Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of simvastatin on clomiphen response in clomiphen – resistant women with polycystic ovary syndrome

Protocol summary

Summary

Polycystic ovary syndrome (PCOS) is one of the most common causes of anovulatory infertility and affects 5-10% of women of reproductive age.The objective of this study is to test the effects of simvastatin on clomiphene response in cases of clomiphen citrate-resistant (CC- R) polycystic ovary syndrome (PCOS) patients . Methods: In this quasi experimental study, we enrolled 25 anovulatory PCOS women who failed to ovulate by using only CC at Amir-Al-Momenin University General Hospital in Semnan, Iran. All patients received cyclic oral contraceptives (30µg of ethinyl estradiol and 150µg of desogestrol) from the 5th day of their spontaneous or progesterone(P) induced menstrual cycle plus simvastatine (20mg/day)) from the first day of cycle for 2 months. Then patients were given100 mg CC (Clomid, Iran Hormone) for 5 days starting from day 3 of their menstrual cycle. The primary outcome measures were ovulation, and pregnancy rates.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212043386N8**
Registration date: **2012-12-10, 1391/09/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-12-10, 1391/09/20

Registrant information

Name

Azam Azargoon

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2009-05-01, 1388/02/11

Expected recruitment end date

2011-12-20, 1390/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of simvastatin on clomiphen response in clomiphen – resistant women with polycystic ovary syndrome

Public title

Effects of simvastatin on clomiphen response in clomiphen – resistant women with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria: women who were 18-40 years of age, with a period of infertility more than 1.5 years and normal serum prolactin and thyroid function tests, they all had documented patent tubes by hysterosalpingography, had no other infertility factor, and failed to ovulate with a dose of CC of 150 mg /day for 5 days from day 3 of the period. The women who

were diabetic, had hypertension or abnormal renal or liver function tests, and had undergone ovarian drilling were excluded from the study. Hirsutism was diagnosed when the Ferriman and Gallway score was >8(15). The diagnosis of PCOS was according to the Rotterdam Criteria

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **25**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Semnan Uiversity of Medical Sciences

Street address
Basij blvd

City
Semnan

Postal code

Approval date
2009-04-21, 1388/02/01

Ethics committee reference number
2391/Ĩ

Health conditions studied

1

Description of health condition studied
Polycystic ovary syndrome

ICD-10 code
E28.2

ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
ovulation and pregnancy rates

Timepoint
after intervention

Method of measurement
BHCG and sonography

Secondary outcomes

1

Description
Change in BMI,

Timepoint
After intervention

Method of measurement
BMI=WT(kg)/H2(m)

2

Description
Endometrial thickness

Timepoint
On HCG day adminstration

Method of measurement
Sonography

3

Description
Size and numbers of follicles>18mm

Timepoint
On HCG day adminstration

Method of measurement
Sonography

Intervention groups

1

Description
We enrolled 25 anovulatory PCOS women who failed to ovulate by using only CC . All patients received cyclic oral contraceptives (30µg of ethinyl estradiol and 150µg of desogestrol) from the 5th day of their spontaneous or progesterone(P) induced menstrual cycle plus simvastatine (20mg/day)) from the first day of cycle for 2 months. Then patients were given100 mg CC (Clomid, Iran Hormone) for 5 days starting from day 3 of their menstrual cycle

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility center, Amiralmomenin Hospital
Full name of responsible person
Azam Azargoon
Street address
Madar square, Infertility center, Amiralmomenin Hospital
City
Semnan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr. Raheb Ghorbani
Street address
Semnan- Basij Blvd
City
Semnan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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