Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of clomiphene & estradiol valerate with letrozole on endometrial thickness, abortion and treatment results in polycystic ovarian infertile women under induction ovulation

Protocol summary

Summary

The aim of this study is to compare the effect of clomiphene and estradiol valerate with letrozole on endometrial thickness, abortion and treatment results in polycystic ovarian infertile women under induction ovulation. A total of 100 patients with PCOS referring to Besat Hospital infertility clinic were selected and randomly divided into two intervention (two drugs) and control (one drug plus placebo) groups. Inclusion criteria were including; Polycystic ovary syndrome based on Rotterdam Criteria, age between 18 to 48, menstrual disturbances (oligomenorrhea or amenorrhea) , clinical or biochemical hyperandrogenism and exclusion criteria were including; Hyperprolactinemia, thyroid problems, anatomical problem of uterine cavity and fallopian tubes which is approved by hsterosalpingography. Intervention group received 2 clomiphene 50 mg\day from day 3 to day 7 of menstruation and 4 mg estradiol valerate after day 3 to day 14. Control group received 2 ltetrozol 2.5mg/day from day 3 to day 7 of menstruation, for similarity and also blindness of study, placebo was gave to this group. For the two groups at day 14 of the menstrual cycle to evaluate the endometrial thickness transvaginal ultrasound was done by a radiologist. In terms of retarded menstruation BHCG would be checked and if pregnancy was positive they would be followed-up until the third month of the pregnancy. Data will be recorded in a check list.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052612789N11**
Registration date: **2015-07-11, 1394/04/20**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-07-11, 1394/04/20

Registrant information

Name

Masoud Rasolabady

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Kurdistan University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of clomiphene & estradiol valerate with letrozole on endometrial thickness, abortion and treatment results in polycystic ovarian infertile women under induction ovulation

Public title

Comparing the effect of clomiphene and estradiol valerate with letrozole

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: polycystic ovary syndrome based on Rotterdam Criteria; age between 18 to 48 years old; menstrual disturbances (oligomenorrhea or amenorrhea); clinical or biochemical hyperandrogenism. Exclusion criteria: hyperprolactinemia; thyroid problems; anatomical probleb of uterin cavity and fallopian tubes which is approved by hsterosalpingography.

Age

From **18 years** old to **48 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Sampling was done using blocks of 4 and patients were randomly placed in one of the two groups. The researchers had no role in determining groups and also patients were not aware of grouping.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kurdistan University of Medical Sciences

Street address

Kurdistan University of Medical Sciences, Pasdaran St., Sanandaj, Iran

City

Sanandaj

Postal code

Approval date

2015-02-10, 1393/11/21

Ethics committee reference number

Muk.Rec.1393.15

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Endometrial thickness

Timepoint

Day 14 of the menstrual cycle

Method of measurement

Transvaginal ultrasound

2

Description

Pregnancy

Timepoint

One month after the menstrual cycle

Method of measurement

positive BHCG and ultrasound

3

Description

Abortion

Timepoint

Three months (in the case of Pregnancy)

Method of measurement

The patient's medical record

Secondary outcomes

1

Description

Endometrial thickness improvement

Timepoint

On day 14 of the menstrual cycle

Method of measurement

Transvaginal ultrasound

Intervention groups

1

Description

Intervention group received 2 clomiphene 50 mg\day from day 3 to day 7 of menstruation and 4 mg estradiol valerate after day 3 to day 14.

Category

Treatment - Drugs

2

Description
Control group received 2 ltetrozol 2.5mg/day from day 3 to day 7 of menstruation, for similarity and also blindness of study, placebo was gave to this group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Lale Tangestani
Street address
Besat Hospital, Keshavarz St., Mardokh Cross Road, Sanandaj, Iran
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Kurdistan University of Medical Sciences
Full name of responsible person
Ebrahim Ghaderi
Street address
Kurdistan University of Medical Sciences, Pasdaran St., Sanandaj, Iran
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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
Vice Chancellor for Research, Kurdistan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty