Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Study aim

The effect of cinnamon consumption on symptoms, severity of headache, inflammatory markers and anthropomethric 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 anthropomethric 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
Isfehan
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.
City
Isfahan
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Isfehan
Postal code
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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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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
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Isfehan
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81746-73461
Phone
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Email
sh_haghjoo@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
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Associate Professor
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Other areas of specialty/work
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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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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