

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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

Name

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

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Isfahan University of medical science, Hezar Jarib Ave

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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

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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

Full name of responsible person

Sheyda Rezaei

Position

Masters student

Latest degree

Bachelor

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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