

# 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 compare the number of ovarian antral follicles in the group receiving fennel capsules and the control group. To compare 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 intervention to check the number of antral follicles. Antimullerian 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 cigarette 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

##### Name

Shirin Hasanpoor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1479 6770

##### Email address

hasanpoorsh@tbzmed.ac.ir

##### 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.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

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

Shirin Hasanpoor

##### Street address

South Artesh Street-Tabriz city- East Azarbaijan

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

05138665793

#### Phone

+98 41 3553 9161

#### Email

info@alzahrahosp.tbzmed.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Parviz Shahabi

##### Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz

##### City

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##### Province

East Azarbaijan

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5168743953

##### Phone

+98 41 3335 7310

##### Email

research-vice@tbzmed.ac.ir

#### 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

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Maryam Banaei

##### Position

Ms.c student of Midwifery

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Latest degree**

Master

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**Person responsible for updating data****Contact****Name of organization / entity**

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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