

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Oct 2023

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)

Phone

+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

Isfahan

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

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

Shaghayegh Haghjoo

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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

Ph.D.

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

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maede babapour golafshani

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Masters student

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Bachelor

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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

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