Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 May 2021

Evaluating the effects of viamin 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)

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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 viamin 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 following 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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

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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
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

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PhD candidate in Nutritional sciences

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Person responsible for updating data

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Full name of responsible person

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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