

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of induction and ovulation with Clomiphene plus Letrozole versus Clomiphene plus HMG in Clomiphene resistant polycystic ovary syndrome

Protocol summary

Summary

Objective: Comparison of induction and ovulation with clomiphene plus letrozole versus clomiphene plus HMG in clomiphene resistant polycystic ovary syndrome (PCOS). Design Prospective randomized controlled study. Setting: Shahid Akbar Abadi hospital and Royan institute of infertility and a private practice setting. Major inclusion criteria: one year infertility history diagnosed as PCOS and resistant 2-3 cycles to Clomiphene and then 2 cycles to letrozole. Major Exclusion criteria: tubal abnormalities; endocrine problem. Intervention(s): 200 Patients diagnosed PCOS and clomiphene resistant that more over do not respond to letrozole 2.5 mg daily for 5 days for 2 cycles, will be randomly allocated to 2 groups. First group with treat with either Clomiphene plus letrozole therapy (n = 100) and second group with Clomiphene plus HMG therapy (n = 100). Patients in the first group have 100 mg of clomiphene daily starting day 5 of the menses for 7 days plus 5 mg of Letrozole daily starting day 5 of the menses for 5 days (100 patients), and patients in the second group have 100 mg of clomiphene daily starting day 3 of the menses for 5 days plus HMG 150 I.U (100 patients). All patients will be monitored by trans-vaginal ultrasound for the mean follicular volume and thickness of the endometrium on days 10, 12, and 14 of the cycle. Main Outcome Measure(s) Number of growing and mature follicles, occurrence of ovulation, endometrial thickness, occurrence of pregnancy.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015090323621N3**

Registration date: **2015-12-11, 1394/09/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-11, 1394/09/20

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

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of induction and ovulation with Clomiphene plus Letrozole versus Clomiphene plus HMG in Clomiphene resistant polycystic ovary syndrome

Public title

Evaluation of effectiveness of clomiphene plus Letrozole versus Clomiphene plus HMG in female 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 consensus on diagnostic criteria; By clomiphene resistance that meant failure of ovulation after 100-150 mg CC for 5 days for 2-3 cycles and then resistant to letrozole 2.5 mg daily for 5 days for 2 cycles. 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

2-3

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Closed Packet

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, shahid Hemmat highway, Tehran

City

Tehran

Postal code

Iran

Approval date

2015-11-01, 1394/08/10

Ethics committee reference number

IR.IUMS.REC.1394.25296

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 ultrasound

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 ultrasound

4

Description

Follicle size

Timepoint

Day 11 of the menstrual cycle

Method of measurement

Transvaginal ultrasound

5

Description

Endometrial thickness

Timepoint

Day 11 of the menstrual cycle

Method of measurement

Transvaginal ultrasound

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

Intervention group 1: 100 mg of Clomiphene (Ovumid; Iran Hormone, Tehran, Iran) daily starting day 5 of the menses for 7 days plus 5 mg of Letrozole (Letrozole 2.5 ; SOHA Pharmaceutical Co, Tehran, Iran) daily starting day 5 of the menses for 5 days.

Category

Treatment - Drugs

2

Description

Intervention group 2: 100 mg of Clomiphene (Ovumid; Iran Hormone, Tehran, Iran) daily starting day 3 of the menses for 5 days plus HMG 150 I.U.(Merional; IBSA Institute Biochimique SA, CH-6903 Lugano)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Abadi hospital

Full name of responsible person

Dr Sara Norouzi

Street address

Akbar abadi hospital, Molavi St

City

Tehran

2

Recruitment center

Name of recruitment center

Royan Infertility Institute

Full name of responsible person

Dr Mahnaz Ashrafi

Street address

Royan Infertility Institute, Banihashem square, Ebrahimi St, Sayyad e Shirazi Hwy

City

Tehran

3

Recruitment center

Name of recruitment center

Private setting clinic

Full name of responsible person

Dr Mahnaz Ashrafi

Street address

Rouyan Alley, Keshavarz Blvd

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 Norouzi

Position

Resident of Obstetrical and Gynecology

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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**Person responsible for updating data****Contact****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