Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Letrozole and Dexamethasone on pregnancy outcome in Poly cystic ovarian syndrome patients candidate for intra uterine insemination: Randomized Clinical trial

Protocol summary

Study aim

The Effect of Letrozole and Dexamethasone on ovulation and pregnancy outcome in patients with polycystic Ovarian Syndrome

Design

A prospective , randomized, single blind clinical trial with two arm parallel group design consisited of 100 infertile poly cystic ovarian syndrome patients. Randomisation was done using computer with concealed randomization sequence. Phase of trial is 1-2

Settings and conduct

This study was done on patients who referred to Milad infertility center . Group A received Letrozole from 3th day of their cycle for 5 days and group B received 5 mg Letrozole from 3th day of their cycle for 5 days and 0.5 mg Dexamethazon for 10 days. Serum hormones level (LH, Estradiol , Androstenedion, testosterone) and folliculogenesis were assessed in all patients. When the dominant follicles reached 18 mm in diameter ovulation was triggered with 5000Iu IM hCG. IUI was performed 36 hours later. Pregnancy test was done after 14 days. Statistician analyzed data without any information about the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women at the age of 20-35 years old; having at least one patent Fallopian tube; normal sperm analysis of spouse. Exclusion criteria: smoking; underlying disease (heart, kidney, liver or Endocrine disease)

Intervention groups

Group A received Letrozole tablet from third day of cycle for 5 days and group B received Letrozole tablet from third day of cycle for 5 days and Dexamethazon tablet 0.5 mg for 10 days. Serum hormones level (LH, Estradiol , Androstenedion, testosterone) and folliculogenesis were monitored in patients. Ovulation was triggered with hCG (5000Iu) when the dominant follicles reached 18 mm in diameter. Intra uterine insemination (IUI) was performed 36 hours later.

Main outcome variables

hormones including luteinizing hormone, estradiol , androstenedion and testostrone; pregnancy rate .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170315033085N4**
Registration date: **2018-07-29, 1397/05/07**
Registration timing: **retrospective**

Last update: **2018-07-29, 1397/05/07**
Update count: **0**

Registration date

2018-07-29, 1397/05/07

Registrant information

Name

malihe afiat

Name of organization / entity

Mashhad medical school

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2608

Email address

afiatm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2013-02-03, 1391/11/15

Expected recruitment end date

2014-04-09, 1393/01/20

Actual recruitment start date

2013-04-09, 1392/01/20

Actual recruitment end date

2014-04-19, 1393/01/30

Trial completion date

empty

Scientific title

The Effect of Letrozole and Dexamethasone on pregnancy outcome in Poly cystic ovarian syndrome patients candidate for intra uterine insemination: Randomized Clinical trial

Public title

letrozole and Dexametazon effect in Poly cystic ovarian syndrome patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

AGE: 25-35 years at least one patent Fallopian tube normal sperm analysis of spouse presence of poly-cystic ovarian syndrome

Exclusion criteria:

Smoking underlying disease (heart, kidney, liver or Endocrine)

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

1-2

Groups that have been masked

- Data analyser

Sample size

Target sample size: **106**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

Blinding (investigator's opinion)

Single blinded

Blinding description

Data was sent in form of two Group (A and B) to the person responsible for data analysis and analyzer wasn't not aware of the intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ghoraishi department, Daneshgah Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

91897-95-96

Approval date

2013-02-02, 1391/11/14

Ethics committee reference number

IR.MUMS.REC.1391.803

Health conditions studied

1

Description of health condition studied

polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Luteinizing hormone

Timepoint

Third and 12th day of menstrual cycle

Method of measurement

laboratory Test

2

Description

Testestron

Timepoint

Third and 12th day of menstrual cycle

Method of measurement

laboratory Test

3

Description

Anderestandion

Timepoint

Third and 12th day of menstrual cycle

Method of measurement

laboratory Test

4

Description

Esteradiol

Timepoint
Third and 12th day of menstrual cycle
Method of measurement
laboratory Test

5

Description
Pregnancy
Timepoint
14 days after Intrauterine insemination
Method of measurement
laboratory Test, pregnancy test

Secondary outcomes

1

Description
Dominant follicles
Timepoint
12th day of Menestural cycle
Method of measurement
vaginal Sonography

2

Description
Endometrium thickness
Timepoint
12th day of Menestural cycle
Method of measurement
vaginal Sonography

Intervention groups

1

Description
Control group: group A received letrozole tablet (abouraihan , Iran) 5 mg from day 3 of menstrual cycle for 5 days .They were monitored hormonal and Sonographical on day 3 and day 12 of cycle. Ovulation was triggered with injection 5000 Iu HCG (karma, Germany) when the dominant follicle reached 18 mm in diameter. A single IUI was performed 36 hours later. The Luteal phase was supported with the progesterone suppository (Cyclogest, 400 mg , Actavis, UK) . pregnancy test was don 14 day later.
Category
Treatment - Drugs

2

Description
Intervention group: group B received letrozol 5 mg(Abouraihan-Iran) from 3th day of menstrual cycle for 5 days plus Dexamethazon tablet 0.5 mg (Iran hormone) for 10 days. They were monitored hormonal and Sonographical on day 3 and day 12 of cycle. Ovulation was triggered with injection 5000 Iu HCG (karma, Germany) when the dominant follicle reached 18 mm in diameter. A single IUI was performed 36 hours later. The Luteal phase was supported with the progesterone suppository (Cyclogest, 400 mg , Actavis, UK) . pregnancy test was don 14 day later.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Milad Hospital
Full name of responsible person
Dr Malihe Afiat
Street address
Emamreza hospital, Ebne Sina Blvd,Shariati Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Malihe Afiat
Position
Assistance Professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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9189757565
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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
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