Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effect of soy isoflavones supplementation on symptoms of headache and CGRP in women with migraine

Protocol summary

Study aim
The effect of soy isoflavones supplementation on symptoms of headache and CGRP in women with migraine

Design
A randomized controlled clinical trial with parallel groups, double-blind, randomized

Settings and conduct
The target population includes those with migraines referred to the khorshid Clinic and Imam Musa Sadr Clinic,diagnosed according to the criteria of the International Headache Society (HIS) by a neurologist . Split and study for 8 weeks. Before and after the intervention, severity of headache, frequency of headache and duration of headache, serum CGRP level , depression, stress, anxiety and quality of life of migraine patients will be measured.

Participants/Inclusion and exclusion criteria
women,18 years to before menopause,Low risk for both breast and endometrial cancer and no problem in gynecologist breast examination,diagnosis of migraine by a neurologist,Willingness to participate in the study

Intervention groups
Intervention group: One soybean meal per day for eight weeks Control group: One placebo daily with food for eight weeks

Main outcome variables
Symptoms of migraine (severity, frequency, duration of migraine), CGRP level, depression, stress, anxiety, quality of life in migraine patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20121216011763N44**
Registration date: **2020-02-27, 1398/12/08**
Registration timing: **registered_while_recruiting**
Last update: **2020-02-27, 1398/12/08**
Update count: **0**

Registration date
2020-02-27, 1398/12/08

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
2020-02-20, 1398/12/01

Expected recruitment end date
2020-07-22, 1399/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of soy isoflavones supplementation on symptoms of headache and CGRP in women with migraine

Public title
The effect of soy isoflavones in migraine

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women from the age of 18 to menopause Diagnosis of migraine by a neurologist Willing to work with the project
Exclusion criteria:
With breast cancer and endometrial cancer Problem or risk of breast or endometrial cancer in a breast examination by a gynecologist Having a family history of endometrial and breast cancer OCP medication use

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
The total number of samples randomly will be divided into two groups by random blocks and each group will consist of 44 persons. The blocking method will be used for randomization. To do this, a random allocation sequence will be created through the reputable website https://www.sealedenvelope.com/simple-randomiser/v1/lists.

Blinding (investigator's opinion)
Double blinded

Blinding description
Both the supplement and the placebo are similar in appearance and are labeled by a research team member who is not involved in the intervention and evaluation, thus the researcher directly involved in the evaluation and intervention is not aware of the nature of the prescribed supplement and patients are also unaware of the type of supplement they receive.

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
Hezar Jarib

City
esfahan

Province
Isfehan

Postal code
8135798111

Approval date
2019-12-23, 1398/10/02

Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.532

Health conditions studied

1

Description of health condition studied
migraine

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
Migraine symptoms (severity, frequency, duration of migraine)

Timepoint
At baseline and after eight weeks

Method of measurement
Questionnaire

2

Description
Serum levels of calcitonin-associated peptide (CGRP)

Timepoint
At baseline and after eight weeks

Method of measurement
Laboratory analysis (blood test)

Secondary outcomes

1

Description
Depression, stress, anxiety

Timepoint
At baseline and after eight weeks

Method of measurement
DASS-21questionnaire

2

Description
Quality of Life in Migraine Patients

Timepoint
Quality of Life in Migraine Patients

Method of measurement
Migraine –Specific Quality of Life(MSQ)questionnaire

Intervention groups

1

Description
Intervention group: Eat one soybean daily with food for eight weeks
Category
Treatment - Drugs

2

Description
Control group: One placebo (50 mg of starch) daily with food for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Khorshid clinic
Full name of responsible person
Gholamreza Askari
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Ostandari St.
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2

Recruitment center
Name of recruitment center
Imam Musa Sadr Clinic
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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?
No
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
Gholamreza Askari
Position
Associate professor
Latest degree
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maede babapour golafshani

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Major part of information will be available for population.

When the data will become available and for how long

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 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