Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The effect of fennel extract on antimullerian hormone and ultrasound criteria in infertile women with Occult premature ovarian failure: a randomized controlled clinical trial.

Protocol summary

Study aim
To comparison the number of ovarian antral follicles in the group receiving fennel capsules and the control group. To comparison AMH levels in the group receiving fennel capsules and the control group.

Design
Clinical trial with control group, triple blind, randomized, parallel groups, phase 3 on 60 patients. Randomizer software is used for randomization.

Settings and conduct
In this three-blind clinical trial (participants, researcher and data analyst) patients referred to Al-Zahra infertility clinic of Tabriz underwent trans vaginal ultrasound of the ovary on the third day of menstrual cycle once before the start of the interventionto check the number of antral follicles. Antimullerin hormone level will be assessed on the same day by one expert. Drug or placebo, is placed in numbered opaque glasses, and in this way, participants will be placed in groups. During the intervention period the participants will receive three fennel capsules with a dose of 30 mg or three placebos daily. will be taken daily orally. At the end of the second month of the intervention, on the third day of menstruation, AMH tests and trans-vaginal ultrasound will be performed on the participants again.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1) Antimullerian hormone>1 , or reduction of ovarian follicular reserve by transvaginal ultrasound (reduction of antral follicles less than 6 in each ovary) 2) The presence of menstrual cycles 3) Having both ovaries Exclusion criteria: 1) Using alcohol and cigarrete 2) Obesity, BMI >30

Intervention groups
Intervention group: 30 mg fennel capsules made by Barnj Essens Company will be used. Control group: They will receive placebo in the form of 60 oral gelatin capsules.

Main outcome variables
Antimullerian hormone levels, number of ovarian antral follicles

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20111219008459N15**
Registration date: **2023-02-05, 1401/11/16**
Registration timing: **prospective**

Last update: **2023-02-05, 1401/11/16**
Update count: **0**

Registration date
2023-02-05, 1401/11/16

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-04, 1402/01/15

Expected recruitment end date
2023-07-06, 1402/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of fennel extract on antimullerian hormone and ultrasound criteria in infertile women with Occult premature ovarian failure: a randomized controlled clinical trial.

Public title

The effect of fennel extract on antimullerian hormone and ultrasound criteria in infertile women with Occult premature ovarian failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1) Evidence suggesting occult premature ovarian failure: antimullerian hormone > 1, or reduction of ovarian follicular reserve by transvaginal ultrasound (reduction of antral follicles less than 6 in each ovary) 2) Presence of menstrual cycles 3) Age 20-40 years 4) Having Both ovaries 5) No other causes of female infertility including fallopian tube disorders, endocrine system disorders and uterine disorders, endometriosis, hyperprolactinemia and sexual disorders based on the patient's medical record. 6) Not using complementary herbal medicines in the last three months

Exclusion criteria:

1) Alcohol consumption and smoking 2) Obesity, BMI >30 3) Willingness to use donated eggs 4) Having a history of cancer, radiotherapy and chemotherapy 5) People with ovarian cysts and uterine myoma 6) People being treated with the antibiotic ciprofloxacin (46) 7) Presence of menopause symptoms (hot flashes, night sweats)

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a randomized controlled clinical trial.The participants will be randomly assigned to two groups of 30 with an allocation ratio of 1:1 using the block method of four and six. So that all 6 possible ways of placing the participants in a block of four (2 people in the intervention group and 2 people in the control group) and 19 possible positions in a block of 6 (3 people in the intervention group and 3 people in the control group) with the letters I and C that represent the intervention and control groups, respectively, is written and the random series of number of these arrangements (from 1 to 25) was obtained by using www.randomizing.org. The bottles of medicine or placebo will be numbered from 1 to 60 based on the random order obtained. In order to hide the allocation, it will be done by a person not involved in sampling.The received intervention, i.e. drug or placebo, is placed in numbered opaque glasses, and in this way, participants will be placed in groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants, researcher and data analyst will be unaware of the type of intervention received. The received intervention, i.e. drug or placebo, will be placed in similar opaque glasses (participant blinding). Random allocation and numbering of medicine and placebo bottles will be done by a person not involved in sampling (researcher blinding) and the data analyzer will be unaware of the group allocation (analyzer blinding).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

South Shariati Ave.

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Tabriz

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5138947979

Approval date

2023-01-28, 1401/11/08

Ethics committee reference number

IR.TBZMED.REC.1401.966

Health conditions studied

1

Description of health condition studied

Occult premature ovarian insufficiency

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Comparison of the number of ovarian antral follicles in the group receiving fennel capsules and the control group
Timepoint
At the beginning of the study (before the start of the intervention) 2 months after the start of the intervention
Method of measurement
Real time transvaginal ultrasound with Madison v20 brand, which is made in South Korea

2

Description
Comparison of AMH levels in the group receiving fennel capsules and the control group
Timepoint
At the beginning of the study (before the start of the intervention) 2 months after the start of the intervention
Method of measurement
AMH laboratory kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 30 mg fennel capsules manufactured by Barnage Essential Oil Company will be used. One capsule will be consumed daily for 2 months.
Category
Treatment - Drugs

2

Description
Control group: Placebo capsules that are similar in appearance (shape, size, color, etc.) to fennel capsules produced by Barch Essential Oil Company and will be consumed daily by Badmet participants for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Tabriz 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available