

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

The effect of high-dose of vitamin B1 supplementation on serum CGRP neuropeptide levels and features of episodic migraine in women

Protocol summary

Study aim

Determining the effect of high-dose of vitamin B1 supplementation on serum CGRP neuropeptide level and features of episodic migraine in women.

Design

Clinical trial with placebo control group, with parallel groups, double blinded, randomized, on 40 patients, randomization with blocks of size 4 using software

Settings and conduct

This study will be performed in Sina Hospital in Tehran. Before and after the intervention, demographic information, headache characteristics and anthropometric indicators are recorded. Patients will receive vitamin B1 supplements or placebo for 12 weeks. At the beginning and at the end of the study, a food and physical activity reminder questionnaire is completed. Also, serum levels of CGRP neuropeptide and serum B1 and activity level of red blood cell transketolase will be measured at the beginning and at the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: willingness to participate in the study, 18 to 45 years old, BMI between 18.5-30, Diagnosis of episodic migraine headache based on the criteria of the Classification Committee of the International Headache Society (IHS) 3rd edition (beta version), Not taking a new medication to prevent migraine headache or changing its dose in the last 2 months. Exclusion criteria: Vitamin B1 supplement consumption with any dose and consumption of any type of multivitamin containing vitamin B1 during the last three months, pregnancy and lactation, Having known gastrointestinal diseases, diabetes, liver disorders, kidney disorders, congestive heart failure, high blood pressure, cancer.

Intervention groups

Patients will receive 300 mg thiamine tablets (intervention group) or placebo (control group) 3 times daily (every 8 hours) for 12 weeks.

Main outcome variables

Number of headache attacks per month; Headache severity (VAS); Duration of headache attacks (hours per month)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140804018677N24**

Registration date: **2023-03-11, 1401/12/20**

Registration timing: **prospective**

Last update: **2023-03-11, 1401/12/20**

Update count: **0**

Registration date

2023-03-11, 1401/12/20

Registrant information

Name

soodeh razeghi Jahromi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8500

Email address

razeghi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-21, 1402/02/31

Expected recruitment end date

2023-08-22, 1402/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of high-dose of vitamin B1 supplementation on serum CGRP neuropeptide levels and features of episodic migraine in women

Public title

The effect of high-dose of vitamin B1 supplementation on episodic migraine in women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participate in the study 18 to 45 years old BMI between 18.5-30 Diagnosis of episodic migraine headache based on the criteria of the Classification Committee of the International Headache Society (IHS) 3rd edition (beta version) Suffering from headache for more than three months Not taking a new medication to prevent migraine headache or changing its dose in the last 2 months

Exclusion criteria:

Vitamin B1 supplement consumption with any dose and consumption of any type of multivitamin containing vitamin B1 during the last three months Pregnancy and lactation Use of antipsychotic drugs Smoking Having known gastrointestinal diseases (malabsorption, IBD, etc.), diabetes, liver disorders (cirrhosis and types of hepatitis), kidney disorders (renal failure), congestive heart failure, high blood pressure, cancer

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The Block randomization method is used to randomize the patients. For randomization, we will visit www.sealedenvelope.com and use the randomization tab to make a list considering the number of intervention groups, sample size and block size (4 is selected for current study). The prepared list that contains the pattern of patient allocation will be obtained and used. this site is designed in such a way that there is no limit on the number of groups for random allocation. According to the total number of samples required for the study, which is 40 patients (20 patients in the intervention group (A) and 20 patients in the control

group (B)), 10 blocks with a volume of four includes two groups A and B will be randomly selected using the software, such as (BAAB), (ABBA), (AABB), (BBAA), (ABAB). Then 40 pockets (20 pockets containing paper containing A and 20 pockets containing B) will be prepared based on sample size. According to a list of blocks, a trained person outside of the research team will be set the row of pockets. After admission of each patient will be given a pocket and assigned to Group A (intervention) or B (control group), and the sample process will be performed sequentially until the end of completion of sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

It is a double blind study. A third person out of study team (clinic secretary) have the sequence of codes that provide the team with sealed pockets coded as A or B at the time of sampling. The following groups of people involved in the trial: participants, research team including principle investigator, data collectors, and outcome assessors will be blind. After analyzing the data investigators and outcome assessors will be unblinded about A and B group allocation to supplement and placebo. Patients in supplement and placebo groups will receive packages of similar capsules.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Nutrition and Food Industry Research Institute

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town, Tehran

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2023-01-22, 1401/11/02

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1401.068

Health conditions studied

1

Description of health condition studied

Episodic Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

Number of headache attacks per month

Timepoint

Baseline and at the end of the study

Method of measurement

Daily headache registration questionnaire

2

Description

Severity of headache attacks

Timepoint

Baseline and at the end of the study

Method of measurement

Daily headache registration questionnaire - visual analog scale

3

Description

Duration of headache attacks

Timepoint

Baseline and at the end of the study

Method of measurement

Daily headache registration questionnaire

Secondary outcomes

1

Description

Number and dose of painkillers

Timepoint

Baseline and at the end of the study

Method of measurement

Daily headache registration questionnaire

2

Description

Serum Calcitonin gene-related peptide (CGRP) level

Timepoint

Baseline and at the end of the study

Method of measurement

Blood test

3

Description

The activity level of Erythrocyte transketolase enzyme

Timepoint

Baseline and at the end of the study

Method of measurement

Blood test

4

Description

Serum vitamin B1 level

Timepoint

Baseline and at the end of the study

Method of measurement

Blood test

Intervention groups

1

Description

Intervention group: Thiamin (300 mg), dana darou company, three times daily for 12 weeks

Category

Treatment - Other

2

Description

Control group: Placebo (300 mg), dana darou company, three times daily for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr. mansoureh togha

Street address

Imam Khomeini Street

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6312 1506

Email

toghae@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
Nutrition and Food Industries Research Institute

Full name of responsible person

Dr. Azita Hekmatdoost

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7483

Email

soodehrazeghi@gmail.com

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

No

Title of funding source

Shahid Beheshti University of Medical Sciences, Faculty of Nutrition Sciences and Food Industries, Nutrition and Food Industries Research Institute

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soodeh Razeghi Jahromi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7483

Email

soodehrazeghi@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

| | |
|---|--|
| Not applicable | principal investigator of the study 6 months after publishing the article. |
| Informed Consent Form | When the data will become available and for how long |
| No - There is not a plan to make this available | Starting 6 months after publication |
| Clinical Study Report | To whom data/document is available |
| Yes - There is a plan to make this available | University researchers |
| Analytic Code | Under which criteria data/document could be used |
| Undecided - It is not yet known if there will be a plan to make this available | No other criteria |
| Data Dictionary | From where data/document is obtainable |
| Undecided - It is not yet known if there will be a plan to make this available | Email to soodehrazeghi@gmail.com |
| Title and more details about the data/document | What processes are involved for a request to access data/document |
| Coded data of the participants, study protocol, and report of the main output of the study would be available in case of researchers' reasonable request sending to | Sending email to me |
| | Comments |