

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Soy Isoflavone on hot flushes, endometrial thickness and breast clinical and sonographic features

Protocol summary

Study aim

The objective of this study is to determine the effect of Isoflavone on menopausal symptoms, breast density and endometrial thickness

Design

In this research, 204 eligible patients referring to hot flash Association were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

The objective of this study is to determine the effect of Isoflavone on menopausal symptoms, breast density and endometrial thickness. This study, clinical trials, double-blind, placebo- control, single center are conducted in Arash women's hospital. The patients were divided into 2 groups, the first group received soy extracts as 50 mg isoflavone in form of a tablet, one before lunch and one before dinner (soy menopause tablets - nature made) and the second group were given placebo resembling the active drug in size and shape in the same manner. Both groups had the regimen for 12 wk. patients were evaluated for breast examination (BE) and breast sonography (BS) as well as vaginal sonography at initial presentation and at 6th and 12th week follow-ups.

Participants/Inclusion and exclusion criteria

Women over 40 yr of age with body mass index in range of 20-35Kg/m² who complained of hot flushes were chosen for our goals. Women with previous history of cancer, diabetes mellitus or renal, hepatic, and heart failure or abnormal uterine bleeding, mioma, ovarian cyst, Poly Cystic Ovarian syndrome(PCOS), endometriosis, hormone therapy during the last three months, consumption of drugs interacting with intestinal absorption, a known history of breast disease or the detection of breast mass or nodules in breast examination, patients who had a suspicious history of probable sensitivity to soy products, Patients with disability or known history of drug or alcohol

consumption w, Cigarette smoking and caffeine consumption were excluded from this study

Intervention groups

the intervention group received soy extracts as 50 mg isoflavone in form of a tablet, one before lunch and one before dinner (soy menopause tablets - nature made) and the control group were given placebo resembling the active drug in size and shape in the same manner. Both groups had the regimen for 12 wk

Main outcome variables

hot flash, breast density and endometrial thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100706004329N5**

Registration date: **2018-02-06, 1396/11/17**

Registration timing: **retrospective**

Last update: **2018-02-06, 1396/11/17**

Update count: **0**

Registration date

2018-02-06, 1396/11/17

Registrant information

Name

Sadaf Alipour

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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salipour@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-05-01, 1394/02/11

Expected recruitment end date

2016-10-27, 1395/08/06

Actual recruitment start date

2015-05-01, 1394/02/11

Actual recruitment end date

2016-10-27, 1395/08/06

Trial completion date

empty

Scientific title

Effect of Soy Isoflavone on hot flushes, endometrial thickness and breast clinical and sonographic features

Public title

Soy Isoflavone on hot flushes, endometrial thickness and breast clinical and sonographic

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

over 40 years of age body mass index in range of 20-35Kg/m² With hot flushes

Exclusion criteria:

Women with previous history of cancer, diabetes mellitus or renal, hepatic, and heart failure or abnormal uterine bleeding, mioma, ovarian cyst, Poly Cystic Ovarian syndrome(PCOS), endometriosis hormone therapy during the last three months, Patients with disability or known history of drug or alcohol consumption Cigarette smoking and caffeine consumption

Age

From **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **204**

Actual sample size reached: **204**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done systematically. based on days of the using the coin, it was determined that the intervention in the first day of this study was determined using the coin. Then, depending on the days of the week, the medicine or the placebo was prescribed respectively to eligible participate in the study Random allocation was performed by a methodologist. Medicines were placed in similar packets and list of random allocation of patients were not disclosed to dispensing practitioners. To conceal the random allocation process, a random 10-digit code corresponding to the identification number of

the patient was written on each medicine packet. Every day epidemiologist give these packets to the dispensing nurse, who was unaware of the contents of each packet. When the doctor declared the eligibility of patients, the nurse gave packets to them according to the identification numbering.

Blinding (investigator's opinion)

Double blinded

Blinding description

When the doctor declared the eligibility of patients, the nurse gave packets to them according to the identification numbering. The doctor evaluating the outcomes is a third person who is unaware of the random allocation process and type of treatment. To analyze the data, a statistician who is separate from the study process and who is unaware of all the processes performed will be used.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical Sciences

Street address

Qods St, Keshavarz Blvd

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Tehran

Province

Tehran

Postal code

1653915981

Approval date

2015-04-29, 1394/02/09

Ethics committee reference number

IR.TUMS.REC.1394.144923

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

Hot flash

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

hot flashing were categorized in mild, moderate and severe

Timepoint

before and 6 and 12 months after intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

Endometrial thickness

Timepoint

Before and 6, 12 months after intervention

Method of measurement

Endometrial thickness was evaluated using ultrasonography

2

Description

Breast changes

Timepoint

Before and 6, 12 months after intervention

Method of measurement

Breast sonography

Intervention groups

1

Description

Intervention group: received tablet Soyagol (50 mg isoflavone) ,Goldaru Pharmaceutical Company , one before lunch and one before dinner, for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: were given placebo resembling the active drug in size and shape in the same manner. One tablet before lunch and one before dinner, for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Arash Women's Hospital

Full name of responsible person

Sadaf Alipour

Street address

Arash Women 's Hospital, Rashid Ave, Resalat Highway, Tehranparse,T

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Ahmad Rezaee

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Sadaf Alipour

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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