

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluating the effects of vitamin D on CGRP levels, inflammatory markers, Treg/Th17 balance and episodic migraine characteristics in Adult migraineurs

Protocol summary

Study aim

To determine the effects of vitamin D compared to placebo on CGRP levels, inflammatory markers, Treg/Th17 balance and episodic migraine characteristics in Adults migraine

Design

The present study will be conducted as a 16-week phase 1 randomized double-blind placebo-controlled trial on 80 episodic migraineurs allocated in 2 parallel groups each consisted of 40 episodic migraine patients who will receive vitamin D or placebo. From the beginning of the study, A and B codes are available to researchers to recruit the patients using twenty 4-Block Randomizations.

Settings and conduct

The study will perform at the tertiary headache clinic of Sina University Hospital. Information on demographic data and headache characteristics will be collected. A blood sample will be taken at 8 cc. Patients will be randomized to either the intervention or placebo group at the beginning of the fifth week for 12 weeks.

Participants/Inclusion and exclusion criteria

episodic migraine patients according to ICHDIII criteria aged 18 to 45 years

Intervention groups

Patients in the intervention group will receive 1 capsule containing 2,000 IU of vitamin D per day in addition to routine medications prescribed by our study neurologist. While the placebo group will receive 1 placebo capsule which will be indistinguishable from vitamin D capsules in taste and appearance. Patients will be asked to not change their medications during the study.

Main outcome variables

headache attack frequency per month; headache severity (VAS); attack duration (min per month)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151128025267N6**

Registration date: **2018-07-11, 1397/04/20**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-11, 1397/04/20**

Update count: **0**

Registration date

2018-07-11, 1397/04/20

Registrant information

Name

Maryam Mahmoudi

Name of organization / entity

School of Nutritional Sciences & Dietetics, Tehran University of Medical Sciences,

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 5975

Email address

m-mahmoudi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of vitamin D on CGRP levels, inflammatory markers, Treg/Th17 balance and episodic migraine characteristics in Adult migraineurs

Public title

Evaluating the effects of vitamin D on migraine headache and its possible associated factors

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

having BMI between 18.5-30 kg/m2 Migraine diagnosis according to The International Classification of Headache Disorders 3rd edition having 3-15 migraine headache attacks in last 3 months suffering from migraine for at least 6 months prior to study

Exclusion criteria:

unwillingness to participate in the study daily consumption of NSAIDs in 3 months prior to study taking vitamin D supplements in 3 months prior to study taking magnesium, calcium, zinc, vitamin B groups and vitamin C supplements during the study period taking anti-epileptic drugs such as topiramate, sodium valproate and carbamazepine taking thiazide diuretics, Glucocorticoid, statins and orlistat taking anti-psychotic drugs menopause pregnancy and lactation suffering from gastrointestinal disorders (IBD, IBS,...), liver and kidney disorders, cancer, Sarcoidosis, rickets, and osteomalacia based on physician diagnosis and/or past medical history

Age

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

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

according to double-blind nature of this trial, from the beginning of the study, A and B codes are available to researchers to recruit the patients using twenty 4-Block Randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

Only one of the staff of the headache department is aware of the type of assigned intervention for each patient (vitamin D or placebo, which are marked by A or B codes). Finally, after collecting the data, she unseals

the codes for researchers, the statistical analyst, and those who prepare the manuscript.

Placebo

Used

Assignment

Parallel

Other design features

The duration of this randomized, double-blind, placebo controlled trial will be 16 weeks, consisting of 4-week of baseline followed by 12-week intervention. Also, patients will be instructed to fill out a headache diary designed by our headache specialist neurologist in order to provide headache characteristics including headache severity, duration of attacks, number of attacks, and number of days with headache in the month. Patients will be asked to not change their medications during the study.

Secondary Ids

empty

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

Tehran University of Medical Sciences

Street address

Ghods Street

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-04-08, 1397/01/19

Ethics committee reference number

IR.TUMS.VCR.REC.1397.094

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

migraine headache

ICD-10 code

G43

ICD-10 code description

Migraine

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

migraine attack frequency per month

Timepoint

baseline-end of study

Method of measurement

headache diary

2

Description

attack severity

Timepoint

baseline-end of study

Method of measurement

headache diary-visual analogue scale

3

Description

headache attack duration (min per month)

Timepoint

baseline-end of study

Method of measurement

headache diary-visual analogue scale

Secondary outcomes

1

Description

serum 25 (OH) D3

Timepoint

baseline- end of study

Method of measurement

laboratory test

2

Description

serum vitamin D receptor

Timepoint

baseline- end of study

Method of measurement

laboratory test

3

Description

determining inflammatory status (including serum levels of iNOS, IL 6, Cox 2, CGRP, and IL10)

Timepoint

baseline- end of study

Method of measurement

laboratory test

4

Description

Determining Treg/th17 balance (including serum levels of TGF b and IL-17)

Timepoint

baseline- end of study

Method of measurement

laboratory test

5

Description

serum prolactin levels

Timepoint

baseline- end of study

Method of measurement

laboratory test

Intervention groups

1

Description

Intervention group: intervention group will receive 1 capsule which contains 2000 of vitamin D every day for 12 weeks

Category

Prevention

2

Description

Control group: placebo group will receive 1 capsule of placebo with the same smell and taste as vitamin D during 12-week period.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina University 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

Tehran University of Medical Sciences

Full name of responsible person

Ms Fatemeh Javadi

Street address

Shahid Naderi Street

City

Tehran

Province

Tehran
Postal code
14155-6117
Phone
+98 21 8895 5975
Email
javadi_fateme@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
60
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

2

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ms Bahare Pourghaz
Street address
Dr Gharib Street
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6690 3066
Email
pourghaz.bahar@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
40
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
Tehran University of Medical Sciences
Full name of responsible person
Dr Maryam Mahmoudi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
No: 44 Hojjat-dost Alley, Naderi St., Keshavarz Blvd,
Tehran, Iran
City
Tehran
Province
Tehran
Postal code
14155-6117
Phone
+98 21 8895 5975
Fax
+98 21 8895 5975
Email
m-mahmoudi@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Zeinab Ghorbani
Position
PhD candidate in Nutritional sciences
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Shahid Naderi Street
City
Tehran
Province
Tehran
Postal code
14155-6117
Phone
+98 21 8895 5975
Email
zghorbani@razi.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person

Zeinab Ghorbani

Position

PhD candidate in Nutritional sciences

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Shahid Naderi Street

City

Tehran

Province

Tehran

Postal code

14155-6117

Phone

+98 21 8895 5975

Email

zghorbani@razi.tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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