Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Phone

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Email address

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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
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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
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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
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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
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Other areas of specialty/work
Nutrition
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Person responsible for updating data

Contact

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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

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

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

Data Dictionary

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

Title and more details about the 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 principal investigator of the study 6 months after publishing the article.

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

University researchers

Under which criteria data/document could be used

No other criteria

From where data/document is obtainable

Email to soodehrazeghi@gmail.com

What processes are involved for a request to access data/document

Sending email to me

Comments