# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

24 Nov 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
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Iran (Islamic Republic of)
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**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**
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Esfahan University of Medical Sciences
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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.
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Nutrition
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## Person responsible for scientific inquiries

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maede babapour golafshani

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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**