

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Clinical Trial of the Effect of Fennel and Estrogen Compared with Estrogen Alone on Duration of Endometrial Thickness to Reach 8 millimeters in Women with Indication for Fetus Donation

Protocol summary

Summary

(1) Objective: To compare the effect of fennel and estrogen with estrogen alone on endometrial thickness
(2) Design: Randomized, not-blinded, not-placebo-controlled, single-center, exploratory trial
(3) Setting and conduct: Participants: All women referred to Infertility Clinic at Fatemieh Hospital with the indication for fetus donation
Inclusion criteria: indication for fetus donation
Exclusion criteria: none
Sample size: 100 patients
(4) Intervention: All patients will receive low dose tablet of oral contraceptive from the third day of menstrual cycle until the 21st day. Then from day 14 to 28 one ampule of gonadotropin releasing hormone (Buserelin) 0.5 milliliter will be administered subcutaneously daily. On the day 28 all patients will receive oral tablets of estradiol valerate 6 milligrams/day. But the intervention group along with estradiol will receive fennel as herbal tea, made with 10 grams of fennel boiled with 50 milliliter water for 20 minutes. On the 30th day and then every 3 days transvaginal ultrasound will be done to measure endometrial thickness. During this period 0.2 milliliter Buserelin will be continued subcutaneously.
(5) The intervention time: from the 28th day of menstrual cycle until the endometrium reaches 8 millimeters in thickness
(6) Main outcome measure: number of days for endometrium to reach 8 millimeters in thickness

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014120210617N2**

Registration date: **2015-01-15, 1393/10/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-15, 1393/10/25

Registrant information

Name

morteza Sedaghat Kia

Name of organization / entity

zaums

Country

Iran (Islamic Republic of)

Phone

+98 54 1244 9540

Email address

morimedico@yahoo.com

Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-03-01, 1393/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial of the Effect of Fennel and Estrogen Compared with Estrogen Alone on Duration of Endometrial Thickness to Reach 8 millimeters in Women with Indication for Fetus Donation

Public title

Effect of Fennel on endometrial thickness

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: all women with indication for fetus donation; giving written consent to inclusion
Exclusion criteria: none

Age
From **18 years** old to **51 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamadan University of Medical Sciences

Street address

Opposite Mardom Park, Shahid Fahmideh St,
Pajouhesh Sq, Daneshgah Blvd

City

Hamadan

Postal code

Approval date

2014-05-17, 1393/02/27

Ethics committee reference number

/16/35/9/699پ

Health conditions studied

1

Description of health condition studied

female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

The time for endometrium to reach 8 millimetres in thickness

Timepoint

30th day of menstrual cycle and then every 3 days until reaching 8 milliliters in thickness

Method of measurement

Counting days

Secondary outcomes

1

Description

Endometrial thickness

Timepoint

Thirtieth day of menstrual cycle and then every 3 days

Method of measurement

Transvaginal ultrasound

Intervention groups

1

Description

Intervention group: patients will receive low dose tablet of oral contraceptive from the third day of menstrual cycle until the 21st day. Then from day 14 to 28 one ampule of gonadotropin releasing hormone (Buserelin) 0.5 milliliter will be administered subcutaneously daily. On the day 28 patients will receive oral tablets of estradiol valerate 6 milligrams/day and fennel as herbal tea, made with 10 grams of fennel boiled with 50 milliliter water for 20 minutes. On the 30th day and then every 3 days transvaginal ultrasound will be done to measure endometrial thickness. During this period 0.2 milliliter Buserelin will be continued subcutaneously.

Category

Treatment - Drugs

2

Description

Control group: patients will receive low dose tablet of oral contraceptive from the third day of menstrual cycle until the 21st day. Then from day 14 to 28 one ampule of gonadotropin releasing hormone (Buserelin) 0.5 milliliter will be administered subcutaneously daily. On the day 28 patients will receive oral tablets of estradiol valerate 6 milligrams/day (without fennel). On the 30th day and then every 3 days transvaginal ultrasound will be done to measure endometrial thickness. During this period 0.2 milliliter Buserelin will be continued subcutaneously.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Teaching Hospital

Full name of responsible person

Mahnaz Yavangui

Street address

Pasdaran St

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Saed Bashirian

Street address

Opposite Mardom Park, Shahid Fahmideh St,
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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

Hamadan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Sarah Nazari Valashedjerdi

Position

Resident in Obstetrics and Gynecology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Mahnaz Yavangui

Position

Specialist in obstetrics and gynecology, Subspecialty
in female infertility

Other areas of specialty/work

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Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty