Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Curcumin on Symptoms and Severity of Headache and pro Inflammatory Markers ,Symptoms of Depression ,Anxiety and Stress in Women with Migraine

Protocol summary

Study aim

The effect of curcumin on symptoms and severity of headache and pro inflammatory markers ,symptoms of depression ,anxiety and stress in women with migraine

Design

In this study 44 eligible migraine patients are selected. The participants were randomly assigned to tow groups of intervention and control. Group allocation was concealed by assigning a unique code to each participants.

Settings and conduct

The present study is a double-blind randomized clinical trial study. Participant and researcher will not be aware of the type of intervention they have been assigned. The subjects in this study will be assigned into tow groups and 22 will be in each groups.patients in the intervention and control groups receive 1000 mg of curcumin or placebo for 8 weeks per day.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.Age between 20-50 years old 2. Migraine by the neurologist 3. To participate in the study 4. No symptoms of depression and anxiety and severe stress 5. No anti-oxidant supplementation (vitamin E, vitamin C, selenium, zinc, beta-carotene) and vitamins 6. No tension headaches. 7. No anti-migraine medication. 8. No severe chronic diseases, such as cancer, hepatitis, pancreatitis, diabetes, thyroid disorders, kidney and liver disease Exclusion criteria: 1. Not willing to participate in the study. 2. Use of antioxidant, vitamin and anti-migraine drugs. 3. Cataracts for chronic diseases and tension headaches. 4. Induce allergic symptoms due to curcumin supplementation. Pregnancy and lactation or any major change in lifestyle or diet

Intervention groups

The intervention group received 2 supplemental curcumin (curcumin 500 mg capsule from Karen Company) for 8 weeks and control subjects received 2 placebo capsules (500 mg corn starch) for 8 weeks.

Main outcome variables

Interleukin-6 - Calcitonin gene-related peptide

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121216011763N34**
Registration date: **2018-08-18, 1397/05/27**
Registration timing: **retrospective**

Last update: **2018-08-18, 1397/05/27**
Update count: **0**

Registration date

2018-08-18, 1397/05/27

Registrant information

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Gholamreza Askari
Name of organization / entity
Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 31 1792 2110
Email address
askari@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-30, 1396/10/09

Expected recruitment end date

2018-08-01, 1397/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Curcumin on Symptoms and Severity of Headache and pro Inflammatory Markers ,Symptoms of Depression ,Anxiety and Stress in Women with Migraine

Public title

Effect of Curcumin on Migraine

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 20-50 years Diagnose of migraine by neurologist willing to participate on study Lack of severe depression and anxiety and stress Not taking Vitamin and Antioxidant supplements (Vitamin E and C ، Selenium ، Zinc and Beta carotene) Not having tension headaches Not taking Anti migraine drugs The absence of severe chronic disease such as Cancer ، Hepatitis ، pancreatitis ، diabetes ، Thyroid disorders ، Kidney and Liver disease Having no inflammatory diseases or history of heart disease and stroke and taking anti-inflammatory drugs

Exclusion criteria:

Unwilling to participate in the study Use of antioxidant supplements, vitamins and anti-migraine drugs Chronic diseases and tension headaches Indication of allergic symptoms due to curcumin supplementation Pregnancy and lactation, or any major change in lifestyle or diet

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **44**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple randomization method was used, randomization unit was used individually and we used statistical software. We assigned each participant to study a code and entered the code into SPSS software. The software selected a random number.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to eliminate the error from the patient's and researcher's awareness of the type of treatment received and its possible effect on the outcome of the study, we will conduct a double-blind study. Due to the fact that placebo and supplementation of curcumin are completely in the capsule, the participants and the researcher are not aware of the type of supplement they received.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی اصفهان

Street address

Isfahan University of medical science, Hezar Jarib Ave

City

Isfahan

Province

Isfehan

Postal code

8135798111

Approval date

2018-03-04, 1396/12/13

Ethics committee reference number

IR.mui.rec.1396.2.086

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

G43

Primary outcomes

1

Description

Severity of migraine, migraine frequency and duration of headache

Timepoint

The beginning and the end of the study

Method of measurement

Questionnaire

Secondary outcomes

1

Description
Levels of IL-6, CGRP and TAC
Timepoint
The beginning and the end of the study
Method of measurement
Laboratory method

Intervention groups

1

Description
Intervention group: Two oral supplementation curcumin 500 mg are given for 8 weeks.
Category
Other

2

Description
Control group: Two placebo (corn starch) 500 mg for 8 weeks.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Khorshid Hospital
Full name of responsible person
Gholamreza Askari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
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
Esfahan 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
Esfahan University of Medical Sciences
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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
A lot of information will be available to people.
When the data will become available and for how long
After printing the article
To whom data/document is available
researchers
Under which criteria data/document could be used
To do similar designs
From where data/document is obtainable
Answer the person
What processes are involved for a request to access data/document
By email, they can access the information.
Comments