

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of the efficacy of Metformin and Simvastatin in treatment of infertile patients

Protocol summary

Summary

1-objective: comparison of metformin & simvastatin in management of infertility 2-Design: randomized Clinical trial, not blinded . 3-setting & conduct: 40, 20-35 years old women with PCOS and infertility history after matching BMI and normalizing TSH and Prolactin are divided into 2 groups of 20. In Third day of menstruation periods, Hirsutism staging and lab data such as Total Testosterone, LH, FSH, TG , Cholestrole (LDL, HDL), GTT with 75g Glucose were done. Previous tests have been repeated again in the third day of period and hirsutism staging was done, then ICSI protocol was started. the largest diameter of follicles were examined by trans vaginal ultrasound. the numbers of oocyte mitosis 2 after puncture, the numbers of embryo grade A after sperm injection and the risk of OHSS were evaluated. 2 weeks after embryo transfer, Pregnancy was proved by β -HCG and ultrasound was done after 6 weeks to determine Abortion and ectopic pregnancy and then during 12 weeks of pregnancy patients were followed. participants: Inclusion criteria: PCOS, 20-35 years, history of infertility for at least one year. Exclusion criteria: Tubal, anatomical factors, malformations, male factors, endometriosis. Receiving Metformin, Clomiphene or letrozole within 3 months, IUI within 3 months ago, the underlying disease, such as kidney problems, lung disease, diabetes melitus, antiphospholipid syndrome, history of hyperlipidemia and relating drugs. 5- intervention: One group treated with OCP daily+ Metformin TDS for 8 weeks and another group treated with OCP + Simvastatin daily for 8 weeks. 6-main outcome measures variables: rate of pregnancy

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202138994N1**

Registration date: **2012-12-06, 1391/09/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-12-06, 1391/09/16

Registrant information

Name

Mandana Rouzitalab

Name of organization / entity

Ahwaz Jundishapur University of Medicen Sciences

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Recruitment status

Recruitment complete

Funding source

Ahwaz Jundishaour University of Medical Science, Vice Chancellor for Research and Technology

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2012-11-21, 1391/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of Metformin and Simvastatin in treatment of infertile patients

Public title

Comparison of the efficacy of Metformin and Simvastatin in patients with polycystic ovarian syndrome(PCOS) in Intra Cytoplasmic Sperm Injection(ICSI)cycles.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: PCOS, age 20-35, previous history of infertility for at least 1year. Exclusion criteria: tubal infertility, anatomical factors & malformations, male infertility factors, endometriosis, receiving metformin , clomiphene or letrozol, IUI in last 3 months, underline disease such as renal, pulmonary, diabetes mellitus, anti phospholipid syndrome and hypertriglyceridemia and receiving anti hyperlipidemia drugs

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahwaz Ethic Committee of Jundishapur University of Medical Sciences

Street address

Ahwaz Jundishapur University of Medical Sciences, Esfand avenue, Golestan bulvard

City

Ahwaz

Postal code

61357-15794

Approval date

2011-12-24, 1390/10/03

Ethics committee reference number

u-90218

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

Pregnancy rate

Timepoint

16 weeks

Method of measurement

Serum B-HCG

Secondary outcomes

1

Description

Body mass index

Timepoint

Before and 2 month after intervention

Method of measurement

BMI index

2

Description

TG,Chol(HDL,LDL),FSH,LH,Total Testesteron,GGT with 75 g glucose

Timepoint

Before and 2 month after intervention

Method of measurement

Lab data analyze

3

Description

Staging of hirsutism

Timepoint

2 month after intervention

Method of measurement

standard scaling score system

4

Description

Ovarian hyperstimulation syndrome

Timepoint

After puncture

Method of measurement

Physical exam and sonography

5

Description

Number of oocyte in mitosis 2

Timepoint

After puncture

Method of measurement

Lab data analyze

6

Description

Number of fetus in grade A

Timepoint

After sperm injection

Method of measurement

Lab data analyze

7

Description

Cases of ectopic pregnancy

Timepoint

6 weeks after fetus transfer

Method of measurement

Sonography

8

Description

cases of abortion

Timepoint

6 weeks after fetus transfer

Method of measurement

physical exam and sonography

Intervention groups

1

Description

group 1: metformin 500 mg TDS and oral contraception pill daily for 2 month

Category

Treatment - Drugs

2

Description

group 2: simvastatin 40 mg daily and oral contraception pill daily for 2 month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahwaz Reserch & Infertility Center of Emam Khomeiny Hospital

Full name of responsible person

Mandana Rouzitalab

Street address

Emam Khomeiny Hospital, Azadegan avenue

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Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahwaz Jundishapur University of Medical Sciences,Vice Chancellor for Research and Technology

Full name of responsible person

DR Fegghi.Mostafa

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahwaz Jundishapur University of Medical Sciences,Vice Chancellor for Research and Technology

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

Ahwaz Jundishapur University of Medical Sciences

Full name of responsible person

Mandana Rouzitalab

Position

Gynecology and Obsteteric resident

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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