Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of therapeutic results of letrozole, tamoxifen, estradiol and vitamin E regimen with letrozole, tamoxifen and estradiol regimen in stimulating ovulation in infertile women with polycystic ovary syndrome: a double-blind randomized clinical trial study

Protocol summary

Study aim

Comparison of therapeutic results of letrozole, tamoxifen, estradiol and vitamin E diet with letrozole, tamoxifen and estradiol diet in stimulation of ovulation in infertile women with polycystic ovary syndrome

Design

In this study, computerized block randomization (12 blocks) will be done. An independent epidemiologist who is not involved in conducting the study will use a randomized block computer program (stata software) to generate allocation codes.Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 90 patients.

Settings and conduct

This study will be conducted as a prospective clinical trial on infertile women with PCOS who referred to Jahrom women's clinic during 1401-1402.

Participants/Inclusion and exclusion criteria

Entry criteria: Infertile women with polycystic ovary syndrome who have not had a history of pregnancy after 12 months of unprotected intercourse / at least 40 years old Exit criteria: Non-consent to participate in the study/drug sensitivity to letrozole or tamoxifen or estradiol or vitamin E/the existence of any other pathology that has led to infertility in the patient or his wife/liver or kidney dysfunction/diabetes mellitus type one or two/disorders Thyroid/congenital adrenal hyperplasia/abnormal hysterosalpingography

Intervention groups

Infertile women with polycystic ovary syndrome who have not had a history of pregnancy after 12 months of unprotected intercourse / at least 40 years old

Main outcome variables

Pregnancy, follicle size, follicle number, follicle thickness, multiple births, drug side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150407021653N20**
Registration date: **2023-12-14, 1402/09/23**
Registration timing: **prospective**

Last update: **2023-12-14, 1402/09/23**
Update count: **0**

Registration date

2023-12-14, 1402/09/23

Registrant information

Name

Athar Rasekh Jahromi

Name of organization / entity

Jahrom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 5432 6602

Email address

a.rasekh@jums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-30, 1402/11/10

Expected recruitment end date

2024-04-29, 1403/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of therapeutic results of letrozole, tamoxifen, estradiol and vitamin E regimen with letrozole, tamoxifen and estradiol regimen in stimulating ovulation in infertile women with polycystic ovary syndrome: a double-blind randomized clinical trial study

Public title
Comparison of therapeutic results of letrozole, tamoxifen, estradiol and vitamin E regimen with letrozole, tamoxifen and estradiol regimen in stimulating ovulation in infertile women with polycystic ovary syndrome: a double-blind randomized clinical trial study

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Female gender Infertile who have not had a history of pregnancy after 12 months of unprotected intercourse Suffering from polycystic ovary syndrome At least 40 years old

Exclusion criteria:
Non-consent to participate in the study drug sensitivity to letrozole or tamoxifen or estradiol or vitamin E the existence of any other pathology that has led to infertility in the patient or his wife liver or kidney dysfunction diabetes mellitus type one or two Thyroid disordes congenital adrenal hyperplasia abnormal hysterosalpingography

Age
From **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, computer block randomization (block size of 12) will be performed An independent epidemiologist not involved in the study will use a computerized block randomization program to generate allocation codes. The randomization sequences will be placed in sealed, light-resistant envelopes.The research assistant will open the sealed, numbered and opaque envelopes containing the allocation codes. After signing the informed consent form, the eligible participants will be divided into two equal groups of Letrozole, Tamoxifen, Estradiol, Vitamin E and Letrozole, Tamoxifen. , estradiol

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, blinding is done bilaterally. None of the participants and outcome assessors know which study group someone is in. It should be mentioned that at the beginning of the study, the general introduction of the study groups will be done for the participants and after getting their consent, random allocation will be done and the participants will be randomly assigned to two treatment groups A and B. Also, the controller, who examines the patients from the beginning to the end of the study in the obstetrics and gynecology clinic, is not aware of which group the patient is in.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
research ethic committee of Jahrom university of medical science

Street address
Motahari Boulevard, Shahidan Firouzi Street, Jahrom University of Medical Sciences

City
jahrom

Province
Fars

Postal code
7414846199

Approval date
2023-02-19, 1401/11/30

Ethics committee reference number
IR.JUMS.REC.1401.135

Health conditions studied

1

Description of health condition studied
Polycystic ovary syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pregnancy

Timepoint
One day after the fall in menstruation.

Method of measurement

ß-HCG titer test

Secondary outcomes

1

Description
Follicle size, follicle number and follicle thickness
Timepoint
Days 3, 7 and 12 of the cycle
Method of measurement
sonography

2

Description
multiple births
Timepoint
Week 6 of pregnancy
Method of measurement
sonography

3

Description
Drug side effects
Timepoint
The total time of the intervention
Method of measurement
Examination by the doctor and self-reported by the patient based on previous training

Intervention groups

1

Description
Intervention group: People participating in the study are randomly divided into two groups A and B with equal sample size.For group A, from the third to the seventh day of the menstrual cycle, daily letrozole at a dose of 5 mg (two tablets of letrozole 2.5 mg), tamoxifen at a dose of 20 mg (10 mg twice a day), estradiol and vitamin E at a dose of 100 mg is prescribed daily for 25 days
Category
Treatment - Drugs

2

Description
Control group: People participating in the study are randomly divided into two groups A and B with equal sample size.For group B (control), from the third to the seventh day of the menstrual cycle, daily letrozole at a dose of 5 mg (two tablets of letrozole 2.5 mg), tamoxifen at a dose of 20 mg (10 mg twice a day), estradiol for 25 The day is prescribed
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Obstetrics and Gynecology Clinic of Jahrom
Full name of responsible person
Athar Rasekh
Street address
Honari clinic-Alley 25-Motahari Blvd- Jahrom City
City
Jahrom
Province
Fars
Postal code
7415713945
Phone
+98 71 5434 2006
Email
Drrasekh@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jahrom University of Medical Sciences
Full name of responsible person
Kavoos solhjoo
Street address
Motahari Boulevard, Shahidan Firouzi Street, Jahrom University of Medical Sciences
City
Jahrom
Province
Fars
Postal code
7414846199
Phone
+98 71 5434 0409
Email
pazhuheshi@jums.ac.ir
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 raskh

Position
Non-faculty specialist doctor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
No 25 Ave,Mothari Blvd,Jahrom City

City
Jahrom

Province
Fars

Postal code
7415713945

Phone
+98 71 5434 2006

Email
a.rasekh@jums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Jahrom University of Medical Sciences

Full name of responsible person
athar raskh

Position
Non-faculty specialist doctor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
No 25 Ave,Mothari Blvd,Jahrom City

City
Jahrom

Province
Fars

Postal code
7415713945

Phone
+98 71 5434 2006

Email
a.rasekh@jums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Jahrom University of Medical Sciences

Full name of responsible person
mohamad javad karimi

Position
student

Latest degree
Bachelor

Other areas of specialty/work
General Practitioner

Street address
Jahrom Motahari Blvd. Shahidan Firouzi St. Shahid Daneshpur Blvd

City
Jahrom

Province
Fars

Postal code
7414846199

Phone
+98 71 3786 7364

Email
mjkarimi7413@gmail.com

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
Not applicable

Data Dictionary
Not applicable