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 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
Isfehan
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
Isfehan
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
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5554 0026
Email
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
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone

+98 31 5554 0026

Email

zahravahedpoor@gmail.com

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

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8115187159

Phone

+98 31 5554 0026

Email

tabatabaee.sh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Zahra Vahedpour

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8115187159

Phone

+98 31 5554 0026

Email

zahravahedpoor@gmail.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