Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

The randomized, single -blinded clinical trial comparing OCP effect before frozen embryo transfer versus gonadotropin – releasing hormone agonist injection on improving the outcome of pregnancy in infertile patients with hyper androgenic poly-cystic ovary syndrome in the IVF/ICSI cycle

Protocol summary

Study aim

Investigation the effect of OCP with GNRH agonist on improving pregnancy outcome in patients with hyper androgenic polycystic ovarian disease (PCOD).

Design

In this study, 120 infertile patients with hyper androgenic PCOD after signing informed consent assessing inclusion and exclusion criteria will recruit to study and will be randomly divided into two groups A&B. Patients in group A receive OCP before frozen- thawed embryo transfer and patients in the group B receive GNRH agonist. Pregnancy outcome will be evaluated after embryo transfer in two groups.

Settings and conduct

The location of the study will be the infertility ward in Dr Shariati Hospital. This is a single-blind trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Sign the informed consent form, Patients with hyper androgenic polycystic ovary syndrome based on Rotterdam 2003. Exclusion criteria: Patients with hyper- anderogenism caused by drugs or congenital adrenal hyperplasia or who have been suspected of having Cushing's syndrome or an androgen – secreting neoplasm, known sever organ dysfunction or mental illness, being pregnant or being in post-miscarriage period, being in post- partum period, breastfeeding, being in the 6 weeks after delivery.

Intervention groups

Patients in group A will receive the OCP before frozen-thawed embryo transfer (Rokinz LD) for 2 months. Patients in group B will receive GNRH agonist (Luprolide acetate 3.75 mg) every 4 weeks for a total of two doses. Hormone therapy for both groups will be started with 8 mg estradiol valerate orally per day for 14 days.

Main outcome variables

The endometrial thickness, the implantation rate, the clinical pregnancy rate, the live birth rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140818018842N17**
Registration date: **2020-01-05, 1398/10/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-05, 1398/10/15**
Update count: **0**

Registration date

2020-01-05, 1398/10/15

Registrant information

Name

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Name of organization / entity

Research Institute for Hematology, Oncology and Stem Cell Transplantation,Tehran University of Medic

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The randomized, single -blinded clinical trial comparing OCP effect before frozen embryo transfer versus gonadotropin – releasing hormone agonist injection on improving the outcome of pregnancy in infertile patients with hyper androgenic poly-cystic ovary syndrome in the IVF/ICSI cycle

Public title
Effect of treatment by OCP on infertility in PCOD patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Oligo ovulation or anovulation. Clinical and/or biochemical signs of hyper- androgenism. Polycystic ovaries.
Exclusion criteria:
Patients with hyper- anderogenism caused by hormonal drugs or other medications. Patients who have known sever organ dysfunction or mental illness. Pregnant women or being in Post- miscarriage period. breastfeeding. being in the 6 week postpartum period. Patients had congenital adrenal hyperplasia or were suspected of having Cushing s syndrome or an androgen – screening neoplasm.
Age
From **20 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
The computer gives each patient a code number. And the code numbers are then allocated to the treatment groups A (OCP receiver) and B (GNRH agonist receiver). In this study, neither the participants nor the researchers know which participants belong to the placebo group, nor the intervention group. Only after all data have been recorded do the person not involved in the study.
Blinding (investigator's opinion)
Single blinded
Blinding description
The computer gives each patient a code number. And the code numbers are then allocated to the treatment groups A (OCP receiver) and B (GNRH agonist receiver). In this study, neither the participants nor the researchers know which participants belong to the placebo group, nor the intervention group. Only at the end of the study, the results are reported by a person not involved in the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University Medical Sciences
Street address
Ethics Committee of Tehran University of Medical Sciences, Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2018-11-10, 1397/08/19
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1397.531

Health conditions studied

1

Description of health condition studied
Patients with hyper androgenic polycystic ovarian disease
ICD-10 code
Female inf
ICD-10 code description
N97.0

Primary outcomes

1

Description
Endometrium thickness
Timepoint
Before starting treatment and embryo transfer.
Method of measurement
Trans vaginal ultra-sonography

2

Description

The number of positive chemical pregnancy test

Timepoint

14 days after embryo transfer

Method of measurement

Laboratory test (BHCG over than 40 IU)

3

Description

The number of successful clinical pregnancy

Timepoint

6 to 8 weeks after embryo transfer

Method of measurement

Fetal Heart in Trans vaginal ultrasonography

4

Description

Miscarriage rate

Timepoint

Abortion before 12 weeks of pregnancy

Method of measurement

Fetal death before 12 weeks in ultrasonography.

Secondary outcomes

1

Description

Live birth rate

Timepoint

At 28th week of pregnancy

Method of measurement

Trans abdominal ultrasonography

Intervention groups

1

Description

Intervention group: Receive of the OCP (Rokinz LD), daily 2 months before frozen- thawed embryo transfer.

Category

Treatment - Drugs

2

Description

Control group: Receive depot preparation of the GNRH agonist (Luprolide acetate 3.75 mg) before frozen-thawed embryo transfer, one dose every 4 weeks, totally two doses.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Ward, Dr shariati Hospital

Full name of responsible person

Shima Tavakolian

Street address

Infertility Ward, Dr shariati Hospital, North Kargar, Tehran Town.

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Tehran

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asamaei@razi.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Technology, Tehran University of Medical Sciences.

Full name of responsible person

Dr Mohammad Ali Sahraeian

Street address

Tehran University of Medical Sciences, Qods Avenue, Keshavarz Boulevard.

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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

Deputy of Research and Technology, Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Shima Tavakolian

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
All data is published after being unidentified.

When the data will become available and for how long
starting 24 months after publication.

To whom data/document is available
Infertility researchers.

Under which criteria data/document could be used
Submith a valid academic Certificate.

From where data/document is obtainable
Send email to: hamed_m97@yahoo.com

What processes are involved for a request to access data/document
Receive the data at least 3 month later.

Comments