

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

progesterin primed ovarian stimulation protocol in patients with the polycystic ovarian syndrome in assisted reproductive technology cycles

Protocol summary

Study aim

The purpose of this study is to compare and compare pregnancy rates using progesterone prime protocol and antagonist protocol in patients with the polycystic ovarian syndrome who are the candidate for ART.

Design

The clinical trial with the randomized control group

Settings and conduct

Randomized clinical trial without blindness,

Participants/Inclusion and exclusion criteria

Inclusion criteria: infertile PCOS patients which are the candidate for ART Exclusion criteria: systemic disease; history of endocrine disorder; intrauterine abnormality (uterine polyp & submucosal fibroma & intrauterine adhesions); severe endometriosis; and azoospermia of partner.

Intervention groups

progesterone prime group: since the second day of the cycle all patients Will receive 150 unit of cinal f(cinagen-Iran) Subcutaneously and 20 mg dydrogesterone (Duphaston) orally. when dominant follicle reaches to 17 mm, final triggering will be done and 36 hours later. all embryo will be freez in cleavage stage and frozen embryo transfer will be done 2 months latter. Antagonist group: since the second day of the cycle all patients Will receive 150 unit of cinal f(cinagen-Iran) Subcutaneously.vaginal sonography will be done for all women since 6th day of cycle. When dominant follicle reached to 12-13 mm, cetrotide (Merck- Serono Germany).25 mg will be injected daily subcutaneously. when dominant follicle reaches to 17 mm, final triggering will be done and 36 hours later. all embryo will be freez in cleavage stage and frozen embryo transfer will be done 2 months later.

Main outcome variables

Clinical pregnancy rat

General information

Reason for update

Update corrections and study results

Acronym

IRCT registration information

IRCT registration number: **IRCT20110509006420N18**

Registration date: **2018-08-20, 1397/05/29**

Registration timing: **retrospective**

Last update: **2021-06-28, 1400/04/07**

Update count: **2**

Registration date

2018-08-20, 1397/05/29

Registrant information

Name

Maryam Eftekhar

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Country

Iran (Islamic Republic of)

Phone

+98 35182470856

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eftekhar@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

2018-05-22, 1397/03/01

Actual recruitment end date

2018-06-24, 1397/04/03

Trial completion date

2019-01-07, 1397/10/17

Scientific title

progesterone primed ovarian stimulation protocol in patients with the polycystic ovarian syndrome in assisted reproductive technology cycles

Public title

progesterone primed ovarian stimulation protocol in the polycystic ovarian syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

infertile PCOS patients which are candidate for ART

Exclusion criteria:

women older than 40 years old History of endocrine disorder Severe endometriosis Azoospermia

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by sealed envelopes.

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 Infertility Research Center,
Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Bouali

City

Yazd

Province

Yazd

Postal code

8916877391

Approval date

2018-05-20, 1397/02/30

Ethics committee reference number

IR.SSU.RSI.REC.1397.003

Health conditions studied

1

Description of health condition studied

Female infertility, unspecified

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

chemical pregnancy

Timepoint

Two weeks after embryo transfer

Method of measurement

Serum BhCG

2

Description

Clinical pregnancy

Timepoint

Two weeks after positive BhCG

Method of measurement

sonography

Secondary outcomes

1

Description

Miscarriage rate

Timepoint

Loss of pregnancy before 20 gestational week

Method of measurement

Absence of fetal heart activity in ultra sound sonography

Intervention groups

1

Description

Intervention group: since the second day of the cycle all patients Will receive 150 unit of cinal f(cinagen-Iran) Subcutaneously and 20 mg dydrogesterone (Duphaston) orally. when dominant follicle reaches to 17 mm,final triggering will be done by HCG (Pregnyl - Germany) intramuscular and .2cc decapeptide(Ferring, Germany) Subcutaneously and 36 hours later oocytes pick up will be done.48 latter all embryo will be freeze in cleavage stage and frozen embryo transfer will be done 2 months latter after preparation of endometrium by estrogen and progesterone.

Category

Treatment - Drugs

2**Description**

Control group: Antagonist group: since second day of the cycle all patients Will receive 150 unit of cinal f(cinagen-iran) Subcutaneously When dominant follicle reached to 12-13 mm, cetrotide (Merck- Serono Germany).25 mg will be injected daily subcutaneously. when dominant follicle reaches to 17 mm, final triggering will be done by HCG (Pregnyle - Germany) intramuscular and .2cc decapeptide(Ferring, Germany) Subcutaneously and 36 hours later oocytes pick up will be done.48 latter all embryo will be freeze in cleavage stage and frozen embryo transfer will be done 2 months later after preparation of endometer by estrogen and progestrone

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Yazd Research and Clinical Center for Infertility

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Robab Davar

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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

Yazd University of Medical Sciences

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 University of Medical Sciences

Full name of responsible person

Maryam Eftekhar

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Associate professor

Latest degree

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Person responsible for updating data

Contact

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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

Due to the privacy of patients

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

The study protocol, the statistical analysis map, the clinical study report will be available after the publishing of the article

When the data will become available and for how long

After publishing the article

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

use in the retrospective study

From where data/document is obtainable

Yazd research and clinical center for infertility

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

Request from the Research Deputy, submitted to the Research Council of the Center if the request accepts its referral to the security and after completion of the relevant forms, the request is referred to the research experts and then get the data. سایر توضیحات فا خالی

Comments

Trial results

Please tick if results have been published

Yes

Summary result posting date

2021-03-17, 1399/12/27

Table of baseline comparison

Participant flow diagram

Table of variable outcomes' results

Table of adverse events

First publication date

empty

Abstract of published paper

AbstractBackground: In vitro fertilization is an important therapy for women with the polycystic ovarian syndrome (PCOS). The use of new ways of improving clinical results is yet required. Objective: This study was aimed to investigate the efficacy of progesterone primed ovarian stimulation (PPOS) and compare with conventional antagonist protocol in PCOS. Materials and Methods: A total of 120 PCOS women who were candidates for assisted reproductive technology treatment were enrolled in this RCT and were placed into two groups, randomly (n = 60/each). The PPOS group received 20 mg/day Dydrogesterone orally since the second day of the cycle and the control group received antagonist protocol. The pregnancy outcomes including the chemical and clinical pregnancy, the miscarriage rate, and the percent of gestational sacs/transferred embryos were compared in two groups. Results: Number of MII oocyte, maturity rate, Number of 2 pronuclei (2PN) and serum estradiol levels on trigger day were statistically lower in PPOS group (p = 0.019, p

=0.035, $p = 0.032$, $p = 0.030$), respectively. Serum LH level on trigger day in PPOSgroup was higher than antagonist group ($p = 0.005$). Although there wasn't severe ovarian hyperstimulation syndrome in any participants, mild and moderate ovarian hyperstimulation syndrome was less in PPOS group ($p = 0.001$). Also, the chemical and clinical pregnancy rates were higher in the antagonist group, although it was not statistically significant ($p = 0.136$, $p = 0.093$ respectively). Conclusion: Our study demonstrates that PPOS does not improve the chemical and clinical pregnancy rate of infertile women with PCOS.