack

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231009059670N1**
Registration date: **2024-02-19, 1402/11/30**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-19, 1402/11/30**
Update count: **0**

Registration date

2024-02-19, 1402/11/30

Registrant information

Name

Hoda sadat Homayouni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3661 7507

Email address

hoda.homayoni91@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date

2024-09-05, 1403/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of migroherb herbal drug(Tanacetum parthenium, Matricaria chamomilla and magnesium) and Venlafaxine on the severity and frequency of headache and the quality of life of migraine sufferers

Public title

Comparison effect of migroherb herbal drug(Tanacetum parthenium, Matricaria chamomilla and magnesium) and Venlafaxine in migraine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ages 18-65 years Confirmation of episodic migraine by a neurologist according to the latest ICHD definition

Exclusion criteria:

Use of corticosteroids Use of vitamin D, calcium and riboflavin supplements Using other anti-migraine drugs (including beta-blockers, anti-seizures, calcium blockers, tricyclic antidepressants, nerve block or stimulation) except sodium valproate 200 mg daily Presence of tension headache Diagnosis of chronic migraine Having a history of liver, kidney and hyper parathyroid diseases Pregnancy and breastfeeding People with trigeminal autonomic cephalalgia and neuralgia People with secondary headaches Patients using OCP and undergoing HRT treatment Migraine headache onset age after 50 years Excessive consumption of alcohol and drugs Known cases of psychosis, major depression, bipolar disorder

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by block method (Permuted block randomization) so that first all 4 blocks containing two codes A and B are prepared (4 blocks) then random blocks are selected by placement using a table of random numbers. 26 blocks) These blocks form a sequence of 104 A and B codes, each code is randomly assigned to one of the groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Medicines are made and prepared in Barij Essan Pharmaceutical Company in the same packaging, appearance and size. Then they are coded based on the codes that have been previously prepared using a table of random numbers. The doctor prescribes the coded drug for each group without knowing the type of each code. The data collector and the data analyzer also Based on the type of code, two groups will be monitored until the study is completed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ravandi street;Shahid beheshti hospital

City

Kashan

Province

Isfehan

Postal code

8715973447

Approval date

2023-11-12, 1402/08/21

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1402.182

Health conditions studied

1

Description of health condition studied

migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

Impact on quality of life

Timepoint
At the beginning of the study (before the start of the intervention) and one month, two months and three months after the start of Migroherb or Venlafaxine
Method of measurement
HIT6 (Headache Impact Test) questionnaire

2

Description
Headache attacks frequency
Timepoint
At the beginning of the study (before the start of the intervention) and three months after the start of migroherb or venlafaxine
Method of measurement
MIDAS (Migraine Disability Assessment) questioner

3

Description
Severity of headache attacks
Timepoint
At the beginning of the study (before the start of the intervention) and three months after the start of migroherb or venlafaxine
Method of measurement
MIDAS (Migraine Disability Assessment) questioner

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The recipient of venlafaxine capsules 37.5 mg daily along with sodium valproate 200 mg daily. The duration of this intervention is three months.
Category
Treatment - Drugs

2

Description
Intervention group: Recipient of mi⌋roherb capsules (containing 50 mg of magnesium, 100 mg of feverfew, 150 mg of Matricaria chamomilla) produced by Barij Essence Company, which should be taken every 12 hours with plenty of water, and 200 mg sodium valproate tablets daily. The duration of this intervention is three months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology Clinic of Shahid Beheshti Hospital, Kashan
Full name of responsible person
Seyed Ali Masoud
Street address
Beheshti hospital ;Ravandi street ;Kashan;IRAN
City
Kashan
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Isfehan
Postal code
8715973447
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+98 31 5500 5725
Fax
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Email
hoda.homayoni91@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hodasadat Homayouni
Street address
Gotbe Ravandi street;Shahid Beheshti hospital
City
Kashan
Province
Isfehan
Postal code
8715988111
Phone
+98 31 5554 0026
Email
Education@Kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Barijessence Pharmaceutical company
Proportion provided by this source
80
Public or private sector
Private
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

Kashan University of Medical Sciences

Full name of responsible person
Hodasadat Homayouni

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Neurology

Street address
plate 13;Aftab dead end; alley 13;1st Apadana street; Isfahan

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Hodasadat Homayouni

Position
resident

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Data file of participants (except personal information including age and phone number)

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
For use in research to improve the treatment process of migraine sufferers on the condition of mentioning the source of the received information and preserving the principle of trustworthiness

From where data/document is obtainable
Hodasadat Homayouni mobile :09132283085 email : hoda.homayoni91@gmail.com

What processes are involved for a request to access data/document
A clear explanation of the reason and purpose of needing to access information

Comments