Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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 isoflavonein 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)
Phone
00982177888751 - 00982177883195
Email address
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
City
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 ulthrasonography

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

City
Tehran

Province
Tehran

Postal code
1653915981

Phone
+98 21 7771 9922

Email
sadafalipour@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ahmad Rezaee

Street address
Qods St, Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
1653915981

Phone
+98 21 8892 5071

Email
tumspr@tums.ac.ir

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

Street address
Arash Women 's Hospital , Tehran University of Medical SciencesArash Women 's Hospital, Rashid Ave, Resalat Highway, Tehranparse
City
Tehran
Province
Tehran
Postal code
1653915981
Phone
+98 21 7771 9922
Email
sadafalipour@yahoo.com

Person responsible for scientific 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
Street address
Arash Women 's Hospital , Tehran University of Medical SciencesArash Women 's Hospital, Rashid Ave, Resalat Highway, Tehranparse
City
Tehran
Province
Tehran
Postal code
1653915981
Phone
+98 21 7771 9922
Email
sadafalipour@yahoo.com

Person responsible for updating data

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
Street address
Arash Women 's Hospital , Tehran University of Medical SciencesArash Women 's Hospital, Rashid Ave, Resalat Highway, Tehranparse
City
Tehran
Province
Tehran
Postal code
1653915981
Phone
+98 21 7771 9922
Email
sadafalipour@yahoo.com

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