Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of efficacy of vaginal progesterone on pregnancy rate in women with polycystic ovarian syndrome using combination therapies for ovulation induction

Protocol summary

Summary

The aim of this study is evaluation of vaginal progesterone effect on pregnancy rate in infertile women with polycystic ovary syndrome. The single-center clinical trial study will be performed on 200 infertile patients with inclusion criteria that referred to Kashan infertility center in 2012. Inclusion criteria consist 20 -35 years, having Rotterdam criteria (having 2 from 3 following criteria: Oligomenorrehea or amenorrhea, polycystic ovaries in sonography, clinical or biochemical evidences of hyperandrogenism). The patient with abnormal hormonal assay in the third day of menstruation (including FSH, TSH, prolactin, 17 Hydroxy progesterone and testosterone), tubal obstruction in HSG or laparoscopy and infertility due to male factor will be excluded. Patients will receive letrozole (5 mg) or clomiphene (100 mg) daily during 3-7 days of menstruation. Then, gonadotropin(150 IU) daily will be taken from 5-9 days of cycle. Control sonography for evaluation of ovarian response and endometrial thickness will be done on 10th or 11th day of cycle and gonadotropin dose will be adjusted. If there are at least one dominant follicle with 18-20 mm and endometrial thickness is 6-8 mm in sonography, HCG ampoule (5000 IU) intramuscular will be injected. Then, patients randomly assigned to case and control groups. Case group, will be received vaginal progesterone suppository (400 mg) daily for 14 days and control group will not receive progesterone. On last day of receiving progesterone in case group, pregnancy test will be done in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206072967N4**

Registration date: **2012-10-07, 1391/07/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-10-07, 1391/07/16

Registrant information

Name

Fatemeh Foroozanfar

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 36 1446 0180

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Recruitment status

Recruitment complete

Funding source

Vice chancellor of research, Kashan University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2013-02-18, 1391/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of vaginal progesterone on

pregnancy rate in women with polycystic ovarian syndrome using combination therapies for ovulation induction

Public title
Vaginal Progesterone effect on pregnancy rate in infertility women with polycystic ovarian syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria consist 20 -35 years, having Rotterdam criteria (having 2 from 3 following criteria: Oligomenorrehea or amenorrhea, polycystic ovaries in sonography, clinical or biochemical evidences of hyperandrogenism). The patient with abnormal hormonal assay in the third day of menstruation (including FSH, TSH, prolactin, 17 Hydroxy progesterone and testosterone), tubal obstruction in HSG or laparoscopy and infertility due to male factor will be excluded.
Age
From **20 years** old to **35 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
In this study, randomization is done based on randomized numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences
Street address
Ghotbe Ravandi Blvd , Pezeshk Blvd
City
Kashan
Postal code
Approval date
2010-01-20, 1388/10/30
Ethics committee reference number
4366.1.5.29.P

Health conditions studied

1

Description of health condition studied
Infertility and Polycystic Ovarian Syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Pregnancy
Timepoint
Last day of receiving progesterone suppository
Method of measurement
Blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: letrozole (Femara; Novartis Pharma AG, Switzerland) 5 mg daily during 3-7 days of menstruation and then, 150 IU gonadotropin (Merional, IBSA, Switzerland) daily will be given from 5-9 days of cycle. After day 10 of the menstrual cycle , If there are at least one dominant follicle with 18-20 mm and endometrial thickness is 6-8 mm in sonography, 5000 IU of HCG ampoule (Choriomon, IBSA, Switzerland), intramuscular will be injected. Then, vaginal progesterone suppository (Cyclogest, serano, Istanbul, Turkey) 400 mg daily.will be given for two weeks.
Category
Treatment - Drugs

2

Description
Intervention group 2: clomiphene (100 mg, daily) during 3-7 days of menstruation and then, 150 IU gonadotropin (Merional, IBSA, Switzerland) daily will be given from 5-9 days of cycle. After day 10 of the menstrual cycle , If there are at least one dominant follicle with 18-20 mm and endometrial thickness is 6-8 mm in sonography, 5000 IU of HCG ampoule (Choriomon, IBSA, Switzerland), intramuscular will be injected. Then, vaginal progesterone suppository (Cyclogest, serano, Istanbul, Turkey) 400 mg daily.will be given for two weeks.
Category

Treatment - Drugs

3

Description
Control group 1: letrozole (Femara; Novartis Pharma AG, Switzerland) 5 mg daily during 3-7 days of menstruation and then, 150 IU gonadotropin (Merional, IBSA, Switzerland) daily will be given from 5-9 days of cycle. After day 10 of the menstrual cycle , If there are at least one dominant follicle with 18-20 mm and endometrial thickness is 6-8 mm in sonography, 5000 IU of HCG ampoule (Choriomon, IBSA, Switzerland), intramuscular will be injected.

Category
Treatment - Drugs

4

Description
Control group 2: clomiphene (100 mg, daily) during 3-7 days of menstruation and then, 150 IU gonadotropin (Merional, IBSA, Switzerland) daily will be given from 5-9 days of cycle. After day 10 of the menstrual cycle , If there are at least one dominant follicle with 18-20 mm and endometrial thickness is 6-8 mm in sonography, 5000 IU of HCG ampoule (Choriomon, IBSA, Switzerland), intramuscular will be injected.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Infertility Center of Shahid Beheshti Hospital

Full name of responsible person
Dr.Fatemeh Foroozanfard

Street address
Shahid Beheshti Hospital , Parastar Blvd , Ghotbe Ravandi Blvd,Kashan

City
Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor of research, Kashan University of Medical Sciences

Full name of responsible person
Dr.Gholam Ali Hamidi

Street address
Medical College, Pezeshk Blvd, Ghotbe Ravandi Blvd.

City
Kashan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor of research, Kashan 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
Kashan University of Medical Sciences

Full name of responsible person
Dr. Fatemeh Foroozanfard

Position
Obstetrician and Gynecologist, Infertility and IVF Fellowship/ Assistant professor

Other areas of specialty/work

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Full name of responsible person
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Position
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Other areas of specialty/work

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Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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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