

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of vitamin D3 on frequency and severity of migraine headache in patients referred to neurology clinic of Rasool Akram Hospital in Tehran,1392

#### Protocol summary

##### Summary

Migraine is common all over the world. In this study we assessed relationship between serum vitamin D level with migraine headache frequency and severity in migraine patients referred to Neurology Clinic of Rasool Akram Hospital, Tehran, Iran, 2013. Totally 70 migraine patients according to neurologist diagnosis were selected. Those with underlying diseases such as hyperparathyroidism, renal stone, renal impairment were excluded. Serum vitamin D level were measured. patients are divided into 2 equal groups. First group is given 1000 IU vitamin D3 daily for 11 weeks. Second group is given the same amount of placebo. 1.5 month later, serum vitamin D level is rechecked in order to preventing hyper vitaminosis of vitamin D. After 3 months all patients are asked to come to the Clinic and their information regarding frequency and severity of headache will be recorded for further comparison and conclusion.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013101415020N1**

Registration date: **2013-12-14, 1392/09/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-12-14, 1392/09/23

##### Registrant information

##### Name

Seyyedeh Maryam Hashemi

##### Name of organization / entity

Semnan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 1444 8996

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Semnan University Of Medical Sciences

##### Expected recruitment start date

2013-10-07, 1392/07/15

##### Expected recruitment end date

2013-11-21, 1392/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of vitamin D3 on frequency and severity of migraine headache in patients referred to neurology clinic of Rasool Akram Hospital in Tehran,1392

##### Public title

migraine headache attacks prevention by prescribing vitamin D

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

inclusion criteria: patients with a diagnosis of migraine headache with no history of underlying diseases such as hyperparathyroidism; cardiac diseases; renal impairment; renal stone; normal or lower serum vitamin D level; no drug history of those interacting with serum

vitamin D level exclusion criteria:increasing in serum vitamin D levels over than normal.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Semnan University of Medical Sciences

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Semnan University of Medical Sciences, Basij Blvd,  
Semnan

**City**

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**Postal code**

3519899951

**Approval date**

2013-09-01, 1392/06/10

**Ethics committee reference number**

92/16/6919

**Health conditions studied****1****Description of health condition studied**

migraine headaches

**ICD-10 code**

G43

**ICD-10 code description**

migraine

**Primary outcomes****1****Description**

frequency of migraine headaches

**Timepoint**

before intervention, 3months after the initial intervention

**Method of measurement**

standard questionnaire

**2****Description**

severity of migraine headaches

**Timepoint**

before intervention, 3months after initial intervention

**Method of measurement**

Visual Analogue Scale

**Secondary outcomes****1****Description**

increasing in serum vitamin D level more than normal level

**Timepoint**

before intervention,1.5 month after the initial intervention

**Method of measurement**

serum vitamin D level in blood sample

**Intervention groups****1****Description**

each patient is given 1000 IU of oral vitamin D3 daily for 11 weeks.

**Category**

Treatment - Drugs

**2****Description**

each patient is given 1000 IU of oral placebo daily for 11 weeks

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Rasoul Akram Hospital

**Full name of responsible person**

Dr Mehdi Moghaddasi

**Street address**

Rasoul Akram hospital,Niyayesh Street,Sattar khan Street,Tehran

**City**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

research deputy of Semnan University of Medical Sciences, Dr Asgari

**Street address**

Semnan University of Medical Sciences, Basij Blvd, Semnan

**City**

Semnan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Semnan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Student

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*