

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effects of soy diet on some of sex hormones in menopausal women with balanced diet.

Protocol summary

Summary

This single-blind cross over randomized control trial is a study for measuring the effectiveness of soy bread diet on several hormones levels in menopausal women with balanced diet. Inclusion criteria: women aged 45-55 years old; follicular stimulating hormone level greater than 40; having any surgical ill; absence history of gynecological cancers; lack history of hormone replacement therapy or use the supplements in the recent 3 month; using usual diets and lack of history for allergic reaction to soy and lack history of oophorectomy, Exclusion criteria: catching surgical ill or abnormal vaginal bleeding; reaction to soy diet and unwillingness to continue working. In this study 60 menopausal women were divided randomly in two groups (A,B) of 30 and hormonal tests (estradiol, sex-hormone-binding globulin, luteinizing hormone, follicular hormone) were done for two groups and then group A received one soy bread diet daily and group B were used their usual diet for 8 weeks. Then two groups were done same tests and then group B received one soy bread daily and group A were used usual diet for 8 weeks. In the end of 8 weeks two group were done same hormonal tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013050513237N1**
Registration date: **2013-05-16, 1392/02/26**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-05-16, 1392/02/26

Registrant information

Name

Fatemeh Bozorgannia

Name of organization / entity

Shiraz University Of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 25 1783 7914

Email address

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of soy diet on some of sex hormones in menopausal women with balanced diet.

Public title

The effects of soy diet on sex hormones

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: women aged 45-55 years old; follicular stimulating hormone level greater than 40; having any surgical ill; absence history of gynecological cancers; lack history of hormone replacement therapy or use the supplements in the recent 3 month; using usual diets

and lack of history for allergic reaction to soy and lack of history of oophorectomy, Exclusion criteria: catching surgical illness or abnormal vaginal bleeding; reaction to soy diet and unwillingness to continue working.

Age

From **45 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Shiraz University of Medical Sciences

Street address

Research Deputy, Shiraz University of Medical Science

City

Shiraz

Postal code

Approval date

2012-06-28, 1391/04/08

Ethics committee reference number

ct-91-6085

Health conditions studied

1

Description of health condition studied

Menopause

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Estradiol

Timepoint

Initial of study, after 8 weeks, at the end of the study

Method of measurement

ELIZA

2

Description

SHBG

Timepoint

Initial of study, after 8 weeks, at the end of the study

Method of measurement

ELIZA

3

Description

FSH

Timepoint

Initial of study, after 8 weeks, at the end of the study

Method of measurement

ELIZA

4

Description

LH

Timepoint

Initial of study, after 8 weeks, at the end of the study.

Method of measurement

ELIZA

Secondary outcomes

empty

Intervention groups

1

Description

B group performed hormonal tests, then used their usual diets and again performed same tests then received one soy bread daily for 8 weeks and in the end performed same tests.

Category

Other

2

Description

Group A performed hormonal tests, then received one soy bread daily for 8 weeks and again performed same tests and then used their usual diet and in the end performed same tests. .

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahary hospital

Full name of responsible person

Fatemeh Bozorgannia

Street address

Quran Gate, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Gholamreza Hatam

Street address

Technology and Research Office, Research Deputy ,
Shiraz University of Medical Science, Zand Street,
Shiraz

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz College Of Nursing Midwifery

Full name of responsible person

Sadigheh Forouhari

Position

Master Of Midwifery, Guide Master

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty
Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty