

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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 Behrooz 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 Hysterosalpingiography 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 Gonad

Timepoint

After intervention, 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 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 Behrooz 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