Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison the effect of letrozole combined FSH and letrozole combined HMG in infertile polycystic ovarian syndrome patients undergoing iui cycle

Protocol summary

Summary

118 clomiphene-resistant PCOS patients with normal TSH, PRL, spermogram and HSG who were referred to Milad infertility center were randomly allocated into two 59 number groups; groups randomly allocated basis two packets A and B. Group 1 received 5 mg daily from 3 th menstrual cycle for 5 day and HMG 75 u daily in 9th and 10th cycle and group 2 received letrozole 5 mg daily from 3rd menstrual cycle for 5 day and Gonal-f (recombinant FSH) 75 u daily in 9th and 10th cycle. From the 10th follicle number and size and endometrial thickness were evaluated by transvaginal sonography. HCG was administered if at least one mature follicle (>18mm) was observed and IUI was performed 36 h later. Vaginal suppository progesterone was used daily for luteal phase support. In this study, the primary outcomes were the positive pregnancy test and observe of gestational sac and fetal heart activity which were seen by abdominal ultrasound. Secondary outcomes were dominant follicle, endometrial thickness and abortion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201703153950N6**
Registration date: **2017-05-20, 1396/02/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-05-20, 1396/02/30

Registrant information

Name

Mina Jafarabadei

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1616

Email address

jafarabadi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-04-03, 1395/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of letrozole combined FSH and letrozole combined HMG in infertile polycystic ovarian syndrome patients undergoing iui cycle

Public title

Comparison the effect of letrozole combined FSH and letrozole combined HMG in induction ovulation.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: PCOS patient; patency at least one fallopian tube; normal semen analysis in male; age between 20-40 years old. Exclusion criteria: addiction

and cigarette use; unsatisfaction for the participation of study; history of previous disease.

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

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **118**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
Vice Chancellor for research, Mashhad University of Medical sciences، near the Hoveizeh Cinema, Daneshgah Street, Mashhad.

City
Mashhad

Postal code
9189757565

Approval date
2015-08-01, 1394/05/10

Ethics committee reference number
IR.MUMS.IKHC.REC.1394.311

Health conditions studied

1

Description of health condition studied
Female infertility associated with anovulation

ICD-10 code
N97.0

ICD-10 code description
Female infertility associated with anovulation

Primary outcomes

1

Description
Chemical pregnancy

Timepoint
14 days after IUI

Method of measurement
Blood sample

2

Description
Clinical pregnancy

Timepoint
one week after positive the blood sample.

Method of measurement
Sonography

Secondary outcomes

1

Description
Follicle larger than 18 mm

Timepoint
14 th day of the menstural cycle

Method of measurement
Transvaginal sonography

2

Description
Endometrial Thickness

Timepoint
14 th day of the menstural cycle

Method of measurement
Transvaginal sonography

3

Description
Abortion incidance

Timepoint
After to positive of pregnancy test

Method of measurement
Transvaginal sonography

Intervention groups

1

Description
Intervention group1: received 5 mg daily from 3th of menstrual cycle for 5 days and HMG 75 u daily in 9th-10th cycle.

Category
Treatment - Drugs

2

Description
Intervention group2: received letrozole 5 mg daily from 3th menstrual cycle for 5 days and Gonal-f (recombinant FSH) 75 u daily in 9th and 10th cycle .
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Milad Infertility Clinic
Full name of responsible person
Dr.Malihe Afiat
Street address
Milad Hospital, Lashkar cross road,Taghi Abad
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Mashhad University of Medical Sciences
Full name of responsible person
Dr. Eslami
Street address
Vice Chancellor of Mashhad University of Medical Sciences, near the Hoveizeh Cinema, Daneshgah Street, Mashhad.
City
Mashhad
Grant name
Grant code / Reference number
922121
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Mashhad 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
Vali -Asr Reproductive Health Research Center
Full name of responsible person
Mallhe Afiat
Position
Infertility Flowship
Other areas of specialty/work
Street address
First floor,Valiasr Hospital 2, Imam Khomeini Hospital, Keshavarz Blvd.
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Person responsible for scientific inquiries

Contact
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Person responsible for updating data

Contact
Name of organization / entity
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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