Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Effect of Adjunctive Treatment with Vitamin D in Adults with Migraine with Vitamin D Deficiency: A Clinical Trial

Protocol summary

Study aim

Determination of the Effect of Adjunctive Treatment with Vitamin D in Adults with Migraine with Vitamin D Deficiency: A Clinical Trial

Design

Blood samples will be taken from patients who have already been given a definitive diagnosis of migraine and have been treated with a drug regimen, and the serum level of vitamin D of the patients will be measured using the ELISA method. According to the ELISA method, vitamin D serum levels are classified as follows: deficiency (serum levels less than 12 ng/ml), insufficient (serum levels 12 to 30 ng/ml), and sufficient (serum levels more than 30 ng/ml). Finally, patients whose vitamin D level is less than 20 ng/ml will be included in the study, and migraine headache indices will be evaluated once before vitamin D supplementation and once after. It should be noted that the current study is a clinical trial and a group is not considered as a control group, but the comparison will be done before and after.

Settings and conduct

Patients referred to Birjand Razi Hospital in 2024

Participants/Inclusion and exclusion criteria

The study population includes patients referred to Birjand Razi Hospital in 2024, who have specific records in the hospital clinic.

Intervention groups

In accordance with the national protocol of vitamin D supplementation, for people diagnosed with vitamin D deficiency by a medical doctor, a 50,000 unit vitamin D supplement is prescribed by the doctor for 8 weeks. In the future, supplementation will continue with a 50,000 unit vitamin D supplement on a monthly basis.

Main outcome variables

Migraine headache indices including migraine severity, average duration of migraine attacks per day, and frequency of migraine attacks per month

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241024063488N1**
Registration date: **2024-10-31, 1403/08/10**
Registration timing: **prospective**

Last update: **2024-10-31, 1403/08/10**
Update count: **0**

Registration date

2024-10-31, 1403/08/10

Registrant information

Name
Ali Fanoodi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 939 561 8075
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alifanoodi@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-20, 1403/11/01

Expected recruitment end date

2025-07-23, 1404/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Adjunctive Treatment with Vitamin D in Adults with Migraine with Vitamin D Deficiency: A Clinical Trial

Public title
Investigating the Effect of Vitamin D in Migraine
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 40 years Confirmation of migraine diagnosis by a neurologist Availability of the desired information Having informed consent to participate in the study
Exclusion criteria:
Patients who do not have the necessary cooperation Suffering from cardiovascular diseases, liver diseases, kidney diseases, primary hyperparathyroidism, tension headache, and hypervitaminosis D Use of corticosteroids and contraceptives Using vitamin D, magnesium, calcium, folic acid, vitamin B6, and vitamin B12 supplements before entering the study
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **44**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Birjand University of Medical Sciences
Street address
Ghafari St.
City
Birjand
Province
South Khorasan
Postal code
9718986696
Approval date
2024-07-13, 1403/04/23
Ethics committee reference number
IR.BUMS.REC.1403.150

Health conditions studied

1

Description of health condition studied
Migraine
ICD-10 code
G43
ICD-10 code description
Migraine

Primary outcomes

1

Description
Migraine headache indices including migraine severity, average duration of migraine attacks per day, and frequency of migraine attacks per month
Timepoint
Migraine headache indices including migraine severity, average duration of migraine attacks per day, and frequency of migraine attacks per month
Method of measurement
Migraine severity will be determined by VAS scale. The result of daily headache will be calculated by multiplying the duration of headache attacks by the headache frequency.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receiving Vitamin D
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Birjand Razi Hospital
Full name of responsible person
Arman Ashayerizadeh
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a_ashayerizadeh@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Web page address
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
Dr. Ali Fanoodi
Position
Medical Doctor
Latest degree
Medical doctor
Other areas of specialty/work
Epidemiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Patient data will not be published due to compliance with ethical principles in the research.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Patient data will not be published due to compliance with ethical principles in the research.
When the data will become available and for how long
Patient data will not be published due to compliance with ethical principles in the research.
To whom data/document is available
Patient data will not be published due to compliance with ethical principles in the research.
Under which criteria data/document could be used
Patient data will not be published due to compliance with ethical principles in the research.
From where data/document is obtainable
Patient data will not be published due to compliance with ethical principles in the research.
What processes are involved for a request to access data/document
Patient data will not be published due to compliance with ethical principles in the research.
Comments