# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Investigating the effect of vitamin D on headache severity in adolescents with migraine

### Protocol summary


**Study aim**
To evaluate the effect of vitamin D supplementation on the severity, duration and frequency of headache attacks in adolescents with migraine.

**Design**
A randomized; parallel group; double-blind (outcome assessor and statistical analyst blinded); phase 3 clinical trial of 112 patients. Randomization was performed using a permuted block method with a block size of 4 to ensure concealed allocation sequence.

**Settings and conduct**
Setting: Pediatric Neurology Clinic of ValiAsr Hospital of Birjand; one hundred and twelve adolescents randomized into two groups; outcome assessor and statistical analyst are blinded.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Age twelve to eighteen years; migraine diagnosis; stable Sodium Valproate dose. Exclusion criteria: Renal disease; recent supplement use; high serum calcium.

**Intervention groups**
Intervention group: Receiving routine treatment with Sodium Valproate tablets; plus weekly consumption of one Vitamin D softgel containing 50000 International Units for 10 weeks. Control group: Receiving routine treatment with Sodium Valproate tablets only; without receiving any additional supplements or placebos.

**Main outcome variables**
Mean headache intensity score; time of measurement at baseline and 10 weeks after the initiation of the intervention; measurement tool is the Visual Analog Scale from score 0 to 10.


### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20251116068013N1**
Registration date: **2026-05-13, 1405/02/23**
Registration timing: **prospective**

Last update: **2026-05-13, 1405/02/23**
Update count: **0**

**Registration date**
2026-05-13, 1405/02/23


**Registrant information**
**Name**
mahya hosseini
**Name of organization / entity**
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Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2026-06-05, 1405/03/15

**Expected recruitment end date**
2026-10-07, 1405/07/15

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Investigating the effect of vitamin D on headache severity in adolescents with migraine

**Public title**
Investigating the effect of vitamin D on headache severity in adolescents

**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Adolescents aged between 10 and 18 years Definitive diagnosis of migraine by a pediatric neurologist based on ICHD-3 criteria Serum vitamin D levels less than 30 ng/ml (deficiency or insufficiency) Willingness to participate and providing informed consent by parents or legal guardians Absence of chronic underlying diseases (cardiac, renal, or hepatic)
**Exclusion criteria:**
Affliction with chronic systemic diseases (including cardiovascular, renal, hepatic diseases, and hyperthyroidism or hypothyroidism) Use of vitamin D supplements in the past three months Consumption of medications affecting vitamin D metabolism (such as specific anticonvulsants or corticosteroids) Presence of morbid obesity (Body Mass Index or BMI > 30 kg/m²) Diagnosis of Diabetes Mellitus Reluctance of the patient or parents to continue participation at any stage of the study Occurrence of severe adverse effects or hypersensitivity to vitamin D supplementation
**Age**
From **10 years** old to **18 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **112**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Participants will be assigned to either the intervention or control group using a Block Randomization method with a block size of 4 and an allocation ratio of 1:1. The randomization sequence will be generated by an independent individual (not involved in clinical care or assessment) using computer-generated random numbers. To ensure Allocation Concealment, sequentially numbered, opaque, sealed envelopes will be used. Upon enrollment, each participant will be assigned a serial number and will receive the corresponding envelope to determine their group assignment.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
To implement blinding, vitamin D supplements will be provided in identical packaging so that the participants (adolescents) remain unaware of their group assignments. Furthermore, the outcome assessor (pediatric neurologist), who evaluates headache severity using the VAS scale and records the frequency of attacks at the end of the third month, will be blinded to the group allocations. Additionally, the statistical analyst will remain blinded to the group identities until the completion of the data analysis process.
**Placebo**
Not used
**Assignment**
Parallel
**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 Blvd
**City**
Birjand
**Province**
South Khorasan
**Postal code**
9717853577
**Approval date**
2025-05-14, 1404/02/24
**Ethics committee reference number**
IR.BUMS.REC.1404.075

## Health conditions studied

### 1

**Description of health condition studied**
Migraine in children and adolescents
**ICD-10 code**
G43
**ICD-10 code description**
Migraine

## Primary outcomes

### 1

**Description**
Headache intensity
**Timepoint**
Before intervention (Baseline), 1, 2, and 3 months after the start of interventio
**Method of measurement**
Visual analogue scale

### 2

**Description**
Duration of headache in hours per day
**Timepoint**
Before intervention and one month after the intervention

and two months after intervention and three months after the intervention

**Method of measurement**

Daily recording with timer

**3**

**Description**

Number of the patient’s headache attacks per month

**Timepoint**

Monthly

**Method of measurement**

Daily recording

**4**

**Description**

Vitamin D

**Timepoint**

Before and after intervention

**Method of measurement**

Laboratory measurement of Vitamin D

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

The intervention group receives 1000 IU of Vitamin D supplement orally per day for 3 months. In addition, routine treatment including Propranolol tablets (20 mg every 12 hours) and Amitriptyline tablets (25 mg at night) is prescribed.

**Category**

Treatment - Drugs

**2**

**Description**

The control group receives only the routine treatment including Propranolol tablets (20 mg every 12 hours) and Amitriptyline tablets (25 mg at night) for 3 months and will not receive Vitamin D supplements.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Pediatric Neurology Clinic, Valiasr Hospital, Birjand

**Full name of responsible person**

Dr. Mahya Hoseini

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Dr. Masoud Yousefi

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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**

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**

Mohammad Kouhbanani

**Position**

Medical student and Investigator

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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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**

Individual participant data will not be shared beyond the final results of the study to maintain patient confidentiality.

**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**

No - There is not 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