

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of cinnamon consumption on symptoms, severity of headache, inflammatory markers and anthropometric indices among patients with migraine headache

Protocol summary

Study aim

The effect of cinnamon consumption on symptoms, severity of headache, inflammatory markers and anthropometric indices among patients with migraine headache

Design

In this study 44 eligible migraine patients will be selected. The participants will randomly be distributed based on the permuted block randomization method into two intervention and control group. Random assignment in each block will be done by the table of random numbers. Group allocation will be concealed by assigning a unique code to each participant.

Settings and conduct

This is a double-blind randomized clinical trial study. The study will be conducted at KHorshid and Imam Moosa Sadr clinics in Isfahan. Participant and researcher will not be aware of the type of intervention group they will be assigned. The subjects in this study will be assigned into two groups and 22 subjects will be in each groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People aged 20-50 years old; Diagnose of migraine by a neurologist; willing to participate in the study. Non-inclusion criteria: Pregnancy and breastfeeding; Menopause; consumption of antioxidants and cinnamon supplements; history of cinnamon sensitivity and allergy; having tension headaches; chronic diseases such as chronic kidney diseases, gastrointestinal diseases and Alzheimer's

Intervention groups

Intervention group: Three capsules each containing 600 mg of cinnamon powder will be taken after each main meal for 8 weeks. Control group: Three placebo capsules each containing 600 mg of corn starch will be taken after each main meal for 8 weeks.

Main outcome variables

Severity of migraine attacks; Frequency of migraine

attacks; Duration of migraine attacks; Migraine Disability Assessment Questioner (MIDAS); Inflammatory factors: IL6 and CGRP; Weight; Waist circumference; waist to hip ratio (WHR); body mass index (BMI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121216011763N36**

Registration date: **2019-01-25, 1397/11/05**

Registration timing: **retrospective**

Last update: **2019-01-25, 1397/11/05**

Update count: **0**

Registration date

2019-01-25, 1397/11/05

Registrant information

Name

Gholamreza Askari

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2110

Email address

askari@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

2018-09-08, 1397/06/17

Actual recruitment end date

2018-11-14, 1397/08/23

Trial completion date

2019-01-13, 1397/10/23

Scientific title

The effect of cinnamon consumption on symptoms, severity of headache, inflammatory markers and anthropometric indices among patients with migraine headache

Public title

Cinnamon, Inflammatory markers and anthropometric indices in patients with Migraine

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Aged 20-50 years old Diagnose of migraine by a neurologist willing to participate in the study

Exclusion criteria:

Pregnancy and breastfeeding Menopause consumption of antioxidants and cinnamon supplements history of cinnamon sensitivity and allergy having tension headaches having chronic diseases such as chronic kidney diseases, gastrointestinal diseases and Alzheimer's

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **44**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will conduct based on permuted block randomization method. Each block will have capacity for 4 subjects. Subjects will be assigned to blocks, based on gender. Then, within each block, subjects will be randomly assigned to treatment or placebo. Random assignment will be done using a random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind clinical trial (participant, researcher) study. The cinnamon capsules and placebo will be produced by Faculty of Pharmacy, Isfahan University of Medical Sciences. Cinnamon capsules and placebo will be in the package with the same shape and color and the patients and researcher will not aware of the content of the pack until the end of the trial.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezarjarib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2018-09-02, 1397/06/11

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.185

Health conditions studied**1****Description of health condition studied**

Migraine

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura

2**Description of health condition studied**

Migraine

ICD-10 code

G43.1

ICD-10 code description

Migraine with aura

Primary outcomes**1****Description**

Severity of migraine attacks

Timepoint

Before the start of the study and 8 weeks after the intervention

Method of measurement

VAS scale

2

Description

Frequency of migraine attacks

Timepoint

Before the start of the study and 8 weeks after the intervention

Method of measurement

Questionnaire

3

Description

Duration of migraine attacks

Timepoint

Before the start of the study and 8 weeks after the intervention

Method of measurement

Questionnaire

4

Description

Migraine Disability Assessment Questioner (MIDAS)

Timepoint

Before the start of the study and 8 weeks after the intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Interleukin 6 (IL6)

Timepoint

Before the start of the study and 8 weeks after the intervention

Method of measurement

enzyme-linked immunosorbent assay (ELISA)

2

Description

Calcitonin Gene-Related Peptide (CGRP)

Timepoint

Before the start of the study and 8 weeks after the intervention

Method of measurement

enzyme-linked immunosorbent assay (ELISA)

3

Description

weight

Timepoint

Before the start of the study and 8 weeks after the intervention

Method of measurement

Mechanical scales

4

Description

Waist Circumference

Timepoint

Before the start of the study and 8 weeks after the intervention

Method of measurement

non-stretching tape measure

5

Description

Waist / hip ratio - WHR

Timepoint

Before the start of the study and 8 weeks after the intervention

Method of measurement

non-stretching tape measure

6

Description

Body Mass Index

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Dividing the weight into kilograms by squared height by meter

Intervention groups

1

Description

The Intervention group will receive three capsules each containing 600 mg of cinnamon powder after each 3 main meals per day for 8 weeks. Cinnamon capsule will be manufactured by Faculty of Pharmacy, Isfahan University of Medical Sciences.

Category

Treatment - Other

2

Description

The control group will receive three placebo capsules (600 mg of corn starch) after each 3 main meals for 8 weeks. The placebo will be manufactured by Faculty of Pharmacy, Isfahan University of Medical Sciences.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorshid clinic

Full name of responsible person

Dr. Gholamreza Askari

Street address

Ostandari Ave.

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Isfahan

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8174673461

Phone

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Email

askari@mui.ac.ir

2

Recruitment center

Name of recruitment center

Imam Musa Sadr clinic

Full name of responsible person

Dr. Gholamreza Askari

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Foroghi Ave.

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askari@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

shaghayegh haghjou

Street address

Hezarjarib Ave., Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

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Email

sh_haghjou@med.mui.ac.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

Azadeh Zareie

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Email

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Azadeh zareie

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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a_z.zarei@yahoo.com

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

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

Major part of informations will be available for population.

When the data will become available and for how long

starting 12 months after publication

To whom data/document is available

Available for people working in academic institutions

Under which criteria data/document could be used

To conduct similar studies

From where data/document is obtainable

Dr. Gholamreza Askari via email: askari@mui.ac.ir

What processes are involved for a request to access data/document

The data will send as soon as possible, after receiving the request.

Comments