Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The comparison of efficacy and outcomes of Triptorelin (Diphereline®) and hCG in ovulation trigger in infertile women with poly cystic ovarian syndrome in IUI cycle: A randomize clinical trial study

Protocol summary

Study aim
To evaluate the effect of two agonists, GnRH (Diphereline) and hCG, on pregnancy.

Design
A control group, community-based and prospective, with parallel groups (intervention and control), randomized, one-step, sample size of 120 people, subjects simple random method using a table of random numbers.

Settings and conduct
In this study, which is done in the educational-medical center of Jahrom, the treatment required to stimulate ovulation includes two Letrozole (2.5 mg) that will be given from the third to the seventh day of the menstrual cycle and the eighth day of the cycle. The patient will have a trans vaginal sonography. If the size of the follicles is less than 18 mm, we will do an ultrasound again on day 12 of the cycle, and based on the size of the follicles and the diameter of the endometrium (three layers, transparent, echogenic), if the desired follicle was between 18-22 mm, to release the egg. One group is given two-tenths of a micro-gram of Diphereline and the other group is injected with 10,000 units of hCG .

Participants/Inclusion and exclusion criteria
Inclusion criteria: infertile women with PCOS aged 15 to 45 years who did not become pregnant one year after intercourse without the use of contraceptives. Non-Inclusion criteria: Age over 45 years, presence of myoma, FSH> 12, endometriosis, history of contact with any substance induced previous ovulation, any contraindication both Diphereline and hCG

Intervention groups
In this study, we have two groups of intervention and control. In the intervention group, we investigated the effect of GnRH agonist (Diphereline) on pregnancy with minimal complications in people with poly cystic ovary syndrome compared to hCG in the control group. In the control group, the common drug, hCG, is used.

Main outcome variables
Pregnancy, multiple births, ovarian hyper stimulation syndrome, drug side effects

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200122046221N3**
Registration date: **2022-03-16, 1400/12/25**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-16, 1400/12/25**
Update count: **0**

Registration date
2022-03-16, 1400/12/25

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-02-20, 1400/12/01
Expected recruitment end date
2023-03-11, 1401/12/20
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison of efficacy and outcomes of Triptorelin (Diphereline®) and hCG in ovulation trigger in infertile women with poly cystic ovarian syndrome in IUI cycle: A randomize clinical trial study

Public title
The comparison of efficacy and outcomes of Triptorelin (Diphereline®) and hCG in ovulation trigger in infertile women with poly cystic ovarian syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infertile women who do not become pregnant one year after cohabitation and intercourse without the use of contraceptives From 15 years old to 45 years old With Poly cystic ovarian syndrome
Exclusion criteria:
Semen analysis and abnormal hysterosalpingography Over 45 years old Myoma Hyperprolactinemia Hypothyroidism Hyperthyroidism FSH> 12 Women with endometriosis History of contact with any substance induced by previous ovulation Kidney and liver disease Any contraindications to Diphereline and hCG Male factor
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, computerized block randomization (blocks size 3 and 9) will be performed, which is the randomization unit, individual and layers of randomization, age of people and randomization tools, table of random numbers. An independent clinical epidemiologist who is not involved in the study will use a randomized blockchain program (STATA14 software) to generate allocation codes. Random sequences will be placed in light-resistant envelopes and sealed. The research assistant will open sealed, numbered and opaque envelopes containing the assignment codes. Eligible participants, after signing the informed consent form, will be divided into two equal groups (hCG group and Diphereline group).
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 Jahrom University of Medical Sciences
Street address
Motahari Blvd
City
Jahrom
Province
Fars
Postal code
7414846199
Approval date
2022-02-05, 1400/11/16
Ethics committee reference number
IR.JUMS.REC.1400.089

Health conditions studied

1

Description of health condition studied
Infertility in women with Poly cystic ovarian syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Pregnancy
Timepoint
End of menstrual cycle
Method of measurement
Serum b-hCG

Secondary outcomes

1

Description
Incidence of ovarian hyperstimulation syndrome
Timepoint
End of menstrual cycle
Method of measurement
Clinical signs and ultrasound

2

Description
Incidence of multiple birth
Timepoint
End of menstrual cycle
Method of measurement
ultrasound sonography

Intervention groups

1

Description
Intervention group: Give two Letrozole tablets (2.5 mg) from Abureyhan Pharmaceutical Company, daily for 5 days for 3-7 days during only one menstrual cycle and then trans vaginal ultrasound on days 12-8 of the cycle to evaluate the thickness, endometrial pattern. After seeing at least one follicle of 18 mm or larger, inject two-tenths of a micro gram of Triptorelin (Diphereline) from the French company IPSEN and finally control women for pregnancy.
Category
Treatment - Drugs

2

Description
Control group: Give two tablets of Letrozole (2.5 mg) daily from Abu Reyhan Pharmaceutical Company, for 5 days during days 3-7 during only one menstrual cycle and then transvaginal ultrasound on days 12-8 of the cycle to evaluate the thickness, endometrial pattern. After seeing at least one follicle 18 mm or larger, inject hCG 10000Iu injection from the German company FERRING and finally control the women in terms of pregnancy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Jahrom university of medical sciences
Full name of responsible person
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Motahhari Blv. Jahrom University of Medical Sciences
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Sponsors / Funding sources

1

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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Jahrom 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
Jahrom University of Medical Sciences
Full name of responsible person
Athar Rasekhjahromi
Position
Associated professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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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