

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The effects of isoflavone supplementation compared with placebo on endometrial histology and serum estradiol levels in premenopausal women with non atypical endometrial hyperplasia

#### Protocol summary

##### Study aim

The aim of this study is to determine the effects of isoflavone supplementation compared with placebo on endometrial histology and serum estradiol levels in premenopausal women with non atypical endometrial hyperplasia under treatment with medroxyprogesterone.

##### Design

Study design: Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive supplements (n=50) or placebo (n=50).

##### Settings and conduct

Among premenopausal women with non atypical endometrial hyperplasia who are referred to Shahid Beheshti Gynecology Clinic affiliated to Kashan University of Medical Sciences, 100 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar. Fasting blood samples will be taken at baseline and 3 months after the intervention. intervention period: 3 months.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 30 to 45 years who are diagnosed with non atypical endometrial hyperplasia. Exclusion criteria: Those taking any hormonal medicine within 6 months prior to enrollment in the study, patients with focal endometrial lesions, atypical endometrial hyperplasia, women with congenital uterine anomalies, and menopause women, Hypersensitivity to soybean products, Unwillingness to cooperate.

##### Intervention groups

Intervention group: Isoflavone 50 mg Tablet (Goldaru Pharmaceutical Company, Tehran, Iran), orally, once a day, for 3 months. Control group: Placebo Tablet (Goldaru Pharmaceutical Company, Tehran, Iran), orally, once a day, for 3 months.

##### Main outcome variables

Endometrial histology is the primary outcome and Serum estradiol levels and drug side effects are secondary outcomes in this trial.

#### General information

##### Reason for update

The updating process was done before publishing the paper to correct the registration information.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200531047614N3**  
Registration date: **2021-01-20, 1399/11/01**  
Registration timing: **registered\_while\_recruiting**

Last update: **2022-06-05, 1401/03/15**

Update count: **1**

##### Registration date

2021-01-20, 1399/11/01

##### Registrant information

###### Name

Mohammad Rajabi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 5554 0026

###### Email address

rajabi-m@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-21, 1399/03/01

##### Expected recruitment end date

2021-07-29, 1400/05/07

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effects of isoflavone supplementation compared with placebo on endometrial histology and serum estradiol levels in premenopausal women with non atypical endometrial hyperplasia

**Public title**

The effects of isoflavone supplementation in the treatment of non atypical endometrial hyperplasia

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women aged 30 to 45 years who are diagnosed with non atypical endometrial hyperplasia

**Exclusion criteria:**

Those taking any hormonal medicine within 6 months prior to enrollment in the study  
Patients with focal endometrial lesions atypical endometrial hyperplasia  
Women with congenital uterine anomalies  
Menopause  
Hypersensitivity to soybean products.  
Unwillingness to cooperate.

**Age**

From **30 years** old to **45 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be randomly assigned into two groups. A randomization list will be generated from 1 to 100 by a random number generator (<https://stattrek.com/statistics/random-number-generator.aspx>) and patients were randomly assigned into each intervention group by their numbers. The block randomization technique with 1:1 ratio will be used to achieve balanced group sizes.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Gynecology Clinic of Shahid Beheshti Hospital, who is not involved in the trial and not aware of random sequences, will assign the participants to the numbered bottles of supplements.

Supplements and placebos are in the same packaging at the pharmaceutical company. Only the code is written on the packages. Patients and researcher will not know the type of intervention. After analyzing the data, pocket codes will be decoded. Participants and investigators/the assessors of the outcomes are unaware of the study groups

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Kashan University of Medical Sciences

**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

8115187159

**Approval date**

2020-05-11, 1399/02/22

**Ethics committee reference number**

IR.KAUMS.MEDNT.REC.1399.006

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

Non atypical endometrial hyperplasia

**ICD-10 code**

N85.0

**ICD-10 code description**

Endometrial hyperplasia

**Primary outcomes****1****Description**

Endometrial histology

**Timepoint**

At the beginning of the study and after 3 months of intervention

**Method of measurement**

Biopsy

## Secondary outcomes

### 1

#### Description

Serum estradiol levels

#### Timepoint

At the beginning of the study and after 3 months of intervention

#### Method of measurement

Elisa

### 2

#### Description

Drug side-effects

#### Timepoint

At the beginning of the study and after 3 months of intervention

#### Method of measurement

questionnaire

## Intervention groups

### 1

#### Description

Intervention group: Isoflavone 50 mg Tablet (Goldaru Pharmaceutical Company, Tehran, Iran), orally, once a day, for 3 months.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Placebo Tablet (Goldaru Pharmaceutical Company, Tehran, Iran), orally, once a day, for 3 months.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Gynecology Clinic of Shahid Beheshti Hospital

##### Full name of responsible person

Dr. Zahra Vahedpour

##### Street address

Ghotbe Ravandi Boulevard, Kashan

##### City

Kashan

##### Province

Isfahan

##### Postal code

8115187159

##### Phone

+98 31 5554 0026

##### Email

zahravahedpoor@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kashan University of Medical Sciences

##### Full name of responsible person

Dr. Hamidreza Banafshe

##### Street address

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banafshe-h@kaums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Kashan 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

Kashan University of Medical Sciences

##### Full name of responsible person

Dr. Zahra Vahedpour

##### Position

Associate Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Gynecology and Obstetrics

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Ghotbe Ravandi Boulevard, Kashan

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##### Province

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Shirin Tabatabaee

**Position**

Resident of gynecology and obstetrics

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

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## Person responsible for updating data

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**Name of organization / entity**

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**Position**

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**Latest degree**

Subspecialist

**Other areas of specialty/work**

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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