Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the efficacy of long-term and short-term doses of letrozole in ovulation induction among patients with polycystic ovary syndrome

Protocol summary

Summary

Introduction:In this study we aimed to compare the long-term and short-term doses of letrozole for improving ovulation induction in polycystic ovary syndrome (PCOS)patients also to evaluate the pregnancy outcomes among these patients. Materials and Methods:This interventional study was conducted at theKosar infertility center of Urmia-Iran in 2015-2016. The study participants included 200 PCOS patients who will be divided randomly into two groups: group I (short-term letrozole group;patients will be received oral letrozole 7.5 mg, from day 3to 7 ofmenstruation) and group II (long-term letrozole group;patients will be received 5mg oral letrozole from day 2or 3o fmenstruation till 10 days (all participants will be received oral letrozole for three menstrual cycles).In the both groups;GONAL-f will injected on days 5, 7, 9 menstrual cycles. Follow up by, transvaginal ultrasound and folliculogram will be performed to follow up follicles size and endometrial thickness.When the follicle size be 18mm or more, HCG (5000 IU) will be injected intramuscular.Participants will undergoing intrauterine insemination(IUI) 24 to 36 hours after HCG injectionand fertility results will be assessed

General information

Acronym

polycystic ovary syndrome

IRCT registration information

IRCT registration number: **IRCT2016030926962N2**
Registration date: **2016-05-08, 1395/02/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-08, 1395/02/19

Registrant information

Name

Tahereh Behroozi Lak

Name of organization / entity

Educational and Treatment Kowsar Center

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 7077

Email address

behroozilak.t@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Urmia University of Medical Sciences

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of long-term and short-term doses of letrozole in ovulation induction among patients with polycystic ovary syndrome

Public title

Comparing the efficacy of long-term and short-term doses of letrozole in ovulation induction among patients with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 38-18 years - poly cystic ovary

syndrome proven - resistance to clomiphene citrate thyroid -Tested normal - normal prolactin - the absence of other causes of infertility, including male factor - normal Hysterosalpangiography Exclusion criteria: Ovarian Cysts- Follicle-stimulating hormone> 10 - Patients with Ovarian Hyper stimulation Syndrome

Age
From **18 years** old to **38 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
no

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Urmia University of Medical Sciences

Street address
Urmia, Resalat Blvd. the end of Jahad St. Research ward, Setad, Urmia university of medical sciences

City
Urmia

Postal code
5714783734

Approval date
2013-12-22, 1392/10/01

Ethics committee reference number
ir.umsu.erc.1392.234

Health conditions studied

1

Description of health condition studied
polycystic ovary syndrome

ICD-10 code
E28.2

ICD-10 code description
E28.2

Primary outcomes

1

Description
The number of mature follicles.

Timepoint
11 cycle days after intervention

Method of measurement
Vaginal ultrasound

2

Description
Endometrial thickness at the time of HCG injection

Timepoint
11 cycle days after intervention

Method of measurement
Vaginal ultrasound

3

Description
The number of Gonal

Timepoint
After intervantion, days 5, 7 and 9 of the cycle

Method of measurement
Vaginal ultrasound

Secondary outcomes

1

Description
Event Pregnancy

Timepoint
After intervention

Method of measurement
Test BHCG

2

Description
Abortion rate

Timepoint
After intervention

Method of measurement
Clinical and sonographic reports

3

Description
Multiple event

Timepoint
After intervention

Method of measurement
Ultrasound Report

Intervention groups

1

Description
Evaluation of Gonal gonadotropin follicle size (Karma) 75 units, single subcutaneous injection around the belly button
Category
Treatment - Drugs

2

Description
Letrozole group long-term (manufactured by SOHA) that will be received oral letrozole on day 2 or 3 of the cycle up to 10 days for 5 mg (per group of 100 people for 3 cycles)
Category
Treatment - Drugs

3

Description
Short-term letrozole group that will be received oral letrozole on day 3 to 7 of the cycle up to 7.5 mg (per group of 100 people for 3 cycles)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Educational and treatment kowsar center
Full name of responsible person
Tahereh Behroozi Lak
Street address
Research ward, Setad , Urmia university of medical sciences
City
Urmia

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research Urmia University of Medical Sciences
Full name of responsible person
Iraj Mohebbi
Street address
Urmia, Resalat Blvd. the end of Jahad St. Research ward, Setad, Urmia university of medical sciences
City
Urmia
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 Urmia 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
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Tahereh Behroozi Lak
Position
Assistant Professor
Other areas of specialty/work
Street address
Urmia, Resalat Blvd. the end of Jahad St. Research ward, Setad, Urmia university of medical sciences
City
Urmia
Postal code
Phone
+98 44 3223 7077
Fax
Email
t.behrooz2@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Educational and treatment kowsar center
Full name of responsible person
Tahereh Behroozi Lak
Position
Assistant Professor
Other areas of specialty/work
Street address
Urmia, Resalat Blvd. the end of Jahad St. Research ward, Setad, Urmia university of medical sciences
City
Urmia
Postal code
Phone
+98 44 3223 7077
Fax
Email

t.behrooz2@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Tahereh Behroozi Lak

Position

Assistant Professor

Other areas of specialty/work

Street address

Urmia, Resalat Blvd. the end of Jahad St. Research ward, Setad, Urmia university of medical sciences

City

Urmia

Postal code

Phone

+98 443223077

Fax

Email

t.behrooz2@yahoo.com

Web page address

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