

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effects of adding Vagifem and vaginal Premarin in increasing endometrial thickness and pregnancy rate in IVF patients whose endometrial thickness was not responsive to conventional regimens, in Shiraz.

Protocol summary

Summary

We will study the effect of vaginal premarin (Estromarin vaginal cream, 2.5 mg, Aburaihan pharmaceutical, Iran) and vagifem (vaginal tablet, 10 mcg, Novo Nordisk, Denmark) on endometrial thickness and embryo implantation in women with failure to achieve optimal endometrial thickness in IVF embryo transfer cycle with conventional estrogen therapy. This is a randomized clinical trial which will be conducted in Shiraz, Iran. Using computer generated block randomization method, 60 women in reproductive age are divided into two groups. Exclusion criteria is women aged less than 24 or more than 42; previous history of tuberculosis; Asherman syndrome or collagen vascular diseases. Also, smokers and alcohol abusers. The patients will receive vaginal Premarin cream 1.25 mg/ day (half of vaginal applicator) and vagifem, one tablet Bid (20 micrograms) is added to previous estrogen regimen. While being checked for endometrial thickness responsiveness. The endometrial thickness, and chemical (positive beta-HCG test with ELISA) and clinical pregnancy (detection of intrauterine sac by vaginal sonography) will be compared in the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012102911306N1**

Registration date: **2013-03-21, 1392/01/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-03-21, 1392/01/01

Registrant information

Name

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Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research; Infertility Research Center, Shiraz University of Medical Sciences

Expected recruitment start date

2013-05-31, 1392/03/10

Expected recruitment end date

2013-11-29, 1392/09/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of adding Vagifem and vaginal Premarin in increasing endometrial thickness and pregnancy rate in IVF patients whose endometrial thickness was not responsive to conventional regimens, in Shiraz.

Public title

Vagifem and vaginal Premarin in pregnancy rate in IVF patients whose endometrial thickness was not responsive

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women with failure to achieve optimal endometrial thickness in IVF embryo transfer cycle with conventional estrogen therapy. Exclusion criteria: women aged less than 24 or more than 42; previous history of tuberculosis; Asherman syndrome or collagen vascular diseases; smokers and alcohol abusers.

Age

From **24 years** old to **42 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

8th Floor, main building of Shiraz University of Medical Sciences, Zand Avenue

City

Shiraz

Postal code

713451978

Approval date

2012-12-04, 1391/09/14

Ethics committee reference number

CT-p-91-4238

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

The largest longitudinal endometrial thickness in fundal area

Timepoint

Before intervention and every few days

Method of measurement

Vaginal ultrasonography

Secondary outcomes

1

Description

Pregnancy rate

Timepoint

Two weeks after embryo transfer

Method of measurement

Measuring level of blood BhCG by ELISA

2

Description

Clinical pregnancy

Timepoint

Four weeks after embryo transfer

Method of measurement

Detecting of intrauterine sac by vaginal sonography

Intervention groups

1

Description

women with failure to achieve optimal endometrial thickness in IVF embryo transfer cycle with conventional estrogen therapy are divided to study groups. In group 1, vagifem, 1 tablet Bid (20 micrograms) is added to previous estrogen regimen.

Category

Treatment - Drugs

2

Description

women with failure to achieve optimal endometrial thickness in IVF embryo transfer cycle with conventional estrogen therapy are divided to study groups. In group 2, Premarin cream 1.25 mg/ day (half of vaginal applicator) is added to estrogen regimen.

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Infertility Research Center

Full name of responsible person**Street address**

4th Floor, Ghadir Hospital, Ghoran Avenue

City

Shiraz

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Vice chancellor for research; Shiraz University of Medical Sciences

Full name of responsible person

Gholam Reza Hatam

Street address

8th Floor, main building of Shiraz University of Medical Sciences, Zand Avenue

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Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research; Shiraz 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**

Infertility Research Center

Full name of responsible person

Hossein Haghbin

Position

Medical student

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Position

fellowship of infertility

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Web page address**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