

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Oct 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 women 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

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Ghotbe Ravandi Boulevard, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

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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

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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Shirin Tabatabaee

Position

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Latest degree

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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