Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of micro-dose human chorionic gonadotropin (hCG) with HMG in PCOS patients with previous Clomiphene Citrate (CC)-resistant anovulation

Protocol summary

Summary

The purpose of this study is to compare the effectiveness of low dose human chorionic gonadotropin (HCG) in combination with Clomiphene citrate to induce ovulation and its endocrine response in patients who had previously failed to ovulate on single Clomiphene citrate therapy. We will also compare the effectiveness and endocrine response of this approach with the regimen of adding HMG to Clomiphene citrate. Infertile women with PCOS, who have shown resistance to Clomiphene Citrate (150 mg- 5 days) in a previous IUI treatment cycle at Royan Institute (Infertility and Reproductive Medicine Research Centre) will be enrolled in this prospective randomized clinical trial study and will be randomly divided into three groups. Control group will receive 100 mg Clomiphene citrate on days 3 to 7 of cycle and 150 mg human menopausal gonadotropin (HMG) during days 7, 8, and 9. An intervention group will receive 100 mg Clomiphene citrate plus 200 IU Human chorionic gonadotropin (hCG; Choriomon; IBSA, Switzerland) intramuscular injection daily when the largest follicle is 12 mm or larger mean diameter. Another intervention group (Group C) will receive 100 mg dose of Clomiphene citrate plus 200 IU Human chorionic gonadotropin (hCG; Choriomon; IBSA, Switzerland) intramuscular injection daily From day 9 (without attention to follicle size). In both experimental groups HCG administration will be continued until the largest follicle is 18-20 mm. Primary outcome measures will be OHSS rate, and multiple pregnancy rate. Other outcome measures are cancellation rate, implantation rate, abortion rate, pregnancy rate, and endometrial status.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138805061141N3**
Registration date: **2009-11-14, 1388/08/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2009-11-14, 1388/08/23

Registrant information

Name
Kiandokht Kiani
Name of organization / entity
Royan Institute
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Royan Institute Research Centre

Expected recruitment start date

2009-06-01, 1388/03/11

Expected recruitment end date

2011-04-01, 1390/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of micro-dose human chorionic gonadotropin

(hCG) with HMG in PCOS patients with previous Clomiphene Citrate (CC)-resistant anovulation

Public title
Micro dose HCG in PCOS patients with previous Clomiphene Citrate (CC)-resistant anovulation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: age under 30 years, primary infertility, PCOS diagnosed by the Rotterdam criteria, by two of the following three features: 1) oligo or anovulation, 2) clinical and/or biochemical signs of hyper androgenism, or 3) polycystic ovaries, previously documented dominant follicle or follicles (R12 mm mean diameter) on transvaginal Ultrasound follicular monitoring, Normal uterine cavity and patent tubes by either hysterosalpingogram or laparoscopy and hysteroscopy, normal fasting glucose and insulin levels, normal serum prolactin, and thyroid stimulating hormone, Estradiol, Progesterone, FSH and dehydroepiandrosterone sulfate levels, normal semen analysis by World Health Organization criteria Exclusion Criteria: previous history of IVF or ICSI treatments, history of hormonal treatment within three month prior to admission (Except OCP, progesterone), history of ovarian cutter or Ovarian drilling, BMI higher than 30, presence of ovarian cyst (more than 30 mm) during third cycle ultrasound

Age
From **18 years** old to **30 years** old

Gender
Female

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **250**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
ClinicalTrials.gov

Secondary trial Id
NCT00947713

Registration date
2009-07-27, 1388/05/05

Ethics committees

1

Ethics committee

Name of ethics committee
Reproductive Medicine Research Center, Royan Institute, ACECR

Street address
Banihashem square, Eastern Hafez Avenue.

City
Tehran

Postal code

Approval date
1388-06-24, 769/01/-633

Ethics committee reference number
EC/88/1040

Health conditions studied

1

Description of health condition studied
PCOS patients with clomid failure

ICD-10 code
E28.2

ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Multiple pregnancy rates

Timepoint
one to 10 days after pregnancy test and after BHCG more than 1000

Method of measurement
observation of gestational sac with fetal heart rate by sonography

2

Description
Ovarian hyperstimulation syndrom

Timepoint
at ovum puncture day, at embryo transfer day and three days after embryo transfer

Method of measurement
clinical symptoms, follicle numbers by sonography, serum estradiol level

Secondary outcomes

1

Description
clinical Pregnancy rate

Timepoint
one to ten days after positive serum BHCG

Method of measurement
sonography and observation of gestational sac

2

Description
Implantation rate
Timepoint
1 to 10 days after positive BHCG
Method of measurement
ratio between observed gestational sac and total number of embryo transfered

3

Description
Cancellation rate
Timepoint
after ovarian stimulation, after insemination in lab, after embryo transfer
Method of measurement
lack of follicle or oocyte by sonography, lack of embryo in lab, and OHSS

4

Description
Miscarriage rate
Timepoint
during first 12 weeks after pregnancy
Method of measurement
clinical symptoms and sonographic criteria

5

Description
Endometer stage
Timepoint
at day 9 of cycle, and repeat every 48 hours
Method of measurement
sonography

Intervention groups

1

Description
100 mg Clomiphene citrate on days 3 to 7 of cycle and 150 mg human menopausal gonadotropin (HMG) during days 7, 8, and 9
Category
Treatment - Drugs

2

Description
100 mg Clomiphene citrate plus 200 IU Human chorionic gonadotropin (hCG; Choriomon; IBSA, Switzerland) intramuscular injection daily when the largest follicle is 12 mm or larger mean diameter
Category
Treatment - Drugs

3

Description
100 mg Clomiphene citrate plus 200 IU Human chorionic gonadotropin (hCG; Choriomon; IBSA, Switzerland) intramuscular injection daily From day 9 (without attention to follicle size)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Reproductive Medicine Research Center, Royan Institute, ACECR
Full name of responsible person
Fatemeh Rastegar
Street address
City

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Reproductive Medicine Research Center, Royan Institute, ACECR
Full name of responsible person
Dr. Ahmad Vosoogh
Street address
Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat Highway,
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Reproductive Medicine Research Center, Royan Institute, ACECR
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

Reproductive Medicine Research Center, Royan Institute, ACECR

Full name of responsible person

Dr. Mahnaz Ashrafi

Position

Head of Endocrinology and Female Infertility Department, Royan Institute/ Gynecologyst

Other areas of specialty/work

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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