

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Comparison of long protocol with ovulation stimulation protocol in frozen embryo transfer cycle in women with polycystic ovarian syndrome: a non-randomized clinical trial

Protocol summary

Study aim

To compare long protocol with ovulation stimulation protocol in frozen embryo transfer cycle in women with polycystic ovarian syndrome

Design

This is a non-randomized clinical trial with control group, phase III, in which eligible patients will be selectively assigned to the intervention and control groups.

Settings and conduct

This study will be performed in the Fatemeh Hospital in Hamadan city on 340 eligible patients. The patients will be selectively assigned to the intervention and control groups. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 45 years Women with polycystic ovary syndrome Exclusion criteria: The first or second time of transfer Uterine abnormality Egg donation Surrogacy

Intervention groups

Intervention group: The long protocol includes a 30 mg birth control pill (manufactured by Aburihan Pharmaceutical Co.) once a night for 14 nights (if the thickness of the endometrium is thin), then GnRH agonist 5.5 mg (manufactured by Sinafect Pharmaceutical Co.) once a day for a week and Estradiol tablet (manufactured by Aburihan Pharmaceutical Co.) 4 to 6 mg for at least 10 days (in case of thin endometrium and absence of ovarian cysts) and intramuscular injection of progesterone (manufactured by Iran Hormon Pharmaceutical Co.) 50 mg daily for 3 to 5 days then embryo is transferred. Control group: Ovulation stimulation protocol including injection of FSH (manufactured by Cinagen Pharmaceutical Co.) 300 mg every 2 to 3 days, then injection of HCG (manufactured by Ronak Daro Pharmaceutical Co.) 5000 units as a single dose and 36 hours later (if at least one follicle reaches more than 18 mm and the thickness of the

endometrium is at least 7 mm) and intramuscular injection of progesterone 50 mg daily for 3 to 5 days, then embryo is transferred.

Main outcome variables

Occurrence of pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N434**

Registration date: **2022-07-09, 1401/04/18**

Registration timing: **prospective**

Last update: **2022-07-09, 1401/04/18**

Update count: **0**

Registration date

2022-07-09, 1401/04/18

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-06, 1401/05/15

Expected recruitment end date

2023-09-06, 1402/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of long protocol with ovulation stimulation protocol in frozen embryo transfer cycle in women with polycystic ovarian syndrome: a non-randomized clinical trial

Public title

Comparison of long protocol with ovulation stimulation protocol in frozen embryo transfer cycle in women with polycystic ovarian syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 to 45 years Women with polycystic ovary syndrome The first or second time of transfer

Exclusion criteria:

Uterine abnormality Egg donation Surrogacy

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **340**

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2022-06-25, 1401/04/04

Ethics committee reference number

IR.UMSHA.REC.1401.326

Health conditions studied**1****Description of health condition studied**

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes**1****Description**

Occurrence of pregnancy

Timepoint

12 to 14 days after the completion of intervention

Method of measurement

With pregnancy test

Secondary outcomes

empty

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

Intervention group: The long protocol includes a 30 mg birth control pill (manufactured by Aburihan Pharmaceutical Co.) once a night for 14 nights (if the thickness of the endometrium is thin), then GnRH agonist 5.5 mg (manufactured by Sinafect Pharmaceutical Co.) once a day for a week and Estradiol tablet (manufactured by Aburihan Pharmaceutical Co.) 4 to 6 mg for at least 10 days (in case of thin endometrium and absence of ovarian cysts) and intramuscular injection of progesterone (manufactured by Iran Hormon Pharmaceutical Co.) 50 mg daily for 3 to 5 days (If the thickness of the endometrium is at least 7 mm) then embryo is transferred.

Category

Treatment - Drugs

2

Description

Control group: Ovulation stimulation protocol including injection of FSH (manufactured by Cinagen Pharmaceutical Co.) 300 mg every 2 to 3 days, then injection of HCG (manufactured by Ronak Daro Pharmaceutical Co.) 5000 units as a single dose and 36 hours later (if at least one follicle reaches more than 18 mm and the thickness of the endometrium is at least 7 mm) and intramuscular injection of progesterone 50 mg daily for 3 to 5 days, then embryo is transferred.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan city

Full name of responsible person

Dr. Zakieh Yarahmadi

Street address

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

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6517838695

Phone

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zakiyehyarahmadi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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info.research@umsha.ac.ir

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Zakieh Yarahmadi

Position

Resident of Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Mahnaz Yavangi

Position

Gynecologist

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available