

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of pregnancy rate with clomiphene citrate and letrozole and clomiphene alone in infertile patients with polycystic ovary syndrome

Protocol summary

Summary

Objectives: To compare the induction of ovulation and pregnancy with letrozole and clomiphene and combination therapy in polycystic ovary syndrome.

Design: Cohort prospective intervention.setting: Shahid Akbar Abadi. **Inclusion criteria:** women with a history of infertility for more than one year and which were diagnosed with anovulation and polycystic ovary syndrome in 2003 based on the revised criteria.

Exclusion criteria: women more than 40 and less than 20 years old, pipes anatomical problems approved by HSG, partner impaired sperm analysis based on a modified World Health Organization criteria, such as hypo- or hyperthyroidism; endocrine problems, Hyperprolactinemia; karyotype abnormalities.

Intervention: 450 patients that were randomized with non-probabilistic methods available are divided into three groups of 150. Group A, B, C, respectively, treated with 100 mg clomiphene, letrozole 5 mg and 100 mg clomiphene citrate with letrozole 5 mg from the third day of menstrual cycle for 5 days. Transvaginal sonography will be performed in 11th day of menstrual cycle to evaluate of ovulation. The number of mature follicles, endometrial thickness, the presence of pregnancy, multiple pregnancies and abortions will be recorded under 20 weeks. The main outcome variables: the presence of ovulation, endometrial thickness, the presence of pregnancy, the number of mature follicles.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015100223621N4**

Registration date: **2016-01-10, 1394/10/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-10, 1394/10/20

Registrant information

Name

Mahnaz Ashrafi

Name of organization / entity

Iran University Of Medical Sciences, Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 5563 3244

Email address

ashrafi.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pregnancy rate with clomiphene citrate and letrozole and clomiphene alone in infertile patients with polycystic ovary syndrome

Public title

Evaluation of The effect of clomiphene or letrozole in the treatment of infertility

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Women with history of infertility more over than one year and diagnosis of PCOS based on the revised 2003 . Exclusion criteria: Women older than 40 years or younger than 20; fallopian tubes abnormality proved by hysterosalpingography; abnormal semen analysis for their partners according to the modified criteria of the World Health Organization; endocrine problem like hyper or hypo thyroidism, hyperprolactinemia; abnormal karyotype.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **450**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Sealed envelope

Secondary Ids

1

Registry name

Mahnaz Ashrafi

Secondary trial Id

94-02-30-25979

Registration date

1394-03-02, 773/01-17

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Iran Univercity of Medical Sciences

Street address

Tehran,Iran univercity

City

Tehran

Postal code

Approval date

2015-10-04, 1394/07/12

Ethics committee reference number

IR.IUMS.REC.1394 .25979

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

Ovulation

Timepoint

Day 11 of the Menstrual cycle

Method of measurement

Transvaginal sonography

2

Description

Pregnancy

Timepoint

After retard of mense

Method of measurement

Pregnancy test by missuring B-hCG

3

Description

The number of follicles

Timepoint

Day 11 of the menstrual cycle

Method of measurement

Transvaginal sonography

4

Description

Follicle size

Timepoint

Day 11 of the menstrual cycle

Method of measurement

Transvaginal sonography

5

Description

Endometrial thickness

Timepoint

Day 11 of menstural sicle

Method of measurement

Trans aginal sonography

Secondary outcomes

1

Description

Multiple pregnancies

Timepoint

4-6 weeks after menstrual delay

Method of measurement

Pregnancy sonography

2

Description

Abortions under 20 weeks

Timepoint

After pregnancy

Method of measurement

Pregnancy sonography

Intervention groups

1

Description

100 mg daily clomiphene(Ovumid; Iran Hormone, Tehran, Iran) , the third day of menstruation to 5 days

Category

Treatment - Drugs

2

Description

5 mg letrozole (Letrozole 2.5 ; SOHA Pharmaceutical Co, Tehran, Iran) daily, the third day of menstruation to 5 days

Category

Treatment - Drugs

3

Description

100 mg daily clomiphene(Ovumid; Iran Hormone, Tehran, Iran) , the third day of menstruation to 5 days + 5 mg letrozole (Letrozole 2.5 ; SOHA Pharmaceutical Co, Tehran, Iran) daily, the third day of menstruation to 5 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

AkbarAbadi Hospitall

Full name of responsible person

Dr Sara Gharehsheikhlou

Street address

Akbar Abadi Hospitall

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Iran University of Medical Sciences

Full name of responsible person

Dr Seid Ali Javad Mousavi

Street address

Iran University of Medical Sciences, Shahid Hemmat highway, 5th floor

City

Tehran

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 of Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr Sara Ghareh Sheikhlou

Position

Resident of Obstetrical and Gynecology

Other areas of specialty/work

Street address

Akbar Abadi hospital, Molavi St, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 5563 3244

Fax

Email

sara_sheikhlou@yahoo.com

Web page address

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Mahnaz Ashrafi

Position

Associate Professor

Other areas of specialty/work

Street address

Akbar Abadi Hospital, Molavi St, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 5563 3244

Fax

Email

ashrafim@royaninstitute.org

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

Dr Sara Gharehsheikhlou

Position

Resident of OB/GYN

Other areas of specialty/work

Street address

Akbar Abadi Hospital, Molavi St, Tehran, Iran

City

Tehran

Postal code

Phone

002155633244

Fax

Email

sara_sheikhlou@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