

# 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 months; 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 groups 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)

##### Phone

+98 25 1783 7914

##### Email address

bozorganf@sums.ac.ir

#### 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 months; 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

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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*