Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

The effect of phytosomal curcumin supplementation on severity, frequency, duration of headache and inflammatory factors and oxidative stress in patients with migraine

Protocol summary

Study aim
Determination of the effect of Phytosomal curcumin supplementation on the severity, frequency, duration of headache and inflammatory factors and oxidative stress on patients with migraine

Design
Clinical trial, randomized, double-blind, randomized control group of 70 patients. Randomization is done using a valid website and 4-block method.

Settings and conduct
This clinical trial will be performed in the clinics of Khorshid Hospital and Al-Zahra Hospital. Phytosomal curcumin and placebo are administered in exactly the same packages to the patient. Patients and researchers will not be aware of the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: completing the consent form; diagnosis of migraine headache by a neurologist. Criteria for non-entry: consumption of anticoagulants such as warfarin, heparin, aspirin, and ...; pregnancy and lactation; follow a special diet in the last 3 months; use of herbal supplements in the last 3 months

Intervention groups
Intervention group: Phytosomal curcumin capsule, containing 250 mg curcumin once a day. Control group: 1 capsule containing 250 mg of maltodextrin.

Main outcome variables
Before and after the intervention; the severity; duration, and frequency of headache, Sleep quality, as well as serum nitric oxide (NO) and total antioxidant capacity (TAC), TOS, SOD, MDA, CRP will be evaluated.

General information

Reason for update
To enhance the statistical power of the study, we propose increasing the sample size to 70 participants and distinguishing between primary and secondary outcomes.

Acronym

IRCT registration information
IRCT registration number: **IRCT20201129049534N2**
Registration date: **2021-06-23, 1400/04/02**
Registration timing: **prospective**

Last update: **2025-06-03, 1404/03/13**
Update count: **2**

Registration date
2021-06-23, 1400/04/02

Registrant information

Name
Mohammad bagherniya

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-04, 1401/01/15

Expected recruitment end date
2022-07-06, 1401/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of phytosomal curcumin supplementation on severity, frequency, duration of headache and inflammatory factors and oxidative stress in patients with migraine

Public title
Effect of phytosomal curcumin supplementation on patients with migraine

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who agree to participate in the study and complete the informed consent form. Diagnosis of migraine headache by a neurologist using the third edition of the International Headache Disorders Questionnaire. Age: 18 to 80 years old

Exclusion criteria:
Taking anticoagulants such as warfarin, heparin, aspirin, etc. Pregnancy and lactation Follow a special diet in the last 3 months Use of herbal supplements in the last 3 months

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples generate random numbers using a reputable website: https://www.sealedenvelope.com/simple-randomiser/v1/lists. They are randomly assigned to one of two phytosomal curcumin or placebo supplements.

Blinding (investigator's opinion)
Double blinded

Blinding description
For researchers to be blind, phytosomal curcumin and placebo capsules are purchased equally from Sami labs Ltd., India in shape, colour and size. These capsules are coded by someone other than the researchers (A and B) and the researcher distributes them without knowing the type of capsules. Patients and researchers will not be aware of the capsule-type until the end of the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee Vice-Chancellor in Research Affairs - Medical University of Isfahan

Street address
School of Nutrition and Food Sciences, Isfahan University of Medical Sciences,Hezar-jerib Avenue

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2021-06-09, 1400/03/19

Ethics committee reference number
IR.MUI.RESEARCH.REC.1400.110

Health conditions studied

1

Description of health condition studied
Migraine headache

ICD-10 code
G44.3

ICD-10 code description
Migraine headache

Primary outcomes

1

Description
Severity of migraine headache

Timepoint
At baseline and end of the study

Method of measurement
VAS scale

2

Description
Frequency of migraine headache

Timepoint
At baseline and end of the study

Method of measurement
Number of migraine headache attacks per month

3

Description
Duration of migraine headache

Timepoint

At baseline and end of the study

Method of measurement

The average duration of migraine headache attacks per hour per headache

4

Description

Quality of life

Timepoint

At baseline and end of the study

Method of measurement

Questionnaire

5

Description

Sleep quality

Timepoint

At baseline and end of the study

Method of measurement

Sleep quality questionnaire

Secondary outcomes

1

Description

Malondialdehyde (MDA)

Timepoint

At baseline and end of the study

Method of measurement

Calorimetry

2

Description

Superoxide dismutase (SOD)

Timepoint

At baseline and end of the study

Method of measurement

Calorimetry

3

Description

Total oxidant status (TOS)

Timepoint

At baseline and end of the study

Method of measurement

Calorimetry

4

Description

Total Antioxidant Capacity (TAC)

Timepoint

At baseline and end of the study

Method of measurement

Calorimetry

5

Description

C reactive protein (CRP)

Timepoint

At baseline and end of the study

Method of measurement

Elisa

6

Description

Nitric Oxide (NO)

Timepoint

At baseline and end of the study

Method of measurement

Elisa

Intervention groups

1

Description

The intervention group will receive a capsule containing Phytosomal curcumin in the amount of 250 mg of curcumin once a day after breakfast for 8 weeks.

Category

Treatment - Drugs

2

Description

The control group will receive capsule (1 capsule) containing a placebo. Each capsule contains 250 mg of maltodextrin for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorshid hospital

Full name of responsible person

Mehrnaz shojaei

Street address

Ostandari Street

City

Isfahan

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2

Recruitment center

Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Behruz Ataei
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Hezar-jerib Ave
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8174673461
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ethics@behdasht.gov.ir
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
Mohammad Bagherniya
Position
Assistant Professor
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Person responsible for updating data

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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
Study information will be published after the individuals are unidentified and after the project is completed.
When the data will become available and for how long
Access period starts six months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
For further analysis
From where data/document is obtainable
Dr. Mohammad Baghernia bagherniya@nutr.mui.ac.ir
What processes are involved for a request to access data/document
After reviewing the request and making it fully clear about the purposes of using the data, the data will be provided.
Comments