

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

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

Protocol summary

Study aim

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

Design

In this study, 74 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 GNRH agonist before frozen- thawed embryo transfer and patients in the group B receive placebo. 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 double -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 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 GNRH agonist before frozen- thawed embryo transfer (Luprolide acetate 3.75 mg) every 4 weeks for a total of two doses. Patients in group B will receive placebo. 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, clinical pregnancy rate, live birth rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140818018842N15**

Registration date: **2018-10-24, 1397/08/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-24, 1397/08/02**

Update count: **0**

Registration date

2018-10-24, 1397/08/02

Registrant information

Name

Leyla Sharifi Aliabadi

Name of organization / entity

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

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 3691

Email address

ctu@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-10, 1397/02/20
Expected recruitment end date
2018-11-11, 1397/08/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

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

Public title

Effect of treatment by GNRH agonist on infertility in PCOD patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Oligoovulation or anovulation. Clinical and/or biochemical signs of hyperandrogenism. Polycystic ovaries.

Exclusion criteria:

Patients with hyperandrogenism 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

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **74**

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 (GNRH agonist receiver) and B (placebo 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)

Double blinded

Blinding description

The computer gives each patient a code number. And the code numbers are then allocated to the treatment groups A (GNRH agonist receiver) and B (placebo 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

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

2018-05-05, 1397/02/15

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.096

Health conditions studied

1

Description of health condition studied

Patients with hyper androgenic polycystic ovarian disease

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

Endometrium thickness

Timepoint

Before starting treatment and embryo transfer.

Method of measurement

Trans vaginal ultrasonography

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

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 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

2

Description

Control group: Received placebo (Normal saline, with the same shape to GNRH agonist) before frozen embryo transfer.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Ward, Dr shariati Hospital

Full name of responsible person

Sahar Rashidi

Street address

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

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 84901

Fax

+98 21 8822 0050

Email

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.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3619

Fax

+98 21 8163 3623

Email

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

Sahar Rashidi

Position

Fellowship of infertility

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Tehran University of Medical Science. Keshavarz
Boulevard, North Kargar

City

Tehran

Province

Tehran

Postal code

1417653761

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+98 21 84901

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+98 21 8822 0050

Email

asamaei@razi.tums.ac.ir

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: sahar.rashidi.dr@gmail.com

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

Receive the data at least 3 month later.

Comments