

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- androgenism caused by drugs or congenital adrenal hyperplasia or who have been suspected of having Cushing's syndrome or an androgen – secreting neoplasm, known severe 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 (Rokin 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 Medicine

Country

Iran (Islamic Republic of)

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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- androgenism caused by hormonal drugs or other medications. Patients who have known severe 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.

AgeFrom **20 years** old to **45 years** old**Gender**

Female

Phase

3

Groups that have been masked

- Investigator
- Data analyser

Sample sizeTarget 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 (Rokin 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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+98 21 84901

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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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rmo@tums.ac.ir

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

Submit 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