Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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

2015-03-21, 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 effectivness 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 Siensces, 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 menstural delay
Method of measurement
pregnancy sonography

2

Description
Abortions under 20 weeks
Timepoint
after pegnancy
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 hospitall
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
Privite setting clinice
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 Univercity of Medical Sciences
Full name of responsible person
Dr Seid Ali Javad Mousavi
Street address
Iran Univercity 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 Univercity 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 Gynocology
Other areas of specialty/work
Street address
Akbar abadi hospital, Molavi St, Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 5563 2277
Fax
Email
sr.norouzi@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran Univercity 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

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