

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating Effect of Fennel (*Foeniculum vulgare*) on Endometrial Thickness in Infertile Women treated with Clomiphene Citrate

Protocol summary

Endometrial thickness; Number of follicles; Successful fertilization rate

Study aim

To determine and compare endometrial thickness, number and size of follicles, and successful fertility rate in infertile women treated with Clomiphene Citrate in the fennel intervention group and the control group

Design

A controlled, parallel-group, randomized, phase 0 clinical trial on 60 patients. The randomizer.org website was used for randomization.

Settings and conduct

In this study, infertile women treated with clomiphene citrate B who were referred to the obstetrics and gynecology and infertility clinic were randomly assigned to two intervention groups with fennel capsules and a control group. Demographic characteristics were recorded using a relevant questionnaire and the history of underlying diseases was recorded by the researcher. The endometrial thickness was determined by an obstetrics and gynecology and infertility specialist using an ultrasound device with the specifications of the Honda HS 2600 model. The number of follicles in both ovaries was also evaluated and recorded by the obstetrics and gynecology and infertility specialist using the same ultrasound device.

Participants/Inclusion and exclusion criteria

Inclusion: Infertility for at least 2 years. Exclusion: Not willing to participate in the study, history of allergy to fennel, allergic asthma, seizures, liver disease, and cancer.

Intervention groups

In both groups, Clomiphene citrate tablets were prescribed one tablet (50 mg per day) daily from the third day of the menstrual cycle to the seventh day (for seven days). In the intervention group, each infertile woman was prescribed two fennel supplement capsules (fennel barrage essential oil capsules) daily in addition to Clomiphene citrate from the first day of the menstrual cycle to the last day.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241118063767N2**

Registration date: **2024-12-05, 1403/09/15**

Registration timing: **retrospective**

Last update: **2024-12-05, 1403/09/15**

Update count: **0**

Registration date

2024-12-05, 1403/09/15

Registrant information

Name

Mansooreh Sadat Mojani Qomi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2641 5547

Email address

mansooreh.moujani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-31, 1402/10/10

Expected recruitment end date

2024-10-21, 1403/07/30

Actual recruitment start date

2023-12-31, 1402/10/10

Actual recruitment end date

2024-09-25, 1403/07/04

Trial completion date

2024-09-25, 1403/07/04

Scientific title

Investigating Effect of Fennel (Foeniculum vulgare) on Endometrial Thickness in Infertile Women treated with Clomiphene Citrate

Public title

Investigating Effect of Fennel (Foeniculum vulgare) on Endometrial Thickness in Infertile Women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Consent to participate in the study 25-35 years of age Infertility for at least 2 years

Exclusion criteria:

Unwillingness to participate in the study History of allergy to fennel plant compounds People with allergic asthma Epilepsy Liver diseases Cancer

Age

From **25 years** old to **35 years** old

Gender

Female

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization: The allocation of individuals to groups is done in the form of a four-block random allocation. First, the size of each block is specified (four-block), then the list of blocks is specified with the help of the randomizer.org website and numbers are assigned to them (numbers 1 to 15 for 60 people), and each of the numbers on the list is placed in an envelope for its own treatment allocation. Then, individuals entering the study randomly select envelopes containing numbers between one and 15, and the allocation of individuals to two groups, 1 and 2, is determined based on a list of blocks of four for each number.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

In this study, two groups of infertile women were studied. The first group was considered as the control group and was treated only with Clomiphene citrate, and the second group was considered as the intervention group and received fennel capsules in addition to Clomiphene citrate.

Secondary Ids

empty

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

Research Ethics Committees of Islamic Azad Tehran Medical Sciences University

Street address

Yakhchal St., Gholhak, Dr. Shariati Ave.

City

Tehran

Province

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Postal code

1941933111

Approval date

2024-11-17, 1403/08/27

Ethics committee reference number

IR.IAU.PS.REC.1402.574

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

Infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

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

Endometrial thickness

Timepoint

14 days after starting fennel capsules

Method of measurement

Ultrasound machine with Honda HS 2600 model specifications

Secondary outcomes**1****Description**

Number of Follicles

Timepoint

14 Days after consuming Fennel

Method of measurement

The number of follicles in both ovaries by a gynecologist and infertility specialist using an ultrasound device

Intervention groups

1

Description

Intervention group: Clomiphene citrate and fennel capsules

Category

Treatment - Drugs

2

Description

Control group: Clomiphene citrate

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Obstetrics and gynecology office

Full name of responsible person

Maliheh Adineh

Street address

Level 2, No 14, Sa`di St. Darya Blvd., Shahrak-e-Gharb

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Masoud Parsa Nia

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Level 3, Gole Yakh Headquarters Building, Ayeneh Blvd., Pabarja St., Shariati Ave.

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Mansooreh Sadat Mojani Qomi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Questionnaires without the names of the participants in the project, along with samples of ultrasound images

When the data will become available and for how long

Access begins after the article is published.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

In preparing meta-analysis articles

From where data/document is obtainable

mansooreh.moujani@gmail.com

What processes are involved for a request to access data/document

By sending a letter from a reputable research center or university, stating the exact use of the data, an image of the available data will be available via email.

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

Islamic Azad University

Full name of responsible person

Mansooreh Sadat Mojani Qomi

Position

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