Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of concurrent curcumin and vitamin D supplementation on headache symptoms and calcitonin gene-related peptide level (CGRP) in patients with migraine

Protocol summary

Study aim
The effect of concurrent curcumin and vitamin D supplementation on headache symptoms and calcitonin gene-related peptide level (CGRP) in patients with migraine

Design
Randomized clinical trial

Settings and conduct
Migraine patients who refer to clinics affiliated to Shahrekord University of Medical Sciences are treated with curcumin and vitamin D supplements.

Participants/Inclusion and exclusion criteria
1.Willingness to cooperate with the plan ۲. Diagnosis of migraine by a neurologist based on ICHD-3 criteria. 3. Age 20 to 50 years. 4. No chronic diseases 5. Absence during pregnancy and lactation .. Taking dietary supplements or medication (nutritional supplements, multivitamin mineral and W3 supplements or anti-migraine medications (valproate, amitriptyline, etc.), anti-inflammatory and anti-depressant pills, Aspirin and NSAIDs, contraceptives in the last three months 6. No alcohol and smoking Exclusion criteria: 1. Failure to follow the recommendations and diet. ۲. Failure to refer the person at different stages of the study. 3. Cardiovascular disease, hypertension, diabetes, liver, kidney, thyroid, malignancies and other neurological disorders. 4. Taking nutritional and herbal supplements that affect migraines

Intervention groups
"Intervention group": migraine patients intake curcumin supplement in the form of 500 mg capsules, one per day with routine treatment(Two 200 mg sodium valproate tablets and two 20 mg propranolol tablets) and a soft oral vitamin D capsule with a dose of 2000 international units daily. "Control group": migraine patients intake placebo of curcumin and vitamin D supplement one per day with routine treatment (Two 200 mg sodium valproate tablets and two 20 mg propranolol tablets).

Main outcome variables
Migraine severity, migraine frequency, duration of migraine headache, Calcitonin gene-related peptide

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170929036477N4**
Registration date: **2021-08-10, 1400/05/19**
Registration timing: **prospective**

Last update: **2021-08-10, 1400/05/19**
Update count: **0**

Registration date
2021-08-10, 1400/05/19

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 36688487

Email address
siavashfazelian@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-28, 1400/06/06

Expected recruitment end date
2022-01-05, 1400/10/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of concurrent curcumin and vitamin D supplementation on headache symptoms and calcitonin gene-related peptide level (CGRP) in patients with migraine

Public title
The effect of curcumin and vitamin D s on headache symptoms and inflammation in patients with migraine
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to cooperate with the plan Diagnosis of migraine by a neurologist based on ICHD-3 criteria. Age 20 to 50 years. No chronic diseases (liver, kidney, cardiovascular disease, secondary headache or other types of primary headache except migraine) Absence during pregnancy and lactation No taking dietary supplements or medication (nutritional supplements, multivitamin mineral and W3 supplements or anti-migraine medications (valproate, amitriptyline, etc.), anti-inflammatory and anti-depressant pills, Aspirin and NSAIDs, contraceptives in the last three months Failure to follow a specific diet or exercise program during the last three months
Exclusion criteria:
alcohol and smoking
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible subject be selected with convenience sampling and be randomly assigned into 2 groups of 25 subjects as treatment and control with block sizes of 3 and 6 with proportion 1:1. A person from research team not involved in the recruitment and assigning participants generate allocation sequence using web site of www.Randomization.com.
Blinding (investigator's opinion)
Double blinded
Blinding description
After explaining the purpose of the study, all participants and investigators are blinded to random allocation. Participants in vitamin D group receive vitamin D 1000 IU supplement and curcumin capsules while control group take placebo with the same size and color as vitamin D(Oral paraffin) soft gels and curcumin.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahrekord University of Medical Science
Street address
Kashani Street
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
۸۸۱۳۸۳۳۴۳۵
Approval date
2021-05-11, 1400/02/21
Ethics committee reference number
IR.SKUMS.REC.1400.047

Health conditions studied

1

Description of health condition studied
Migraine
ICD-10 code
G43
ICD-10 code description
Migraine without aura [common migraine]

Primary outcomes

1

Description
Severity of migraine
Timepoint
Before the intervention and at the end of the study
Method of measurement
Visual Analogue Scale

2

Description
Migraine frequency
Timepoint
Before the intervention and at the end of the study
Method of measurement

Question / Number of attacks per month

3

Description
Duration of migraine headache
Timepoint
Before the intervention and at the end of the study
Method of measurement
Question / Number of attacks per month

4

Description
The degree of disability caused by migraines
Timepoint
Before the intervention and at the end of the study
Method of measurement
Headache Impact Test Questionnaire

5

Description
Calcitonin gene-related peptide
Timepoint
Before the intervention and at the end of the study
Method of measurement
blood test

Secondary outcomes

empty

Intervention groups

1

Description
"Intervention group": migraine patients intake curcumin supplement in the form of 500 mg capsules from Karen Company, one per day with routine treatment (200 mg sodium valproate tablets from Sajad Darou 2/day and two 20 mg propranolol tablets from Tolid Darou) and a soft oral vitamin D capsule with a dose of 2000 international units produce by Zahravi Company daily for 60 days.
Category
Treatment - Other

2

Description
"Control group": migraine patients intake placebo of curcumin and vitamin D supplement one per day with routine treatment (two 200 mg sodium valproate tablets and two 20 mg propranolol tablets) for 60 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic Affiliated to Shahrekord University of Medical Sciences
Full name of responsible person
Siavash Fazelian
Street address
Kashani Streets
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88138334335
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Mehraban Sadeghi
Street address
Kashani Street, Vice Chancellor of Research and Technology Shahrekord University of Medical Sciences
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+98 38 3334 2414
Email
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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
Shahre-kord University of Medical Sciences
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
Shahre-kord University of Medical Sciences

Full name of responsible person
Siavash Fazelian

Position
PhD in Nutrition

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Position
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Latest degree
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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