

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Endometrial preparation with letrozol in frozen embryo transfer cycle in woman with pco syndrom

Protocol summary

Study aim

pregnancy outcome of Endometrial preparation with letrozol for frozen thawed embryo transfer in woman with pco syndrom

Design

Two arm parallel 90 patient group quasi randomised as for visited day(odd or even)

Settings and conduct

Infertile PCO patients candidate for frozen thawed embryo transfer stand into two group.in control group will get 6mg estradiol from second day of cycle and serial vaginal sonography will be done from 12th day of cycle when thickness reaches 7mm or more, they receive 400 mg progesterone for 3 days and then embryo transfer will be done.Intervention group will get 5mg letrozol from day 3 to 7 of cycle and vaginal sonography will be done on day 10.If we have 14mm or more dominant follicle ,vaginal sonography will be done every other day till reaching to 17mm follicle and 7-9 mm endometrium.if we don't have dominant follicle on day 10 ,75 mg daily HMG will be add to letrozol and follow up sonography will be done till reaching to our golds.after reaching to dominant follicle 10000 unit HCG will be prescribe at 10 pm and 400 mg daily progesterone will be prescribe after 2 days and 3 days after that ,2 three-day embryo will transfer.If we don't have dominant follicle on 17th days of cycle ,cycle will be canceled.2 weeks after transfer serum BHCG will check and 4 weeks after vaginal sonography will be done for gestational sac and detecting fetal heart rate.

Participants/Inclusion and exclusion criteria

inclusion criteria : infertile pco patient exclusion criteria : other cause of infertility age <20yr and >40yr recurrent abortion uterus malformation

Intervention groups

infertile pco patient candidate for frozen thawed embryo transfer divide to two group ,in control group we use estradiol for endometrial preparation and in other group we use letrozol for endometrial preparation

Main outcome variables

implantation rate chemical pregnancy rate clinical pregnancy rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151013024512N6**

Registration date: **2020-02-29, 1398/12/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-29, 1398/12/10**

Update count: **0**

Registration date

2020-02-29, 1398/12/10

Registrant information

Name

Abbas Aflatoonian

Name of organization / entity

Yazd research and clinical center for infertility

Country

Iran (Islamic Republic of)

Phone

+98 358247085

Email address

abbas-aflatoonian@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-20, 1398/10/30

Expected recruitment end date

2020-08-21, 1399/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Endometrial preparation with letrozol in frozen embryo transfer cycle in woman with pco syndrom

Public title

uterus preparation with letrozol for polycystic patients in frozen embryo transfer cycle

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

infertile pcos patients with frozen embryos

Exclusion criteria:

other cause of infertility age<20yr and age>40 yr recurrent abortion uterus malformations

AgeFrom **20 years** old to **40 years** old**Gender**

Female

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **180****Randomization (investigator's opinion)**

Not 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**

Ethics Committee of Yazd Reproductive Sciences Institute Shahid Sadoughi University

Street address

Yazd Reproductive Sciences Institute, Bouali Ave., Safaeyeh, Yazd, Iran.

City

Yazd

Province

Yazd

Postal code

8916877391

Approval date

2019-09-14, 1398/06/23

Ethics committee reference number

IR.SSU.RSI.REC.1398.023

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**

chemical pregnancy

Timepoint

2weeks after embryo transfer

Method of measurement

serum BHCG

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

clinical pregnancy

Timepoint

2weeks after positive BHCG

Method of measurement

vaginal sonography

Intervention groups**1****Description**

Intervention group :Infertile 20-40 yr PCO candidate for frozen thawed embryo transfer will get 5mg letrozol from day 3 to 7 of cycle and vaginal sonography will be done on day 10.If we have 14mm or more dominant follicle ,vaginal sonography will be done every other day till reaching to 17mm follicle and 7-9 mm endometrium.if we don't have dominant follicle on day 10 ,75 mg daily HMG will be add to letrozol and follow up sonography will be done till reaching to our golds.after reaching to dominant follicle 10000 unit HCG will be prescribe at 10 pm and 400 mg daily progesterone will be prescribe after 2 days and after 5 days of injecting HCG ,embryo transferring will be done.

Category

Treatment - Drugs

2

Description

Control group: Infertile 20-40 yr PCO candidate for frozen thawed embryo transfer will get 6mg estradiol from second day of cycle and serial vaginal sonography will be done from 12th day of cycle when thickness reaches 7mm or more, they receive 400 mg progesterone for 3 days and then embryo transfer will be done.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Research and Clinical Center for Infertility(Yazd Reproductive Science Institute) Shahid Sadoughi Un

Full name of responsible person

Dr.Abass Aflatounian

Street address

Yazd, Bouali Ave, Safayeh, Research and Clinical Center for Infertility

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info@yazd-rsi.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Shahid Sadoughi university of medical science, Yazd ,Iran

Full name of responsible person

Dr Abbas Aflatoonian

Street address

Research and Clinical Center for Infertility,Bouali avenue,Safaiyeh,Iran

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+98 35 3824 7086

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info@yazd-rsi.ir

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,Shahid Sadoughi university of medical science, Yazd ,Iran

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

Yazd research and clinical center for infertility

Full name of responsible person

Abbas Aflatoonian

Position

Obstetrician and Gynecologist,Infertility and IVF Fellowship(Professor)

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd Research and Clinical Center for Infertility,Shahid Sadoughi University of Medical Science

Full name of responsible person

Abbas Aflatoonian

Position

Obstetrician and Gynecologist ,Infertility Fellowship(Professor)

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Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Yasamin Mehrolhasani

Position

Infertility Fellowship

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Safaeiyeh-Bouali avenue

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

No more information exist

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